Len Goodman

P.O. Box 5497
901 W. San Mateo, Suite B
Santa Fe, NM 87502

Office Phone: 505-982-2621
Len's Mobile: 505-310-1491
Email: len@newmexicann.org

Presentation for
Legislative Health & Human Services Committee
Taos Meeting, July 17, 2014

7/16/2014

The Lynn & Erin Compassionate Use Act, 2007, recognized that Cannabis was a medicine needed by many New Mexicans to manage their debilitating illnesses. The LECUA recognized that Cannabis, for many patients, was more effective than the available pharmaceutical drug with virtually no toxicity. LECUA established Cannabis as a valuable resource in the state's pursuit of improved Public Health and Harm Reduction.

Unfortunately, the Dept. has lost sight of its obligation under LECUA to actively educate and promote Medical Cannabis to both citizens and medical practioners. Based on statistics from other Medical Cannabis states, where the regulatory agencies have actively pursued Medical Cannabis education as a Public Health benefit, New Mexico should have some 40,000 patients (approximately 2.5% of the population). The fact that New Mexico has only registered some 16,000 patients reflects the lack of a compassionate pro-active Public Health stance. In addition, some 5,000 registered Patients have become inactive – due primarily to lack of supply, lack of convenience (insufficient distribution points), price, overly burdensome certification and re-certification forms that many medical practitioners find invasive, as well as a lack of educated medical practitioners willing to certify Patients.

According to the DoH Survey 2013, LNPPs were producing 1mm grams annually while Patient need was 4mm grams (exclusive of Patients with Personal Production Licenses). This survey measured Patient need, but not Patient demand. Current LNPP yields have risen, since the survey was taken, to some 2mm grams. As a result, LNPPs have sufficient supply to meet Patient demand but this still amounts to only 50% of Patient need. The remainder of Patient need is being met primarily through purchasing from the illicit market.

To address these issues, he Department needs to:

- Remove or adjust the current LNPP plant count limit in order that LNPPs can produce sufficient medicine for Patient need. A minimum of three times the current plant count is needed to meet Patient need and also allow for sufficient plants for whole plant juicing (non-psychoactive) and to be able to provide seedlings to Patients with PPLs.
- Allow a free market system to function with sufficient supply of Medicine and with no restriction as to demographic locations and with no restriction as to the number of LNPP distribution centers – subject only to local ordinance. This will provide convenient access and competitive pricing to induce Patients to purchase from state legal sources rather than the illicit market.
- Create a statewide outreach program to educate medical practitioners to the safety and efficacy of Medical Cannabis.
- Simplify its certification forms and processes.
- Allow the Medical Advisory Board to set Adequate Supply limits to allow Patients to purchase sufficient Medicine to meet their needs without having to resort to illicit sources.

LECUA authorized and mandated the NM Dept. of Health to create systems for Patient Registry and for cultivation and distribution of Cannabis medicineto qualified New Mexican Patients. The Dept. initially proposed that the state directly cultivate and distribute this medicine. In 2008, the NM Attorney General advised the Dept. against this as it would put state employees at risk of Federal Law Enforcement prosecution. As an alternative, the Dept. decided to request that other New Mexicans expose themselves to this risk. Many of us offered to accept the risk for both compassionate reasons and also for the possibility of financial gain.

The Dept. needs to recognize NM MCP LNPPs as partners and the mechanism for the implementation of LECUA. The Dept. needs to recognize that LNPPs have made very substantial financial investments in their cultivation and distribution facilities while still being subject to the risks of Federal Law Enforcement prosecution. LNPPs and are primary stakeholders and must be actively included in the regulatory decision making process. The Dept. needs to recognize that the LNPPs are a valuable resource as knowledgeable professionals who deal with Patients, their needs and their frustrations on a daily basis and should be the Program's primary resource for information and advice on how to best implement LECUA and make the NM MCP work for Patients, Producers and Regulators. New Mexico led the nation as the first Medical Cannabis state to offer not only Patient Registry, but a regulated cultivation and distribution of Medical Cannabis. That is no longer the case and there is no reason for New Mexico to have given up this leadership and we can recover our visionary role through well-crafted Regulations and proper compassionate over-sight.

Sincerely,

_____

Len Goodman
Chairman & Executive Director
Giving Tree Organics, Inc.
New MexiCann Natural Medicine, Inc.

Len Goodman

P.O. Box 5497
901 W. San Mateo, Suite B
Santa Fe, NM 87502

Office Phone: 505-982-2621
Len's Mobile: 505-310-1491
Email: len@newmexicann.org

Medical Cannabis Program
New Mexico Department. of Health
1190 St. Francis Drive
Santa Fe, NM 87502

6/30/2014

Public Comment to NM Dept. of Health Medical Cannabis Program Proposed Regulations

Presented by Len Goodman
Executive Director, New MexiCann Natural Medicine, Inc.
Licensed Non-Profit Producer, NM Dept. of Health Medical Cannabis Program

New Mexico has been a leader in legislating and regulating the compassionate use of Cannabis as an invaluable medicine for the treatment of certain debilitating medical conditions. In 1978, New Mexico became the first state to pass legislation recognizing the medical value of Cannabis (Controlled Substances Therapeutic Research Act, renamed in 1979 Lynn Pierson Therapeutic Research Program). The LPTRP was administered by the Health and Environment Department and represented the first statewide research and treatment endeavor which provided marijuana and delta-9-THC to cancer chemotherapy patients suffering from the nausea and vomiting caused by their therapy. The LPTRP was funded by the state and cannabis was provided by the US Federal Government for some 256 patients through 1986 when the Federal Government ceased to supply Cannabis.

