DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

March 14, 2014

LCB File No. R004-14

Information Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation.

The proposed regulations are necessary to carry out the requirements of Chapter 453A of the Nevada Revised Statutes (NRS) that require certification of medical marijuana establishments in Nevada. Provisions in this regard have an effective date of April 1, 2014. These provisions were added by an act of the 2013 Nevada Legislature, Senate Bill 374 (Chapter 547, Statutes of Nevada 2013).

The proposed regulations identify provisions for the establishment, licensure, operation, and regulation of medical marijuana establishments in the State of Nevada. The proposed regulations address this new industry as a privileged industry as outlined in NRS 453A.320 and provide processes for accepting/renewing applications, awarding establishment certificates and cards, and establishing requirements for each of the four establishment types related to tracking from seed to sale. Additionally, the regulations revise provisions related to criminal background checks for applicants for medical marijuana cards.

The regulations are needed to ensure oversight standards for medical marijuana establishments. Additionally, the requirements for testing marijuana that is cultivated and produced will assist end users of medicinal marijuana in understanding what is in the product they are ingesting.

2. A description of how public comment was solicited, a summary of the public response and an explanation of how other interested persons may obtain a copy of the summary.

Public comment was solicited through public notices posted at the Division of Public and Behavioral Health offices in Carson City and Las Vegas, the Legislative Building in Carson City, the Grant Sawyer State Office Building in Las Vegas, the Division of Aging and Disability Services in Elko, Early Intervention Services in Las Vegas, Nevada's public libraries, the Washoe County Health District, and the Nevada State Library and Archives. In addition, copies of the notices were distributed through the Division's Medical Marijuana LISTSERV to 843 subscribers.

On October 4, 7, and 8, 2013, the Division held four stakeholder meetings over three days. The sessions focused on each of the four establishment types as well as the application process. These meetings were videoconferenced between Carson City and Las Vegas. A telephone line was also used to extend outreach to as many stakeholders as possible. Over 200 people attended in person with an unknown number of people on the telephone. The Division received considerable feedback over the three days and incorporated recommendations into a comprehensive draft of regulations that were issued with the Small Business Impact Statement on November 22, 2013.

During the stakeholder sessions, there were many comments about the financial requirements, including the $250,000 liquidity requirement and the $5,000 non-refundable application fee. The comments specified these requirements might exclude veterans and individuals from being able to apply for certificates. The Division cannot change these requirements because they are established in the NRS. Commenters were encouraged to participate in and voice their concerns to the Subcommittee on the Medical Use of Marijuana of the Advisory Commission on the Administration of Justice.

In addition, there was interest in staggering the application process to allow for the acceptance of cultivation and laboratory applicants to enter the process first because the product cannot be sold until it is grown and tested by a Nevada-certified independent testing laboratory. After legal review, it was determined this option was not feasible.

The Small Business Impact Questionnaires and the final draft of the regulations were sent to all members of the Division's Medical Marijuana LISTSERV. At the time, there were 559 recipients on this list. These documents were also sent as follows to the:

- Department of Taxation's list of 322 interested persons;
- 339 members of the Retail Association of Nevada;
- 23 members of the Nevada League of Cities; and
- 17 members of the Nevada Association of Counties.

In addition, on November 25, 2013, the Division sent the questionnaire and proposed regulations with a request to distribute through their memberships to the Asian Chamber of Commerce, Boulder City Chamber of Commerce, Carson Valley Chamber of Commerce, Economic Development Authority of Western Nevada, Las Vegas Chamber of Commerce, Las Vegas Global Economic Alliance, Las Vegas Metro Chamber of Commerce, Latin Chamber of Commerce, Laughlin Chamber of Commerce, Mesquite Chamber of Commerce, Mesquite Regional Business, Inc., Nevada Association of Minority Contractors, Nevada Minority Business Development Agency, Nevada Minority Supplier Development Council, Nevada SBDC Business Success Center, Nevada Small Business Development Center (SBDC), Pahrump Chamber of Commerce, Reno Live and Buy Local, Small Business Association in Reno and Las Vegas, University of Nevada – Business Start Up Center, Urban Chamber of Commerce, Ward 5 Chamber of Commerce, Women's Chamber of Commerce of Nevada, and Nevada Workforce Connections.

Six responses were received out of 1,880 questionnaires that were distributed. The comments received from the Small Business Impact Questionnaire were taken into consideration with comments received from a Public Workshop held on December 23, 2013, for possible further revisions to the proposed regulations. The comment period was officially closed on December 31, 2013.

On December 23, 2013, the Division held a Public Workshop that was videoconferenced between Carson City and Las Vegas, and approximately 120 people signed in. The Division

received extensive comments at the workshop, and numerous written comments were submitted for consideration. The Division subsequently made more than 70 changes to the draft regulations based on the comments received. Copies of suggested amendments/comments received were posted on the Division's webpage. After making the changes, the final draft regulations were delivered to the Legislative Counsel Bureau (LCB) on January 13, 2014, and returned to the Division on February 11, 2014.

On February 19 and 24, 2014, the Division held additional stakeholder sessions to answer questions about the proposed regulations as they were redrafted by the LCB. The email notification for the meetings went to 891 recipients. Both meetings were videoconferenced between Carson City and Las Vegas, a conference call line was made available, and the sessions were broadcast over the Internet. The Internet had 192 and 165 views for each meeting, respectively. The meetings helped to identify areas of the regulations where technical changes needed to be made, and those technical changes were provided in the form of an errata for consideration at the same time the regulations were adopted.

