DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

AUGUST 31, 2016

LCB FILE No. R148-15
Informational statement per NRS 233B.066

1. A clear and concise explanation of the need for the regulations.

The proposed regulations are necessary to carry out the requirements of Senate Bill (SB) 276, Senate Bill (SB) 447, and Assembly Bill (AB) 70. Further, they are necessary to address gaps and clarify language in the existing regulatory structure.

The proposed regulations amend and modify existing language in order to clarify existing regulatory language regarding lab testing sample procurement, lab result requirements, retest protocols, definitions of the terms "batch" and "lot," and labeling requirements. New definitions for "Production Run", "Potential Total THC", and "Foreign Matter" were added to the proposed regulations. Additionally, the regulations address serving size for edible and marijuana-infused products, establish limits on edible and infused products equivalent to the statutory limit of 2½ ounces of flower permitted in 14-day period, correct heavy metal testing limits in NAC 453A.658(8), and add language to allow Research and Development (R&D) efforts to occur in the industry.

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

a) How Public Comment was solicited:

i. A Small Business Impact Questionnaire was sent through the program's Listserv to 2,884 Medical Marijuana Establishments and others.
ii. An Industry Stakeholder meeting was held in Las Vegas on Friday, January 15, 2016 in Las Vegas at the Rawson-Neal Psychiatric Hospital, 1650 Community College Dr. Room B-193.
iii. A Public Workshop was conducted on Thursday, February 4, 2016 via videoconference, in Carson City at the Division of Public and Behavioral health, 4150 Technology Way, Room 303 and in Las Vegas at the Rawson-Neal Psychiatric Hospital, 1650 Community College Dr. Room B-193.
iv. A Public Hearing was conducted on Monday, August 29, 2016 via videoconference, in Carson City at the Division of Public and Behavioral health, 4150 Technology Way, Room 303 and in Las Vegas at the Rawson-Neal Psychiatric Hospital, 1650 Community College Dr. Room B-193.

b) Summary of the Public Response:

Marla McDade Williams, MME Consultant for two establishments, one being Philip Peckman, Nevada Cannabis Coalition
Marla stated overall support of the regulations with exception to a few sections. She requested pulling out the sections and issuing an additional "R" number or wait 30 days to allow additional time due to the regulation revisions not being posted for the 30 day

requirement. Sections to be referenced include 20, 27, 28, 30, 32, 38, and 74. Marla states Section 32 has confusion on verbiage related to how an entity that intends to be an independent contractor and work for multiple establishments will be treated. Section 20 limits a caretaker to no more than 2 patients and believes it is problematic and sees no reason for it. Declaring a provisional certificate is the same as a registration certificate. Section 28, requesting to change the timeframe for submission of renewals and states monies will be received in a prior fiscal year rather than the fiscal year it is intended for. Allowing the division to establish an hourly rate to bill MMEs and moving the language that does not relate. Section 30, identified only for relationship to section 32. Section 38, suggests a grandfather clause or time period of 1-2 years for MMEs to become compliant. Section 74, identified only for relationship to the implementation of these regulations.

Dr. Chao-Hsiung Tung, G3 Labs
Referenced section 15(3): requested for "wet weight" to be defined using a percent or standard amount. Section 63(2): requests to establish a guideline for minimum sample sizes of quality assurance test samples.

Will Adler, Nevada Medical Marijuana Association
Mirrored comments from Tung related to section 15 and defining "wet weight". Additionally, mirrored comments from Marla McDade Williams, related to section 32 requesting for a change to not require independent contractors to have an individual card per MME that they will be working for.

Cindy Brown,
Ms. Brown suggested changes to Section 20 that would require NRS453A.200 (3) (a) to be changed to read 5oz. or some other suitable verbiage. Section 30, suggested the customer sign-in sheets should have removable stickers to protect the privacy of patients as other patients are able to see who has signed in. Section 72, stated there are two exceptions that are conflicting, a patient is allowed to grow if they had a card before July, 2013 and if there was no dispensary operating at the time the patient applied for their card. Clarification for the form is requested. Regarding the separation of the law between businesses and patients, she feels there is no clarity and is requesting for some, example provided was the verbiage "collective possess for a caretaker/patient"

Jason Sturtsman, HOPE
Mr. Sturtsman stated he disagrees with the production run of concentrated cannabis being 2.2lbs and believes it should be 5lbs, because it will financially impact cultivation, production, and dispensaries.

Ben Chu, MM Labs on behalf of NBCLA,
Mr. Chu mirrored comments from Dr. Tung relating to section 15 and defining "wet weight". He also comments from Tung related to section 63 stating all of this is for patient safety. It is an attempt to get more standardized testing and consistent result among all laboratories. Additionally, section 27 referring to agent cards for independent contractors and laboratories exclusion. He stated laboratories do utilize technical staffing

organizations that provide staff for in a laboratory and is requesting that laboratories be included on the list for requiring agent cards.

Ellen Spears,
Ms. Spears stated she believes the manufacturing of edibles has been overlooked in the regulations. The minimal requirements within NAC 453A.426-624 is setting food manufacturers up for failure with regards to consumer health and safety. She does not understand the reasoning of why they are not being held up to the same standards as other food manufacturers in the state of Nevada. She recommends to amend the verbiage and include NAC or NRS 446 as a requirement providing three options to verbiage changes:

1. Food manufactures shall follow or use as a current guide, state or local regulations
2. Operation procedures to be validated by a processing authority or
3. Have written food manufacturing HACCP plans as all other food manufacturers do with the US

Michael Delee,
Mr. Delee mirrored previous comments from his client Adler and McDade Williams. Stated a letter was submitted back in April, a response was received, requesting for it to be entered into the record today.