In 2007, with the enactment of the Lynn & Erin Compassionate Use Act, New Mexico became the first state to authorize and regulate the production and distribution of Cannabis. The LECUA mandated the NM Dept. of Health to create regulations for a Medical Advisory Board with responsibility for Patient Registry and Certification, determination of Adequate Supply and the approval of new Debilitating Conditions. The LECUA also mandated the NM Dept. of Health to create an Adequate Supply and Distribution System sufficient to serve the needs of all Certified Patients.

The Dept. of Health promulgated Regulations for the Medical Advisory Board and Patient Registry in 2008, followed by Regulations for Production and Distribution via Licensed Non Profit Producers (LNPPs) and Personal Productions Licenses (PPLs) in early 2009.

These initial Regulations were an important first step. As there were no other states with regulations for Medical Cannabis, there were no guidelines to follow nor any historical experience from which to benefit. These Regulations also needed to take into account DEA and DoJ actions in other states (which were targeting and prosecuting state legal, although unregulated, Cannabis cultivators and distributors)

in an attempt to limit risk of Federal prosecution of the state's cultivation and distribution contractors. The Dept. did a remarkable job in this first attempt at Regulations which made it possible for the Medical Cannabis to begin serving Patients with Safe Access to Safe Medicine while remaining free from Federal actions.

Within some 12 months of the first LNPP being licensed, it became obvious to the NM MCP administrators that the Regulations needed revision – particularly in regard to Adequate Supply. On Dec. 30, 2010, the Dept. promulgated new revised Regulations that increased the number of plants that LNPPs were permitted to grow from 95 to 150 while simultaneously increasing the number of LNPPs to 25.

The supply shortage was in crises from day one. As one of the first LNPPs, New MexiCann, licensed in 2009, was selling out its entire harvest within the first 24 hours of offering. With the initial 95 plant limit, New MexiCann was harvesting rotationally twice a month and Patients were able to access medicine only once every two weeks. With the increased plant count, and our increased skill in cultivation, New MexiCann was able to offer new harvest weekly - but we were still selling out within 24 hours of announcement and turning away some 100 to 250 Patients each week. Patients who could not access Medical Cannabis from LNPPs were turning to the illicit market to meet their needs. LNPP appeals to the Dept. to increase plant count were ignored and the Dept. maintained a position that Supply was sufficient to meet Patient needs. In order to put LNPP assertions of Supply Shortage to rest, the Dept. contracted for an independent survey. This survey was completed in November 2013. It not only substantiated LNPP claims, but also indicated that the Supply Shortage was far greater then LNPP projections and amounted to some 3,000,000 grams annually. The survey concluded that LNPPs were providing only 25% of Patient need (after accounting for Patient Personal Production). As a result, Patients with debilitating medical conditions were doing without and suffering needlessly, returning to the use of toxic narcotics, or putting themselves at risk by purchasing Cannabis from illegal sources.

One would have expected, with the Dept.'s receipt of the survey results and the recognition of its non-compliance with its statutory mandate, that new Proposed Regulations would have been immediately announced to address the supply shortage. Instead, it took two months for the Dept. to announce its intentions and 7 months for the Dept. to hold a Public Hearing. Rather than simply addressing the critical supply shortage by increasing plant count for LNPPs, the Dept. chose to re-write almost all of it Regulations. It did so with no input from the Medical Advisory Board (as per LECUA and its own Regulations), no input from LNPPs, no input from Patient groups, no input from Policy groups and advocates. As a result, Patients, Producers and advocates could not support the Proposed Regulations even though this would mean that the Supply Shortage would continue. All stakeholders were united in the opinion that the Proposed Regulations would so damage the NM MCP, its Patients and Producers, that they had to be opposed – even at the expense of supply. As a result of the Dept.'s refusal to separate (bifurcate) the Proposed Regulations dealing with Plant Count from the all the other Proposed

Regulations, Patients will have to do without an adequate supply of Cannabis medicine for quite some additional time.

Most states considering Medical (or Adult Use) Cannabis Regulations contracted with knowledgeable industry professionals to advise and recommend Proposed Regulations – often at the cost of hundreds of thousands of dollars. Some of us working as LNPPs in New Mexico have that experience. We have worked professionally with state legislative committees and regulatory agencies as well as serving on national Cannabis industry Boards of Directors, national Cannabis policy group committees, and national herbal product trade association working committees. We offered our services to the NM MCP at no charge in order to help craft NM MCP Regulations that would benefit all – Patients, Producers, and Administrators. Unfortunately, these offers were ignored and the result was Proposed Regulations that not only would not adequately address the Supply Shortage, but would also make it more difficult and costly for all Patients and Producers and severely restrict the ability of the NM MCP to meet it statutory obligation to compassionately meet Patient needs and ease their suffering.