The Division has provided several opportunities for interested parties to submit input and comments regarding the proposed medical marijuana regulations, including the economic impact the proposed regulations may have on small businesses in Nevada. Some of the major modifications made to the proposed regulations include:

- Removing the requirement for dispensaries to have a medical director as a consultant which alleviated a significant economic burden;

- Revising the circumstances that would result in an establishment needing to surrender its certificate when changes in ownership are made by making them less stringent;

- Changed the application solicitation period from 60 days to 45 days as public testimony indicated 60 days was a lengthy period of time;

- Eliminated a requirement that would have resulted in only Nevada residents being eligible to work as agents in establishments as testimony indicated this provision was overly restrictive;

- Eliminated a provision that would have required expiration dates to be listed on marijuana and marijuana products because testimony indicated it would have been costly to perform this testing, and the cost could be prohibitive for the consumer;

- Revised the provisions related to the Division making a decision to limit the production of marijuana in the State by requiring that such findings be made in a public hearing; and

- Adjusted the requirements for sanitation to ensure that it is applicable to the type of production and not overly restrictive.

The one area the Division chose not to change was the requirement for an annual audit. The reason it was not changed is Chapter 453A of the NRS specifies that this new industry is a privileged industry and requires significant regulation and oversight to prevent criminal activity. There is potential for a certified establishment to sell marijuana in the illegal market, and it is

essential there be professional financial oversight to assess whether internal controls have been followed as well as to perform an intense review of revenue and expenses to determine whether the numbers are consistent with the activities of the business. Further, audit requirements are charged based on the size of the business; therefore, the Division determined there would not be an undue burden based on the size of the businesses.

The Division received significant comment about the following provisions contained in the regulations:

- Cultivating marijuana in a manner such that it is shielded from any view exterior to the cultivation facility: At this time, this provision is important to protect the integrity of this new industry. In the future, if it is determined that this is not an issue, the regulations can be amended to remove this provision.

- Collecting data regarding physicians who are recommending marijuana to patients: This provision is mandated by NRS 453A.370 and cannot be changed by the Division. However, prior to the law being changed, the Division was required to distribute a copy of a cardholder's completed application to the respective licensing board of a physician. Additionally, NRS 453A.500 and 453A.510 protect a physician from disciplinary action simply because the physician recommends marijuana for his patients. In spite of these laws, the respective boards always have the authority to take disciplinary action for the practice actions of a physician if the board finds the practices violate the provisions of the physician's license.

- Use of organic materials in the cultivation of marijuana: Organic use is permitted if the establishment is able to secure the organic certification from an entity authorized to issue such certification.

- The use of appeals: No provisions are contained specifically for appeals of decisions of the Division. Because this is a privileged certificate, the Division was advised not to include such provisions in the regulations.

- Advertising provisions: The regulations specify that an establishment shall not use any sign or advertisement unless the sign or advertisement has been approved by the Administrator of the Division. The Division is developing guidance in this regard that will be issued to establishments after the implementation date of the law.

The Division received significant comment about the laboratory testing provisions. The NRS require that laboratories be independent of the other three medical marijuana establishment types. A person may not have a financial interest in an independent testing laboratory and the other establishment types. Further, an establishment must have all of its products tested by the independent testing laboratory and all labels of products sold must be standard and only disclose information based on the laboratory analysis. This is a different standard than that in many other states, and the decisions made in this regard were driven by the enabling legislation. No establishment may use its own scientific director to test its marijuana or marijuana products, and an establishment may not send marijuana or marijuana products to an out-of-state laboratory for

testing. A laboratory may become certified by the International Organization for Standardization, but that certification is not in lieu of the requirements of the regulations.

Issues surrounding testing are technical and complex and there are few, if any, models to follow that have a wide level of acceptance at the current time. As a result, the Division will create an Independent Laboratory Advisory Committee that will have public discussions about areas where there is not widespread agreement. The committee will make recommendations to the Division for testing that will be incorporated in a policy manual that must be followed as it relates to certain laboratory tests. As with other provisions, if it is determined that the testing provisions are not adding value, the Division is committed to revising the regulations as needed.

Notes and minutes of the proceedings referenced in the preceding text may be obtained by contacting Joseph Theile, Management Analyst II, at (775) 684-3487, or from the website of the Division at http://health.nv.gov/MedicalMarijuana_Meetings.htm.

3. The number of persons who:

(a) Attended the hearing;

- Carson City: 54 people signed in
- Las Vegas: 96 people signed in
- Elko: 2 people were visible on the video link (they did not sign in or testify)
- Telephone: At least two people were on the phone (one testified)
- Total: 154

(b) Testified at each hearing; and

- Carson City: 3 (Stacey Woodbury, Chelsea Capurro, Peter Krueger)
- Las Vegas: 4 (Bruce Gayle, Marc TerBeek, Dan Rush, Phil Gervasi)
- Telephone: 1 person on the phone (Johnathan Goldsmith)
- Total: 8

(c) Submitted to the agency written statements.

Written Statements Submitted: 1 person (Stacey Woodbury)

(d) For each person identified above, the following information if provided to the Division of Public and Behavioral Health: Name, telephone number, business address, business telephone number, electronic mail address and name of entity or organization represented.