The Proposed Regulations must be withdrawn from consideration and input must be obtained from all stake holders before crafting new Proposed Regulations that will improve the NM MCP rather than harming it. A separation must be made between an increase to plant count to address the Supply Crises and all other Proposed Regulations. An immediate announcement with notice of Public Hearing for a Proposed Regulation that would increase plant count with no other regulatory changes in mandated by statute. All other Proposed Regulations will need much time for input from stake holders and even more time for crafting and writing. Patients suffering from debilitating conditions cannot wait for this process to complete. The plant count increase need was obvious to all except DoH three years ago and no more denial or delay tactics can be tolerated.

As to the specifics of major problems in the Proposed Regulations, I will only address only those issues which directly affect LNPPs and their ability to produce and distribute sufficient supply of Medical Cannabis to NM MCP Patients and to do so cost effectively and efficiently. These issues also affect Patients, but indirectly.

- **LNPP Plant Count – Insufficient to Meet Supply Shortage**
    - According to the DoH November 2013 Survey, Patient need was 4 times LNPP yield.
    - LNPPs utilize plant count differently depending on grow style - which is a function of various factors including available square footage, lighting, soil vs. hydro, capitalization and personal preference.
    - Current Regulations address total plant count while Proposed Regulations distinguish between flowering and vegetative plants and thus do not account for individual LNPP grow styles.
        - For LNPPs, such as New MexiCann, currently flowering some 75 of their 150 plant total with 75 vegetative, the Proposed Regulations could increase yield by 100% with 150 plants in flower.

- For LNPPs, such as Minerva, currently flowering some 100 of their 150 plant total with 50 vegetative, the Proposed Regulations could increase yield by 50% with 150 plants in flower.
- For LNPPs, such as Compassionate Distributors, currently flowering some 120 of their 150 plant total with 30 vegetative, the Proposed Regulations could increase yield by 25% with 150 plants in flower.

- There is no reason to limit plant count at all – no LNPP (or any business) expends time, energy, resources and money on more production than can be sold. Plant count should be a function of market reality for each individual LNPP.
- With sufficient plant count and sufficient yield to meet Patient needs, a legitimate market can function that will lead a cooperative competition resulting in lower prices for Patients.
- Current Dept. of Justice memos establish Federal policy that recognized and abides by state Cannabis Regulations. Experience in Colorado, where many producers cultivate more than 10,000 plants, indicate DoJ's adherence to that policy.
- Conversations between former DoH Sec. Torres and former NM US Attorney Gonzales indicated that the NM DoJ did have some concern for plant counts in excess of 1,000 plants. That concern may still exist in spite of current DoJ policy and NM LNPPs have suggested that the plant count be increased to 999 to provide a level of safety from Federal agencies that may be needed in NM.
- A total plant count of 999 with no differentiation between flowering and vegetative plants (current Regulations) would permit 600+% increases in yield for all LNPPs. This would allow LNPPs to meet all current supply needs as well as expand dramatically as Active Patient numbers increase.
- No additional LNPPs need to be licensed in order to meet Patient needs if the plant count is increased sufficiently.
- Once an increased plant count can no longer supply all Patient needs, either additional LNPPs or a higher plant count will be needed. With a plant count of 999, existing LNPPs could supply sufficient Cannabis to account for projected increases in NM MCP Patient load through 2018.
- LNPPs have each invested between $100,000 and $650,000 into their current production facilities and distribution centers and these investments will have to be increased significantly to utilize larger plant counts.
- Current LNPPs need security in order to make additional substantial investments into their facilities. It will take many years to pay back these loans and current LNPPs need some assurance that they will not be pushed aside by the Administration.

- **LNPP Renewal Fees – Excessive**

- Most states do not limit plant count nor tie license fees to plant count or sales volume.
- Most states' licensing fees are well below New Mexico's current $30,000.
  - Arizona is lowest with a $1,000 annual fee.
  - Only Vermont and Nevada equal NM with $30,000 annual fees.
  - Only Delaware at $40,000 and Connecticut at $75,000 exceed NM.
- New Mexico is among the poorest states and has the highest population percentage living below the poverty level (some 22%).
- Some 50% of all NM MCP Patients are on disability with very limited fixed incomes.
- Most all LNPPs are committed to reducing prices to Patients and expect to do so with a sufficient increase to plant count.
- Increases in Renewal Fees, as well as other cost increases to LNPP in the Proposed Regulations, will increase costs to Patients.
- Programs provided by state government benefitting New Mexicans are Departmental budget items approved by the Legislature and funded by tax revenues and the General Fund. Fees collected by the Department are income and thus budget offsets and not intended to fully fund a program.
- License fees are reasonable fees charged in exchange for granting a privilege and its attendant financial opportunity to the license holder. The license fee recognizes that some license holders will be marginal, some do well enough and some will do extremely well - as is appropriate in a free market economy
- The proposed Renewal Fee of $90,000 is so high that it requires all LNPPs to do very well. Those LNPPs who are only moderately successful will not be able to afford to renew and will have to be replaced by new licensees who will take at least one year, and often two, to be truly productive and effective delivering sufficient quality and quantity Cannabis to Patients.
- The proposed increase in Renewal Fees is disproportionate to the proposed increase in plant count
  - For LNPPs, such as New MexiCann, currently flowering some 75 of their 150 plant total with 75 vegetative, they will pay three times as much while only doubling production. If these LNPPs choose to stay at their present production level, their Renewal Fee will increase from $30,000 to $50,000.
  - For LNPPs, such as Minerva, currently flowering some 100 of their 150 plant total with 50 vegetative, they will pay three times as much while only increasing production by 50%. If these LNPPs choose to stay at their present production level, their Renewal Fee will increase from $30,000 to $50,000.
  - For LNPPs, such as Compassionate Distributors, currently flowering some 120 of their 150 plant total with 30 vegetative, they will pay three times as much while

only increasing production by 25%. If these LNPPs choose to stay at their present production level, their Renewal Fee will increase from $30,000 to $70,000

- LNPPs recommend maintaining the $30,000 Renewal Fee regardless of plant count increase.