The sign in sheets from the meeting are included with this statement as Attachment 1.

4. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Comment was solicited from affected businesses by first establishing a LISTSERV that was used to communicate meeting notices and other pertinent information as the Division proceeded through the regulations development and adoption process. Subsequently, the Division requested input from interested parties through the methods identified in the following paragraphs.

The Division prepared a questionnaire that asked for input regarding the potential impact to small businesses. On November 22, 2013, this questionnaire was sent with a copy of the proposed regulations to all members of the Division's Medical Marijuana LISTSERV, which contains 559 recipients; the Department of Taxation's list of 322 interested persons; 339 members of the Retail Association of Nevada; the 23 members of the Nevada League of Cities; and the 17 members of the Nevada Association of Counties. In addition, on November 25, 2013, the Division sent the questionnaire and proposed regulations with a request to distribute through their memberships to the Asian Chamber of Commerce, Boulder City, Chamber of Commerce (sent to 620 members), Carson Valley Chamber of Commerce, Economic Development Authority of Western Nevada (EDAWN), Las Vegas Chamber of Commerce, Las Vegas Global Economic Alliance, Las Vegas Metro Chamber of Commerce, Latin Chamber of Commerce, Laughlin Chamber of Commerce, Mesquite Chamber of Commerce, Mesquite Regional Business, Inc., Nevada Association of Minority Contractors, Nevada Minority Business Development Agency, Nevada Minority Supplier Development Council, Nevada SBDC Business Success Center, Nevada Small Business Development Center (SBDC), Pahrump Chamber of Commerce, Reno Live and Buy Local, Small Business Association in Reno and Las Vegas, University of Nevada – Business Start Up Center, Urban Chamber of Commerce, Ward 5 Chamber of Commerce, Women's Chamber of Commerce of Nevada, and Nevada Workforce Connections.

The questions on the questionnaire were:

1) How many employees are currently employed by your business?

2) Will a specific regulation have an adverse economic effect upon your business?

3) Will the regulation(s) have any beneficial effect upon your business?

4) Do you anticipate any indirect adverse effects upon your business?

5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Responses

Summary Of Comments Received (6 responses were received out of 1880 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
An annual "audited" set of financial reports could cost tens of thousands of dollars! A set of financial statements "reviewed" by an independent account should be sufficient. [Another section] requires all employees and volunteers be Nevada Residents. Periodically, especially during the initial startup, I anticipate contracting with an out of state organization with years of experience in the industry, to provide guidance. Based on the verbiage of this section they will not be allowed. We should allow a provision for out of state contractors to work in the facilities. Without having third party consultants to work with could cost hundreds of thousands of dollars in set up errors and/or lost revenue. [Another section] requires cross training of all staff for all elements of the business. In cultivation there are a variety of "Intellectual Property" (I.P.) elements at play. It is bad business to train multiple people in all aspects of this business and education them to all of the I.P... Our employee's will be head hunted by the competition to steal this I.P. knowledge!!! Costs of millions a year!!! [Another section] could place a restriction on our compensation package for key employees. We anticipate offering a profit sharing program to incentives our staff which is very generous. This could be construed as "in excess of reasonable allowances." 5 year historical storage is too long. 3 years is more reasonable. This could cost in the tens of thousands of dollars in storage fee. OR, ALLOW US TO SCAN AND ELECTRONICALLY STORE THE DATA. Don't obligate us to maintain the original hard copies.	I am a firm believer in tight regulations will eliminate shady businesses! The key is avoiding regulations that put too much of a burden on the business. Or regulations that result in higher costs of quality products to the patients.	No	No
In no particular order, here are my concerns and comments: • The hard-dollar cost is difficult to project, though likely might range up to two or three	While no specific regulations come to mind, overall this work by the Division and the	Spending many years in Sales & Marketing leadership for	Redefinition of permissible enclosed cultivation facilities

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additional FTE employees. Based upon an exhaustive analysis of other Medical Marijuana (MMJ) States and the underlying MMJ businesses therein, from inception our go-to-market strategy hinged on full "Seed to Sale" operations; medible manufacturing, cultivation, dispensaries. This robust operational footprint is a proven approach to risk mitigation (CO), avoiding supply chain disruption (AZ), attaining earlier-stage financial solvency all while providing exemplary patient care. One pivotal aspect of operational efficiency and thus streamlined costs will be our Nevada-based employees. Section 41(2) states that "Each medical marijuana establishment agent registration card issued pursuant to NRS 453A.332 must indicate the category of the registration card. The person to whom the card is issued may ONLY provide services at the type of medical marijuana establishment for which he or she is registered to provide services." From a business perspective, I am an advocate of specialization. However, at an early stage, organizations grow stronger through cross-training skills. That way, with illness, unplanned absence or termination, operations are not disrupted and patients still receive high-quality care. Also, within a full "Seed to Sale" operation, cross-training and diverse work exposure within multiple establishment-types empowers the employee, providing for both personal preference and career path advancement. As a business owner, I also benefit by being capable of matching specific job functions with personality type and business need. Please consider modifying or expanding this provision to enable registered agents to work in multiple establishment-types if the umbrella organization encompasses several different types of establishments. -- Requirement of an independent certified public accountant audit of the annual financial statement. After working in Silicon Valley with numerous "Startup" companies, I understand the requirement for greater assurances around financial statements. At	regulations themselves ultimately enable the business model itself. Without your work, none of this would be possible considering the Federal Government's stance on Medical Marijuana. Speaking only for myself, I see the regulatory framework as a necessity if our goal is to help patients, operate with transparency and increase tax revenue. Though onerous, this entire effort will create a Net-Good. While I may not agree with everything included within the regulations, rules need to be set so that we might play the game. Nevada is crafting a best-of-breed model that I am confident will be emulated by other states as they stand up medical marijuana.	various technology companies, I believe I bring to the table some astute best practices in launching a business. I am excited to apply my learning to the MMJ Industry in Nevada. [The stipulation] that "a medical marijuana establishment shall not use 1. A name or logo unless the name or logo has been approved by the Administrator of the Division; or 2. Any sign or advertisement unless the sign or advertisement has been approved …." Having helped launch several businesses, best practice is to begin building a social media strategy (Twitter, Website, Tumblr (Blogs), Google Plus, online forums, etc.) before the business opens day one. That enables us to provide value to patients looking for resources, branding our downstream product & service offerings and interact with the community beforehand. We are	to include Greenhouses is of tremendous benefit, though admittedly forces a revamp of strategy to include this added capability. Not only is greenhouse growing a more sustainable and environmentally friendly model, it reduces some of the significant costs associated with indoor lighting models. On the downside, though not outweighing the positives, security costs rise with an outdoor model and new security protocols will need to be crafted and implemented. With this move outdoor and into the sun, please consider enabling agricultural zoning for cultivation facilities.

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the risk of sounding promotional, that is why one of our Founders is a former Director of Internal Audit for the State of Nevada. We thoroughly understand the "business enabling" quality of regulatory compliance and financial transparency. My issue here is more prosaic, firmly rooted in high dollar cost; I estimate this cost alone to be upwards of $50k+ considering our intended "seed to sale" footprint. For perspective, that is the equivalent of a fully-loaded employee. In year one, wherein we project a loss based upon the initial capital requirements, tough choices might ensue around head count. Statistically, the vast majority of first-year startups fail. Within the MMJ Industry, those numbers match up well, with only 25% of Dispensaries generating over $1,000,000 in revenue. Add to this the sobering consequences of IRS tax code 280e which denies dispensaries the ability to claim such typical expenses as rent, payroll, utilities and various other legitimate business expenses. Perhaps consider a phased approach to this cost item, beginning after year two or based upon some overall revenue attainment. -- While no doubt application fees will generate a sizable sum, the real "win" for Nevada is higher taxes and lower unemployment. As we are applying for multiple establishment types, i.e. full "Seed to Sale", our applications will contain much redundancy across leadership team, financials, etc. Ultimately, our team needs to be thoroughly vetted only once, not three of four times. All things considered, I do understand there will be fees associated with data management and validation with multiple applications, so I ask for you to consider some percentage discount on application / license fees based upon data redundancy and reduced cost. If the Status quo remains, our exposure to fees difficult to justify might be upwards of $15k. -- As stated previously, our proposed business footprint includes edible / infused medical marijuana product manufacturing, dispensaries and a supportive cultivation		confused about what marketing and social tactics we can adopt at this time. Also, what is the process for logo or name approval? • Envisioning NV's Medical Marijuana Industry 10 years from now, it becomes imperative that some mechanism / process is established that enables a smooth though diligent transfer of ownership interest. At that time, a similar due diligence process might occur, with associated transfer fees paid to the state. What small business owner does not envision a downstream exit? Without enabling a transfer, the alternative is shuttered doors	

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facility. In an attempt to increase security and while increasing public safety, we are engaged with a professional security firm to scope out best practices and refine our Standard Operating Procedures. After assessing regulations and listening to our "Seed to Sale" plan, he questions the rationale to physically separate a cultivation facility from its "Medible" Kitchen. From his perspective, this unnecessarily increases security and transport risk while increasing cost for in-transport security and another building facility. The entire process is more streamlined and safe if these established might cohabitate. From a business and safety perspective, I ask that you consider amending Section 72 to allow for these complimentary businesses to share a common entry, common amenities like a team break room, bathrooms. As for the financial impact of requiring different buildings altogether, those costs would include additional rent, utilities, security, etc. and would easily increase expense by over $150,000 per year (Lease X 12 plus NNN, various expenses, transport and security).			
I am attempting to be responsive to the Small Business Impact Questionnaire; however it is difficult for me to answer your questions in the format you have provided. I am going to answer as if our company has already been formed, although this will not take place until later this month. 1.Currently there is one employee working on this initiative who would be considered an employee of a small business and another few who are either owners or who are going to be subject to a letter of intent to become employees. 2. Although I have not been able to calculate the dollar amounts in many sections, I will attempt to explain what might be the impact for each of the sections below of the draft regulations sent to us last week. -- We believe that only having 30 days notice of the point values assigned for the application will be too tight a timeframe in addition to all the other documentation and	We feel most of these regulations will help all of the licensed businesses and recognize that this is an opportunity to get into a new business at the ground level. As with any other business model, being one of the first businesses to get licensed is a great benefit.	No	No