- **LNPP Non Refundable Renewal Fee – Really?**
  - The Proposed Regulations require LNPPs to pay the Renewal Fee ($90,000) with submission of the annual Renewal Application. As the Proposed Regulations are written, should the new LNPP license not be issued, the fee is non-refundable and forfeited. I would hope that this is simply sloppy writing and not the intent, but that is what the Proposed Regulations state.

- **LNPP Financial Audit – Expensive and Unnecessary**
  - An audit requirement was add by the Dept. into the current Regulations in December, 2010.
  - Prior to the first required audit of 2011 for 2012 LNPP renewal, the NM Public Accountancy Board issued an opinion letter that a CPA audit of any business (and specifically Medical Cannabis) engaged in Federally illegal activities as per the Controlled Substances Act, even if state legal and compliant, was not advised and could lead to possible License forfeiture.
  - As a result of this letter, the Dept. did not require 2012 LNPP compliance with its Audit Regulation and instead performed its own internal inspections of LNPP books and records utilizing DoH Audit department staff to verify regulatory record keeping compliance by LNPPs.
  - In 2013, for fiscal year 2012, In spite of the NM Public Accountancy Board letter, the Dept. insisted that NM CPAs perform an audit and at LNPP expense. LNPPs suggest that a CPA Audit was still impossible but that a schedule of Agreed Upon Procedures be substituted in place of an actual Audit. LNPPs, with the help of their accountants, drafted a uniform Agreed Upon Procedures document which DoH accepted. The Agreed Upon Procedures took place smoothly at a cost of some $5,000 per LNPP.
  - This same method was accepted by DoH for 2014 License Renewal, for fiscal year 2013.
  - The Proposed Regulations not only formally restate the impossible Audit requirement, but also expand the definition to a Financial Audit which is not only impossible for NM CPAs to perform as per the NM Public Accountancy Board letter, but also would cost LNPPs would be $25,000 to $45,000. These costs to LNPPs would increase costs to Patients. To date, no CPAs have agreed to perform such an audit at any price unless the Board reverses its position and endorses the required Audit. Even with that, many CPAs

have said they would still not perform such an audit as it is in violation of Federal Law as it is aiding in the functioning of a Federally illegal business activity.

- **LNPP Quarterly Financial Statements – On whose Authority?**
  - Currently LNPPs report quarterly to DoH on number of Harvested Plants, flower Yields in grams, Sales by product category in grams or units, Compensation paid to employees and contractors, Purchasing from Vendors, Delivery transactions, quantities Purchased (all purchasing at one time of 1 oz. or more), number of Unique Patients served, number of Patient Transactions, Patients Served per County, Transfers and Transactions between LNPPs, etc.
    - These are Quarterly Reports for LNPPs. These reporting requirements tend to change each quarter. LNPPs are not given the forms with the new reporting requirements until after quarter end. This makes it impossible to set up data collection systems prior to the new reporting quarter in order to easily capture the data required by DoH. LNPPs have to manually go through some 5000 invoices each in every quarter in order to comply with the new quarterly reporting formatting.
    - Other NM Departments (e.g. Taxation & Revenue) provide new forms prior to the reporting period in order to give the reporting entities the ability to reconfigure data collection systems to easily meet the new reporting requirements.
  - In light of the extensive current reporting required by the DoH MCP, what need is there for full Financial Reporting on a quarterly basis? This will require additional expense and labor that will need to be passed on to Patients.
  - As stated in the LNPP New Mexico Cannabis Association legal documents by Jason Marks, provided at the Public Hearing (and attached to this letter), there is no authority given by the Statute for the Dept. to require private business information to be provided to the Dept. Any requirement for Financial Statements is beyond the authority of the Dept. of Health.

- **Testing – A Needed Addition but Excessive**
  - In, early 2010, New MexiCann lobbied DoH to institute mandatory testing for potency (cannabinoid quantification) and for microbiological health and safety. We had found a lab in Las Cruces willing to set up for this testing if the demand would be there to justify the initial expense. The lab principals and I met with then Sec. Vigil. He was not receptive to the idea and the concept was dropped.
  - In 2011, Jeremy Applen contacted me and offered to open a new lab, Page Analytics, if New MexiCann would guarantee to batch test all harvests of all strains. We agreed and began voluntary testing. There are now a total of 3 LNPPs who currently batch test all

harvests of all strains for quantifications and micro with several other LNPPs now performing random testing.