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material for the application that needs to be prepared. In the last draft of the regulations we were provided a draft of the point values. I would encourage the Division to finalize these point values and make them public as soon as possible. In any event we feel that 30 days is too short a time period and would prefer to have 60 days. -- We feel the education requirements for employees will be costly and it is not clear if we need to hire outside consultants for training and education. Other than some basic training requirements, we feel that each business should be able to decide how much training and who will be conducting training for its employees. My understanding from speaking with consultants is that it could cost between $20,000-$30,000 to fully train staff if we are not able to use in-house trainers. If we have a Master Grower who has owned dispensaries and cultivation facilities and has provided training to employees of those facilities, he should be qualified to conduct in house training for us. With respect to health and safety issues for a production facility, an in house chef could train employees on food and safety issues. -- We feel it would be a burden, costly and time consuming to pay for a professionally prepared survey if a local government has not enacted zoning restrictions. If a survey needs to be conducted we feel that our employees are competent to conduct such survey. -- We feel that it is an undue burden to be required to audit according to 'generally accepted accounting principles' at least once every 30 days. The tax code requires a monthly audit, there is a daily inventory control/audit and annually our financials will need to be audited. We feel that if we need to audit according to GAP then this audit would need to be done by a CPA, not internally and that a monthly audit of this kind could run us $2,000 per month. -- We do not feel that child resistant packaging according with Poison Prevention Packaging should be the standard for			

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medical cannabis. If we are able to use the Substitute labeling statement, "Package Not Child-Resistant" in 1700.5b then I suppose we could still use zip lock packaging. Pharmacy bottles are more expensive than zip lock packaging and are worse for the environment. In addition the square labels as currently suggested would completely cover the bottle. If we package everything at the Cultivation facility then our patients/customers will not be able to see the product through the bottle. If we have to package everything at the Dispensary instead of at cultivation then this would cause an impact on how we hire employees and who we hire to weigh each package for sale. Any product containing marijuana also includes edibles and I don't think it's feasible to put a brownie in a child resistant package. -- We feel the size of these labels would cause us to have to package our products in larger pouches than is necessary for the product. Larger packaging is more expensive. The best examples of packaging I saw in AZ were zip lock pouches varying in size by quantity/weight of the product being purchased. Pouches were clear on one side giving patients/customers the opportunity to see the exact product they were purchasing, not just a sample. This is the model we were intending to use. -- We feel that a system for monitoring environmental conditions is vague and that it is probably covered by (i)-(iii) within that same section. A vague requirement such as this is subject to a consultant charging whatever they want because we have no way of quantifying what this should cover. -- We feel this is a very subjective section and after spending a lot of money to get our cultivation and dispensary open we would not want the Division to arbitrarily come to us and say now we could only produce (or cultivate) a certain amount.			

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-- Given that many of the proposed application fees are intended to support the cost of background checks, application review, etc., IF A GROUP / ENTITY applies for multiple licenses, much of the background check and review will be duplicative between license applications. Specifically, my group intends to apply for a minimum of 2 dispensary licenses, a cultivation license, and an edible/infused products license. To pay the up-front fee of $5000 per application, and then the associated license issuance fees IN FULL for each application, leads to significant fees (easily in excess of $15K) that are not truly justified given that our team only needs to be vetted / qualified ONCE. -- Some entities may want to change their structure. For instance, from a business perspective, it may be desirable to start as an LLC, but switch to an S Corp. Note that in this particular example, there is a federally mandated March 15th deadline in a given year to elect S Corp Status, so the state needs to contemplate that changing organization types may need to take place OUTSIDE of the 10 day application period, depending on WHEN the 10 day application period is set each year. It would be appropriate for Section 36 to contemplate entities changing their organization type. Not facilitating organizations being able to change their organization type could easily cost a business $10s or even $100s of thousands of dollars due to different tax treatments at the federal level. Section 36.3: Requirement of a report of audit. In my experience, audits cost anywhere from $15K to $50K for small businesses. This is a significant and undue burden, especially for a startup organization. I would suggest eliminating any request for audit for the first 2 taxable years at a minimum. It might also make sense to establish revenue threshold(s) for the audit requirement and/or more infrequent (e.g., NOT ANNUAL) audits thereafter. -- It is difficult to put a hard dollar cost on this, but there does not appear to be any sort	No response provided	-- From this section it appears that if a group / entity wishes to apply for multiple licenses, as permitted by the legislation, that a separate application must be completed for EACH license. If the Division were open to it, it would be more efficient (and kill fewer trees!) to fill out one longer application covering each of the proposed licenses. -- As we (and I suspect most other) applicants will not have a fully binding lease, nor FULL access to the buildings that we wish to occupy until such time as we obtain licenses, it would be helpful if the Division could spell out some sort of process to, "work with the applicant and landlords to find mutually agreeable time(s) for inspection(s) as required to review the application." Without some process that involves working with applicants and landlords, the application process	No response provided

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of allowance for owners or employees with particular skill sets to obtain an agent card that would allow them to provide services at MULTIPLE establishments of different types (I do read it as saying that a given agent could work at ANY dispensary if they have the 'dispensary' agent card). IF THIS IS TRULY THE INTENT, it could be devastating! Again, my group anticipates owning dispensaries, cultivation, and medibles facilities… as owners / operators we need to be able to enter all of them to provide services. And I can easily envision employees who may have relevant skills for 2 or more establishment types. So, hopefully there will be a process by which agents can obtain registration cards that enable them to provide services at 2 or more establishment types? Furthermore, from a business efficiency, public exposure, and safety/security perspective it is logical to co-locate a medibles / infused products manufacturing facility WITH the cultivation facility. Ideally employees would share a common entrance (better security!), common break rooms and bathrooms (more efficient!), etc. So again, this begets the issue of agent cards if they work as a cultivator and or medibles employee in a building that houses BOTH businesses. I can go on and on about why this makes sense and is in everyone's best interest. -- If we cultivate our own product, and make edible or infused products in a co-located facility, it certainly adds cost and time to test the shake / leaves, etc. prior to utilizing to make, for instance, a concentrate. While this testing can certainly be done, it seems to add an artificial 'step' that costs time and money, and is generally unnecessary given that the final medibles and infused products must be tested in any case before being transferred to a dispensary. -- We plan to grow organically (not hydroponic without pesticides, but true organic, in soil) based on industry standards. However, Section 70 calls for certification, "in a manner consistent with the national organic standards established by the		will be biased toward only those applicants who already own their own building. -- As these businesses get stood up, it will become imperative in the future to create a mechanism to transfer ownership of the establishment and the accompanying registration certificate, obviously with approval by the Division of the new owner(s). This could work very much like the process by which casinos in the state of NV are sold, with sign-off by the overseeing body. -- When you state that you want to reporting to include the "origin" of the marijuana seeds or cuttings, can you please clarify? It seems that we are obligated to obtain seeds or cuttings from existing registry cardholders, do we need to identify the individual? It just seems that this is likely to be a sensitive topic, and	

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USDA." The USDA cannot certify us because the USDA is a federal agency, and medical marijuana is illegal federally. Will the NV Dept. of Agriculture certify us? Even with a local certifying agency the cost of certification (based on web searches and conversations) typically ranges from $2-5K/ year. If we have to bring in a certifying organization from outside the state, the costs will only be higher. Obviously this cost (and any of the others touched on in this document) will end up being passed on to consumers. Is this really what NV wants? A high cost medical marijuana program? I do not think, in the early phases of this program, that organic certification should be required UNLESS a state agency (such as the Nevada Dept. of Agriculture) can do the certification, in which case I am 100% supportive. -- As noted above, if a group desires (as we do) to do both cultivation and edible / infused marijuana products, it makes tremendous business and security sense to co-locate those facilities. Section 72 should be amended to reflect that if 2 such businesses are owned and operated by the same group / entity, that officers, board members, and agents can utilize a common entry, share common spaces (break room, bathrooms), and to extent licensed to do so, work in either business establishment. -- I don't believe you are trying to exclude establishments from using more neutral packaging such as glass, but there is no mention of such in this section. Please call out that glass, etc., are authorized (and hopefully encouraged!). -- This section specifies that expiration dates for medical marijuana products must be determined by appropriate lab-based stability testing. THIS COULD MAKE THIS BUSINESS IMPOSSIBLE! Given my background in the biotechnology world, I fully understand that lab based stability testing will run $10s if not $100s of thousands of dollars PER PRODUCT. Are the "independent testing labs" supposed to do this testing? Are we supposed to do it as		may lead to LOWER QUALITY options in terms of strains of medical marijuana, etc., if full reporting of individual names, etc., is required. NRS 453A.350: The way this is written, I believe it is perhaps intended to apply only to dispensaries? It does not make sense to require an edible marijuana / infused products manufacturing facility to be located in a SEPARATE building from the cultivation facility. There are tremendous business synergies, not to mention a less public presence and lower security risks, by co-locating these facilities if they are owned by the same group. ALSO, this provision specifies commercial or industrial zones only. What about agricultural zones for the cultivation (and possibly medibles) establishments?	

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cultivators / medibles manufacturers? Even using accelerated testing protocols, it typically takes months to stability test a given product. PRACTICAL SENSE needs to come into play here! I implore you! Medical marijuana (flower) is like tobacco in a fine cigar… properly stored it can last for years, and age well! Shelf life will depend in part on how it is initially packaged (e.g., air tight container? Air or nitrogen?), and stored (temperature? Light? Humidity? Packaging?). For edible products and infused products, the primary factor will be the 'normal' shelf life of the non-cannabis ingredients. For instance, if we make a cannabis infused olive oil, the suggested expiration date or "best by" date should be whatever accompanies the olive oil itself… which may be based on knowledge NOT laboratory based stability testing. So, please clarify (or omit!) this section. Requiring true laboratory based stability testing of very small volume products is impossible from an economic perspective. It simply costs too much. MULTIPLE Sections: If there is no licensed independent laboratory in Northern NV, it would be a significant cost burden to our Northern NV based businesses. What can be done to ensure that at least ONE independent laboratory gets stood up in EACH of Northern and Southern NV? What if the lab takes their sweet time (they have up to 12 months) to get the business running? Are we paralyzed in that instance, paying rent, etc., with no ability to sell our medicine through dispensaries? This would be devastating financially!! It makes sense to me that there be a backup plan in place. For instance, perhaps UNR could run the tests? Or perhaps we could sell product WITHOUT testing until such time as an independent lab is up and running in Northern NV? Or perhaps we could do our own testing until such time as an independent lab is up and running in Northern NV? I believe it is imperative for the Division to put some sort of contingency plan in place!!			