- In 2013, DoH issued a memo (not a Regulation) forbidding LNPPs from listing potency, dosing and quantification on edible products unless verified by a certified lab. Subsequently, DoH certified Page Analytics as an approved Lab for the NM MCP – currently the only such lab.
- The Proposed Regulations finally recognize the need for batch testing for quantification and micro.
- Unfortunately the Proposed Regulations go far beyond what is necessary and what is standard in all Medical Cannabis states with mandatory testing. The Proposed Regulations follow the Connecticut model which has not yet been implemented. That model is not only excessively costly and unnecessary, but impossible to meet for any vegetable/herbal/food product - as Connecticut regulators will discover upon implementation.
- I will give a brief overview of the problems below (they are very complex) and will attach the Public Comment document offered to the DoH Public Hearing by Jeremy Applen to this letter.
    - The microbiological standards for health and safety currently being used by Page Analytics far exceed the standards used by most Cannabis Labs nationally and already offer a far greater degree of health and safety assurance than is normative for the industry.
    - The standard proposed in the Proposed Regulations is only used in the US for manufactured pharmaceutical products and are not applied to organic vegetable/herbal/food products.
        - The Netherlands is the only country that applies the proposed standards to Cannabis. The Netherlands approves and utilizes Blue Gamma Irradiation for use on inhalable and ingestible vegetable/herbal products.
        - In the US, the Food & Drug Administration forbids the use of Blue Gamma Irradiation on vegetable/herbal/food products.
    - The Proposed Regulations require testing for heavy metals and contaminants in addition to quantification (for dosing) and microbiological health and safety testing.
        - The Proposed Regulations includes protocols for the use of pesticides and soils.
        - Regular testing for these is an unnecessary expense. Protocol compliance in both the food and the Cannabis industry is normally assured by occasional random testing as the use of soils and pesticides do not vary from harvest to harvest. Federal regulations require that heavy metals be

a disclosed and listed as component of products used for vegetable/herbal/food production and producers current Good Manufacturing Practices insure compliance. The Proposed Regulations will require LNPPs to have cGMP manuals and data sheets available for DoH inspection.

- With the size of the current Medical Cannabis Program and its market, no lab can afford to invest in the equipment and standards needed to complete such testing and it is very unlikely that LNPPs will be able to meet the compliance requirements of lab testing for these substances.
- Should a lab be willing to make the required $250,000 to $500,000 investment, Page Analytics has estimated that each batch test would cost some $800 – compared to the current $175 fee per batch test. New MexiCann is currently spending some $25,000 annually on its present quantification and micro testing for harvested flowers and extracts. This annual expenditure would increase to some $100,000 and would have to be reflected in the price charged Patients for flower Cannabis Medicine.

- The Proposed Regulations require batch testing for all edible products and tinctures.
  - Edibles and tinctures are regular food products with the single difference that they are infused with Cannabinoid extract.
  - As with all food products, the DoH currently requires Cannabis infused production to take place in an approved commercial kitchen that is subject to random inspections for Food Handling Safety.
  - DoH currently requires all LNPP kitchen employees to be trained and obtain basic Food Handling Safety certification.
  - FDA does not require regular food products to be tested for health and safety as a matter of course – only in the case of a reported adverse event.
  - All Cannabinoid extracts used for the production of edibles and tinctures are required to be tested for quantification in order to assure uniform dosing and labeling in all LNPP products.
  - Labeling accuracy for quantification dosing can be accomplished by testing each new product recipe until label specifications are met. Once accomplished, cGMP will insure future compliance with random testing being sufficient.
  - NM LNPPs are very small producers of Cannabis infused products and tinctures. As such, they manufacture in small batches to insure shelf life and freshness. Normal LNPP infused product batches are usually sufficient for at most a two week inventory supply. As an example, New MexiCann

produces Cannabis infused fudge bars in usual runs of 200 bars. If each batch needs testing costing $800 per test, the Patient price per bar would have to increase from its current $15 to somewhere between $20 and $23 to per bar to cover costs and additional handling. This is an unacceptable price for Patients to pay – and with no added value.

- If only quantification batch testing for edibles and tinctures were required, the cost to Patients would increase by only $1 per bar, which most Patients can afford if necessary.

- **LNPP Sale Limit to Patients – Half of Current Regulation Standards**
  - As per both the LECUA and the current DoH MCP Regulations, Adequate Supply definitions are under the authority of the Medical Advisory Board.
    - The Medical Advisory Board definition of Adequate Supply was established in the first MCP Regulations promulgated in 2008/2009 and remains in place.
    - This definition is 6 ounces (170 grams) of flower Cannabis.
    - Concentrates and Cannabis infused products were not included in the definition.
    - The Proposed Regulations include not only flower Cannabis but also add concentrates and infused Cannabis products in the 170 gram limit.
    - The Medical Advisory Board was not consulted or advised of the Proposed Regulation change.
    - The Medical Advisory Board has not recommended a change in the definition of Adequate Supply as required by current Regulations and authorized by Statute.
  - The Medical Advisory Board, in its original establishment of Adequate Supply, allowed for recommending Medical Practitioners to increase the amount of Adequate Supply permitted for any individual Patient as the practitioner deemed medically necessary for the individual Patient's needs.
    - The Proposed Regulations restricts the recommending Medical Practitioner's Adequate Supply increase to 85 grams (a 50% increase).
    - New MexiCann currently has a number of Patients with Medical Practitioner and DoH approval for Adequate Supply in excess of the Proposed Regulation limit. These Patients will lose their ability to access sufficient quantities of Cannabis to meet their medical needs.
    - This Proposed Regulation is a direct disruption of the Patient/Doctor relationship and is beyond the authority of the Dept.
  - From 2009 through 2012, the Dept. viewed Adequate Supply as a *possession* limit and not a purchase limit. That view was changed in 2013 to a *purchase* limit of 6 oz. of flower Cannabis in any given calendar quarter.