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Millions will be diverted, lost efforts, economic downfall, loss, and waste of time that is exhaustive but, being invested: The list of regulations as it is presented stifles the economy, stops progress of the NIH systems, continues to allow great research out of this Country, and if implemented could cause a line to be drawn in the sand by the DEA v. State. This method will encourage human danger? It will be discriminatory? It will not be a good answer that will safely continue the business of Medicine being defined. We all recognize Gonzales v. Raich concludes, "the State does have a right to purport the crimes," AS WELL, the DEA has discretion to take out illegal businesses. Why not compromise by education to accept franchise-able businesses that allows all small business concerns, to become involved by proper license and access, i.e., TbT Group, Inc., which will show clinical trials and studies to support www.theiamb.com, and this will allow the big businesses to come on board to gain NIH Standards to medicine? This would be one idea to grow the economy and satisfy all? IMPACT: Therefore, the thought of TbT Group franchising to help Veterans, VA Directives, Investors, Manufacturers, Developers, DEA, Distributors, NIH, and the common business person who wants in or to become involved in this business is unattainable by these set of Regulatory Method, when, we all too well know that "the feds own the meds" and clinical trials grants all access, so we should as those with clinical business on our minds relate to the standards of collaboration. DEA Registration lists 111 businesses with a right to do business, by proper access to licenses. TbT Group had plans of education symposiums to help all learn how to transition their weed business, to a federal level of safety. The theory of TbT Group would be to open the franchising to the Veterans who cannot stand a chance against big industry dollars,	Checked Yes. NEGATIVE IMPACT, the right regulatory businesses that will increase fed activities, jobs, and add to the State levels are going to have to compete with shady businesses like, Dr. Reefer, those who care about the dollar and not about the patients or their care, or free medicine, or the businesses that that activity brings.	As advocates on behalf of the federal government, we seem foolish if we believe in other methods other than the sciences? Therefore, we believe and know that all activity does have a doorway that is open for green business, if we do this right? We can involve all, but, the pattern must be with a better access to control and in this greedy affair, this TbT will, be the only answer sent that will be inclusively a way for all who can afford to become involved and immediately open offices, and this will allow those with much funding to also do their businesses.	Checked Yes. NO BENEFITS, much disaster, for our project is like the gorilla in the room, everyone knows that it is here, but, no one wants to deal with it, logically?

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grant accessibility by others, b (note: the comment ended at this point)			

Number of Respondents out 1880	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
6	5	3	3	2

Any persons interested in obtaining a copy of the summary may email, call, or mail in a request to Joseph Theile at the Division of Public and Behavioral Health, Medical Marijuana Program, 4150 Technology Way, 2nd Floor, Carson City, NV 89706, (775) 684-3487, jtheile@health.nv.gov. The Small Business Impact Summary has been posted on the Division's website at: http://health.nv.gov/ and http://health.nv.gov/medicalmarijuana.htm where it may be viewed and downloaded.

5. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

Based on input received during the December 23, 2013, Public Workshop, more than 70 changes were made to the final draft of the regulations that were submitted to the LCB. After the regulations came back to the Division from the LCB, some technical changes were made as outlined in the errata and supplemental errata to R004-14P. The sections that were amended were Sections 26, 28, 35, 46, 72, and 120. In addition, one amendment to Section 136 was adopted as submitted by the Nevada State Medical Association.

The following points identify issues that were brought up during the hearing that were not adopted and the reasons why:

- Bruce Gale asked whether the Division intended to amend the provisions at Section 35 prohibiting the 10 percent or more of the stock from being transferred. The amendment will not be made at this time because NRS 453A.334 prohibits the transfer of a medical marijuana establishment certificate.

- Mark Terbeek suggested that a person who performs professional services for an establishment may be required to obtain an agent card, and he asked for reconsideration about the provisions related to agent cards. The Division believes that the language in the

definition at Section 16 of "medical marijuana establishment agent" excludes a consultant who performs professional services for a medical marijuana establishment.

- Phil Gervasi highlighted that Section 60 related to security of the establishment does not include a provision for onsite security. He is correct, however Section 26 requires an applicant "to ensure adequate security measures, including, without limitation, building security and product security." Further, Section 41 specifies that agents must be trained in "The proper use of security measures and controls that have been adopted by the medical marijuana establishment for the prevention of diversion, theft or loss of marijuana." Finally, Section 134 makes the security plans confidential and not releasable as public documents by the Division. Additionally, testimony during the regulations development process indicated there are multiple ways to assure security without requiring an onsite presence in the regulations.

- Peter Krueger, representing the Nevada Medical Marijuana Association, asked the Division to consider eliminating provisions in Section 72 that marijuana cannot be observed from outside an establishment. This amendment was not made at this time as it was determined not to be in the best interests of the State. The Division indicated it needs time to gain high-quality experience regulating this new activity. As it gains experience and as public acceptance of growing, producing, and selling marijuana in the State of Nevada expands, these provisions can be changed.

- Also in Section 72, there were comments during the workshop, but not during the hearing, to revise the provisions related to the limitation on odor exterior to an establishment. The Division is working on internal guidance that will establish a parts-per-million (ppm) standard that will be used if there are complaints in this regard. As a result, there was no need to amend this section because a ppm standard will be an objective standard.