        - This change was made via a DoH memo notification to LNPPs and not by Regulation.
        - This change was made without consultation of input from the Medical Advisory Board.
    - The only new research available to DoH on average Patient usage is the 2013 Supply Shortage Survey. This survey only questioned Patients on their intake of flower Cannabis and ignored concentrates and infused products. As a result, there is no data on usage of concentrates and infused products and no way to measure average Patient usage.
        - Many Patients require more than the current 6 ounce purchase limit per quarter to manage their NM MCP approved conditions. In order to remain functional with reduced pain and symptoms, many Patients supplement their flower intake with concentrates and infused products. These products are not included in the current Regulation definition of Adequate Supply and for which LNPPs have no current sale restriction. In the last month of each quarter, many Patients are forced by Regulation to only purchase concentrates and infused products.
        - For those Patients needing 6 ounces of flower plus concentrates and infused products to manage pain and symptoms, the Proposed Regulations which include all Cannabis products will reduce Patient intake by 25-50%. Many Patients will need to turn to illegal sources in order to survive and function with their debilitating conditions.

- **Volunteer Employees, Overlapping Employees, Management Companies and Lenders**
    - Many Patients wish to help LNPPs out of gratitude or for experience. This has been common practice among many LNPPs. Many Patients with PPLs volunteer to work in LNPP gardens to gain cultivation knowledge at no cost to them – a win/win situation.
        - Many Board members enjoy participating hands-on as trimmers or plant tenders or assisting in customer service and have no desire for compensation as they consider themselves to be an integral member of the LNPP family.
    - A number of Patients with customer service and trim experience work part time for multiple LNPPs. They may prefer a single LNPP employer but at times the work is seasonal or fill-in and working for multiple LNPPs is necessary to create full time work for themselves. These are valuable knowledgeable employees that will be lost to LNPPs and LNPP Patient Care will suffer.
    - It is difficult to establish borrowing relationships for Cannabis businesses.
        - When an individual or entity is found who is supportive of the NM MCP and has the ability to lend, why should they be restricted to financing only one LNPP?
        - When lending institutions finally accept Cannabis businesses as legitimate, the Proposed Regulations will only permit s them to lend to one LNPP.

        - This makes no sense at all.
    - Existing, older established LNPPs have traditionally help newer struggling LNPPs to build-out, avoid costly errors in management structures and systems, reduce the time needed for achieving successful cultivation yields and much more. These established LNPP Executive Directors at times serve as part of the newer or struggling LNPP management teams. Under the Proposed Regulations, these arrangements would be forbidden – with or without compensation.

- **Dept. of Health Medical Cannabis Program Assessment Report**
    - Current Regulations require the Department to issue an Assessment of the NM MCP that *"shall focus on whether the needs of qualified Patients are being met by the Department's administration of the act….. The Department's assessment report shall be issued every two years, shall be a public document and must contain de-identified data upon which the assessment is based."*
    - To my knowledge, no such Assessment Report has ever been performed. If it was, it has not been made public.
    - The Proposed Regulations removes this requirement of reporting and accountability entirely and leaves the Department for no obligation for regulatory, legislative or public transparency or scrutiny.

- **Delivery/Courier Service – a Perfect Example of Not Consulting Knowledgeable Professionals**
    - New Mexico is very large state with limited populations and widely dispersed demographics.
    - As a result, it is very difficult and expensive for rural New Mexican Patients to gain access to LNPP Cannabis.
    - Currently, there are a number of delivery systems for these Patients.
        - Deliveries by single LNPPs to their registered Patients only. These services collect payment directly from Patients, are expensive for Patients, make weekly deliveries, and service only certain sections of the state.
        - Single LNPPs delivering their own Medicine as well as allowing some other LNPPs to consign packages for delivery by the LNPP employee. These LNPPs at times collect payment directly from Patients and always collect delivery fees from Patients, are cost effective for Patients, make infrequent deliveries - once a month to each quadrant of the state.
        - An independent Courier Service for whom Cannabis delivery is a small part of their business. This service does not collect any money from Patients, is very expensive for Patients, deliver within 1 to 3 days and does not deliver to many sections of the state.

- Some four months ago, I outlined a method to DoH for a unified delivery system that would give Patients easier access at a much more affordable rate.
  - This plan called for a consolidated independent license for a Delivery/Courier Service whose employees were not required to be DoH Licensed Employees of an LNPP.
  - Weekly deliveries to each quadrant of the state.
  - A central hub system, similar to UPS and FedEx, based in Albuquerque
  - A consolidation of packages from multiple LNPPs to a given Patient for a single low delivery fee.
- Although I did not hear back from the Dept. on my suggested plan, much of it was incorporated into the Proposed Regulations.
- This plan required at least one day for the service to receive packages from LNPPs, another to sort and consolidate packages, two to three days and nights to make a single quadrant run to many remote communities, a day to return undeliverable packages to the originating LNPP or to hold for delivery the following week.
- This plan also called for the Delivery/Courier Service to collect its delivery fees directly from Patients and to collect payment, if requested, for product via cash, check or credit card.
- The Proposed Regulations require all packages to be delivered within 24 hours, forbid the collection of monies, forbid holding undeliverable packages to be held until the following week's delivery run.
- Due to current Federal Checkpoints in the southern part of the state, current delivery practices necessitate undeliverable packaged to the greater Las Cruces being left with the Las Cruces LNPP for Patient pickup at a later date in order to avoid delivery employees having to traveling north on I-25 through the checkpoints with Cannabis. This practice is also forbidden by the Proposed Regulations and will subject drivers to high risk situations.

Attached find the LNPP NM Cannabis Producers Association Public Comments as submitted by attorney Jason Marks, Jeremy Applen's Page Analytics Public Comment and a marked-up copy of the NM MCP's posted FAQ identifying the errors and misrepresentations of the Dept.

Thank You for Your Consideration.

Respectfully Submitted by:

_____

Len Goodman
Executive Director
New MexiCann Natural Medicine, Inc.

Are the proposed rule changes meant to lead to a reduction in product?

No. The Department of Health is proposing changes to the regulations that are intended to increase the availability of medical cannabis for qualified patients in the Program. Licensed non-profit producers would be permitted under the proposed regulations to triple the number of plants that they grow and the Department also plans to license additional non-profit producers throughout the State of New Mexico after the rule change process is complete.

NOT TRUE: At most, under the these Regulations, LNPPs could increase their flowering plants by 25% to 100% maximum. It would not be possible for LNPPs to triple their product producing plants. See next FAQ for details.

Will fees for all non-profit producers increase under the proposed rules?

No. Non-profit producers who choose to remain at the current plant count would pay essentially the same fee that they pay right now. Non-profit producers would only have to pay the increased fee if they choose to increase their plant count.

NOT TRUE: Current Fee allows LNPPs 150 total plants for $30,000. Under this total plant count some LNPPs flower 75 plants, some 100 plants and some 120 plants. This depends on facility size, number of ights and grow style (dirt vs. hydro, trees vs. "sea of green", etc.) Under the proposed rules, LNPPs are allowed 50 flowering plants for the same $30,000.

For those LNPPs flowering 75 plants (New MexiCann model), the proposed $30,000 fee reduces flowering plants by 25 plants (1/3) and will decrease yield by 33.33%3. For those LNPPs flowering 100 plants, the proposed $30,000 fee reduces flowering plants by 50 plants (1/2) and will decrease yield by 50%. For those LNPPs flowering 120 plants, the proposed $30,000 fee reduces flowering plants by 70 plants (7/12) and will decrease yield by 58.33%

In order to maintain current production levels & yields with no expansion at all, those LNPPs flowering 75 plants (New MexiCann model) would have to pay $60,000 (100% increase). Those LNPPs flowering 100 plants would have to pay $60,000 (100% increase). Those LNPPs flowering 120 plants would have to pay $90,000 (200% increase).

Is it true that the Department of Health developed these regulations without any input from producers and other stakeholders?

No. The Department used information from many sources, including patients in a 2013 survey it commissioned about the Medical Cannabis Program. We have taken written input and met with the Licensed Producers and informed them the Department would be working on new regulations and sought their suggestions on potential issues they would like to see addressed in the regulations. Information was also obtained from the Medical Cannabis Advisory Board, professional organizations, advocacy groups, other medical cannabis states and daily communication with various stakeholders and interested parties.

The Department is currently accepting written comments from the public, and will accept oral comment at the public hearing on June 16th at the Harold Runnels Auditorium, 1190 S. St Francis Drive, in Santa Fe.

The proposed rules are not yet final, and the rules may be amended by the Department in response to public comments received. The Department encourages producers, stakeholders and the public to provide feedback on the proposed rule changes. The perspectives and insights of stakeholders is an integral part of the rule making process.

YES BUT: This is a repeat of the process used in 2010 that caused so much difficulty. While the Dept. did ask for suggestions, at not time did the Dept. inform Patients, LNPPs or the Medical Advisory Board of its thinking. At no time did the Dept. reveal the proposed rule content and ask for input on those proposals prior to publication. Suggestions were made, but in a vacuum. General input, while useful, it does give anyone a chance to comment on the specifics, or even the topics, of the proposed changes. Once a Regulatory Agency has a working draft of its proposed changes, stakeholders need to give input. Had that happened, I believe that the majority of the problems could have been addressed and resolved. Many of the proposed changes were done without adequate understanding of the implications or their consequences.

Why is the department proposing to increase fees?

The Department is proposing (1) to institute a $50 patient registry fee, (2) implement a fee for providing replacement cards, and (3) implement a staggered fee structure for non-profit producers that would impose maximum possible fees on non-profit producers of three-times the current fees, while simultaneously permitting non-profit producers to triple their production (and thus triple their revenue) if they choose.

NOT TRUE: Under the these Regulations, LNPPs fees could triple but but production would increase, depending on grow style from ¼ to double, but there is absolutely no way production could triple. See previous FAQ for details.

Under the proposal, qualified patients currently enrolled in Medicaid are eligible for both a waiver of all of the personal production fee and part of the patient registry fee.

. While we recognize that increased fees can be a burden for some, the Department of Health has to balance its duty to effectively and responsibly carry out its statutory duties of oversight and implementation of the Program and the needs of patients along with the concerns of the producers and other interested parties.