- Prior to the hearing, the Division received a letter via email from Victor Morin, Ph.D., expressing concern about batches and strains of marijuana as it relates to the requirement in Section 120 to "…segregate all harvested marijuana into homogenized batches…" The concern is that the regulation will require an establishment to combine different strains into one testing batch, thereby losing the plant's unique identity. The Division does not believe that is the requirement. The definition of "batch" in Section 2 is that it is a "…specific lot of marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time." The definition of "lot" in Section 12 is that it is "…flowers from one or more marijuana plants of the same strain, in a quantity that weighs 5 pounds or less; or …leaves or other plant matter from one or more marijuana plants, other than full female flowers, in a quality that weighs 15 pounds or less." The reference to "same strain" allows a cultivation establishment to batch unique strains for testing.

The following amendment was adopted:

- An amendment was accepted from the Nevada State Medical Association. The Association's Executive Director, Stacy Woodbury, submitted an amendment to Section 136. This section establishes provisions related to the recommending practices of physicians. The amendment clarifies that the Division is not making a recommendation for disciplinary action to a

respective physician licensing board, but the Division is notifying the respective board for it to consider an investigation of the physician.

6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:

a. Both adverse and beneficial effects; and

- Adverse Effects: There were concerns expressed by stakeholders related to costs outlined Chapter 453A of the NRS, including the $250,000 liquidity requirement contained in NRS 453A.322. The Division cannot change these provisions; however, the Legislature has created the Subcommittee on the Medical Use of Marijuana of the Advisory Commission on the Administration of Justice. The Subcommittee is tasked with considering, evaluating, reviewing, and reporting on the medical use of marijuana, the dispensation of marijuana for medical use, and the laws providing for the dispensation of marijuana for medical use.

- Beneficial Effects: The regulations will provide the required structure and oversight of this new privileged industry. The regulations provide clear guidelines and include requirements for security and tracking of product from seed to sale. This will aid the industry in establishing integrity and aid the Division in preventing diversion of product.

b. Both immediate and long term effects.

- Immediate Effects: The regulations will allow for the application, approval, and creation of medical marijuana establishments to meet the needs of Nevada's medical marijuana cardholders. The regulations will provide for the creation of new businesses and jobs in the State.

- Long Term Effects: Provide integrity to the industry and provide public safety by ensuring Nevada's cardholders have a safe place to obtain their medication.

Anticipated effects on the business which NAC 453A regulates:

- Adverse Effects: There were concerns expressed by stakeholders related to costs outlined in Chapter 453A of the NRS, including the $250,000 liquidity requirement contained in NRS 453A.322. The Division cannot change these provisions; however, the Legislature has created the Subcommittee on the Medical Use of Marijuana of the Advisory Commission on the Administration of Justice. The Subcommittee is tasked with considering, evaluating, reviewing, and reporting on the medical use of marijuana, the dispensation of marijuana for medical use, and the laws providing for the dispensation of marijuana for medical use. Further, the Division established fees at the maximum amount allowed by NRS 453A.344 to ensure there is sufficient revenue to perform adequate oversight of the establishments.

- Beneficial Effects: The regulations will provide the required structure and oversight of this new privileged industry. The regulations provide clear guidelines and include requirements for security and tracking of product from seed to sale. This will aid the industry in establishing integrity and aid the Division in preventing diversion of product.

- Immediate Effects: The regulations will allow for the application, approval, and creation of medical marijuana establishments to meet the needs of Nevada's medical marijuana cardholders. The regulations will provide for the creation of new businesses and jobs in our State.

- Long Term Effects: Provide integrity to the industry and provide public safety by ensuring Nevada's cardholders have a safe place to obtain their medication.

Anticipated effects on the public:

- Adverse Effects: None anticipated.

- Beneficial Effects: Increased public safety by controlling the product form seed to sale. All products must be tested by independent medical marijuana testing laboratories that are certified by the Division. Patients will know what is in the product they are purchasing. If any excess revenue remains from fees after paying the actual costs incurred by the Division in processing the application, including, without limitation, conducting background checks, it must be paid over to the State Treasurer to be deposited to the credit of the State Distributive School Account in the State General Fund.

- Immediate Effects: Increased public safety.

- Long Term Effects: Provide integrity to the industry and provide public safety by ensuring Nevada's cardholders have a safe place to obtain their medication.

7. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the Division of Public and Behavioral Health for inspections and audits required to enforce the regulations with onsite reviews is estimated to be $3,449 per facility, annually. Administrative costs to support program operations and offsite regulation enforcement are anticipated to have an annual cost of $2,701 per facility, using a baseline estimate of 150 approved facilities. Both components demonstrate an estimated total recurring annual cost of $6,150 per facility. No general fund dollars will be used.

8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulatory federal agency.

The Division is not aware of any similar regulations of other State or governmental agencies that the proposed regulations overlap or duplicate.

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

Not applicable.

10. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

Based on fees outlined in NRS 453A.344, each medical marijuana establishment will be charged an annual fee based on type of facility. Each agent of each establishment must also pay for registration.

Using a baseline estimate of 150 approved facilities, the agency anticipates recurring annual revenue for renewal registrations to be $431,250. The funds will be used to support salary costs, operating expenses (such as phone line, email, rent, copy/printing, etc.), and travel costs associated with regulatory requirements and statewide assessments.

Initial registration revenue is anticipated to be $2,249,250 in the first year. In addition to usage identified above, these funds will support initial one-time start-up costs to create, implement, and establish the program. These start-up costs include creating regulations; establishing procedures; research for existing precedence; supporting public outreach; conducting workshops; and equipment/furnishings for new positions required to implement regulations. Any remaining balance of fee revenue, after expenses, will be paid to the State Distributive School Account.