The Medical Cannabis Program relies entirely on fees, and does not receive legislative appropriation for its administration. The Program is unable at this time to continue to meet increased administrative burdens without additional funding. The proposed fees would be used to hire staff to support the administrative and oversight responsibilities of the program, ensure that patients have access to safe product and improve the outreach and education components of the program.

Is it true that the State is increasing the price of medical cannabis?

No. No. The Department of Health does not set prices for medical cannabis.

TRUE BUT: Although the Dept. does not set prices for medical cannabis, fees and administrative burdens do add to the cost of production and distribution and could increase prices to patients.

Is it true that the program is ending and that patients are leaving?

No. Since the program's inception there have always been a percentage of patients who do not renew for various reasons. The number of overall patients has increased since the inception of the program and the number of qualifying conditions has also been increased by the Department during the last two years.

YES BUT: The percentage of patients who have allowed their status to go inactive is very high – almost 1/3 of all patients have dropped out of active status and failed to renew. At the last report given by DoH at the last Medical Advisory Board meeting, the DoH reported that 352 new patients were registered while 350 patients became inactive.

The New Mexico Medical Cannabis Program is thriving, and the proposed rules are intended to meet the needs of the program as it has evolved. In May 2013 there were 9,210 active patients and as of May 30, 2014 there are 11,237 active patients in the program

Why is the Department proposing to decrease the plant count for personal production licenses?

Personal production licenses (PPL) are the one area where the Department most often encounters law enforcement concerns regarding diversion of cannabis. To address this issue, and to also ensure that patients do not exceed the adequate supply of 170 units/six ounces over three months, the Department has proposed a decrease in the number of plants that a qualified patient may possess under a PPL. This plant count proposed is consistent with the number of plants allowed in medical cannabis programs in other states.

YES & NO: The proposed plant count for PPLs is consistant with some states but not with many others. Most, if not all, law enforcement actions against patients with PPLs, have been due to PPLs growing more than the 16 plant (4 mature) plant limit. Those patients with PPLs who exceeded adequate supply, in almost all cases, were patients who were also exceeding the PPL plant count limit. Many patients with PPLs cannot achieve a yield of 3 ounce per mature plant.

The Department also anticipates that the proposed increases in plant totals for non-profit producers will enable non-profit producers to grow and sell significantly more seedlings, and that this will enable qualified patients who hold personal production licenses to grow healthier, more robust plants.

Why is the Department proposing to require criminal history screening for persons who apply for personal production licensure?

This change is being proposed to ensure that medical cannabis is used only by qualified patients for their personal use. The Department is proposing to require criminal history screening for qualified patients who wish to grow cannabis using a personal production license. Persons who have been convicted of violating the controlled substances act may be prohibited from holding personal production licensure.

NO: The fact that a NM MCP registered patient may have been convicted of violating the controlled substances act does not change the fact that they have a Dept. recognized need for medical cannabis. All persons convicted of felonies, find it extremely difficult to find employment and are denied access to public housing. As a result, very few of these patients can afford to purchase medical cannabis and must grow their own in order to have access.

Does the Department intend to require criminal history screening of all applicants for enrollment?

No. The Department is not proposing to require criminal history screening in order for a person to enroll as a patient in the Medical Cannabis Program.

The Department is proposing to change the measurement of "adequate supply" limits for the possession of cannabis from ounces to units. How does this work and why the change?

With respect to dried cannabis leaves & flowers, the 6-ounce limit for a 3 month period has not changed. However, the Department is proposing to change the measurement description from ounces to "units". The change to a "unit"-based system is proposed to address new methods of manufacturing and ingestion of cannabis-derived products (CDPs) that were not widely known when the current Rules were initially created. These include such products as concentrated CDPs.

A "unit" is identified in the rule as one gram of dried cannabis, or 0.2 grams of THC in cannabis-derived products. Thus, for cannabis-derived products, the amount of THC, the primary psychoactive ingredient, is used to determine the unit equivalent.

The proposed limits would look like this:

- Dried leaves & flowers = 170 units = 6 ounces = 170 grams (unchanged from existing rule)
- Cannabis-derived products/chocolate bar = 170 units = .2 grams/200 milligrams X 170 = 34 grams of THC
- Concentrate/wax = 170 units = .2 grams/200 milligrams X 170 = 34 grams of THC at no more than 60% by weight

TRUE BUT: For many Patients who utilize both flowers and Cannabis infused products, this can mean a 50% reduction in the amount of Cannabis that they currently purchase to manage their debilitating conditions.

Why is the Department proposing to limit the amount of THC in high THC products?

The Department is concerned that the documented risks of high THC products outweigh the benefits at this time for the general population of patients in the Program. The proposed 60% cap on THC levels in cannabis-derived products is also generally consistent with the maximum quantity of THC that is contained in most cannabis-derived products, and the Department anticipates that the proposed 60% cap would not impact the availability of cannabis-derived products for qualified patients.

YES BUT: While there have been documents concerning the risks of high THC products, there is no definitive answer. This is still an open question that is being investigated nationally within the cannabis industry and its regulatory bodies.

It's also important to note that if a qualified patient needs a higher concentration of THC due to their medical condition, the patient can request an exception to the rule by submitting a statement from a certifying practitioner verifying that this is medically needed.