Mark Clemmer, Nevada Resident,
Mr. Clemmer thanked for the opportunity to speak and making the documents available to the public. He stated he was unable to understand some of the verbiage in the NAC, specifically related to the infused products. Many others face the same issue and may not have the ability to find the meaning. He is requesting, on behalf of himself and many others, for the verbiage in the future to be kept in simple terms.

Nick Puliz, THC Nevada
Mr. Puliz suggested revising section 68 to include heat and pressure as an additional form of extraction. Clarification for section 68 was requested, asking if there is a limit to the number of times you can request approval from the state to extract. DPBH Staff, responded “no limit”.

Mona Lisa Samuelson, Nevada Resident representing medical marijuana patients
Ms. Samuelson referenced page 92, Section 63(3) stating patients require fresh and live plant matter and believes that if the product passes testing then it should be allowed to be sold directly through the dispensary. Referenced page 96, Section 65(8) stating she believes the 5 grams amount derives from recreational statistics and this is comparable to a daily amount for a medical marijuana patient. It was suggested to incorporate into the NAC, verbiage that would address the issue of Medical Marijuana being looked at as an illegal drug rather than medicine. Pointing out specifically this effects patients when it comes to other state agencies such as CPS or housing.

Dan Schinhofen, Nye County Commissioner, Vice Chair liaison to medical marijuana issues and patient

Mr. Schinhofen commented on his concerns on the sale and moving of medical marijuana establishments, he encourages the division to continuing working with the local municipalities.

Rianna Durett, on behalf of the Nevada Dispensary Association
Ms. Durett stated the organization supports the regulations as written and understands there are revisions that could be written but the process has been prolonged and as a whole the major concerns have been addressed, therefore, believes the regulations should move forward. She highlighted multiple points of concerns that were addressed within the regulations, pointing out while the division was amending regulations, there were other requests from the industry being fulfilled such as opening the patient card office in Las Vegas and implementing the online patient card application access. It was noted they do not want the regulations held up but if any portion were to be held up they request to be contacted.

Second Public Comment:

Marla McDade Williams
Ms. McDade Williams stated she believes relying on an errata that is a written document, when the Legislative Counsel Bureau reviews them, there is no guarantee they will come back the same. She believes it would had been appropriate to allow additional time. As it relates to the independent contractor issue, she agrees with Westom that it is an application from an independent contractor, and envisioned the independent contractor would be responsible for his employees. The regulations are currently written where the MME would be responsible.

Mark Clemmer
Mr. Clemmer reiterated on his previous comment and again requested in the future to keep verbiage as simple as possible. Clarification was asked as to if these currently revised regulations had been approved. Mr. Clemmer stated he still did not understand what the regulations meant. Ms. Phinney requested for Mr. Clemmer work with Mr. Gilbert (Steve Gilbert), stating he will be able to provide you with all the information you need in an understandable manner.

Eli Scislowicz, Cannabinoid Wellness
Mr. Scislowicz stated he has concerns as he did not notice changes to caregivers as related to being a patient and caretaker. He requested for this to be something looked at in the future. Additionally, he questioned if there was current guideline as to how a patient may transport there medical marijuana for the purpose of testing.

Valorie Godino, third party person
Ms. Godino questioned if there is a way for her to know the way the state is interpreting all these regulations. What is the state's interpretation regarding multiple agent cards needed by a Medical Marijuana Establishment employee? Can independent contractors use the agent card a different Medical Marijuana Establishment? One badge should be

sufficient for that contracted employee to use at various Medical Marijuana Establishment.

Mona Lisa Samuelson
Ms. Samuelson requested clarification for section 20, page 13. Does the working mean that you can be a caregiver to only one child or only to one other patient?

Tara Lynn, NV Cann Labs and Caregiver
Ms. Lynn stated she has a terminally ill husband and became a patient in order to have a better understanding of medical marijuana. Now that she is a patient she cannot be his caretaker. She asked the division if this is correct. Ms. Phinney requested for her to work with Mr. Gilbert for clarification.

Carmel Salazar, CHC
Mr. Salazar requested consideration; Las Vegas is a place where many people come to enjoy the culinary and would like to request there be some form of guideline to follow the current regulations. Ms. Phinney stated it is her understanding that the MME regulations are firmer then the food regulations. She could requests for staff to provide guidelines.

Shanna Perry
Ms. Perry commented on the value of medical marijuana and its cost. She would like to see proper state regulations regarding allocating funds received from taxing Medical Marijuana being used to offset the costs to patients.

Eli Scislowicz, NuLeaf Incline Dispensary
Mr. Scisowicz commented on the current tracking system in the Medical Marijuana portal. Scislowicz questioned how to gain approval from the state to sell CBD products that do not contain THC? Westom requested they begin inventorying their stock and comparing to the regulations. The division will send out notification of the proper protocol.

Patrice Sowers, HOPE
Ms. Sowers requested clarification on the food requirements for their kitchen and if there are any additional requirements as a result of the regulations passing. Ms. Phinney directed the question to Westom for an answer. Westom stated Kara Cronkhite would be the person to reach out to after the meeting.

c) How to obtain a copy of the summary:
Any persons interested in obtaining a copy of the summary may email, call, or mail in a request to Marilyn Gray at the Division of Public and Behavioral Health, Medical Marijuana Program, 4150 Technology Way, Suite 106, Carson City, NV 89706, (775) 684-3487, medicalmarijuana@health.nv.gov. A copy of the summary can also be viewed and downloaded on the website: http://dpbh.nv.gov/Reg/MME/MME_-_Home/

3. Number of persons in attendance

a) **Attended the hearing;**
   i. Carson City: 14 people signed in
   ii. Las Vegas: 54 people signed in
b) **Testified at each hearing; and**
   i. Carson City: 3 people provided testimony
   ii. Las Vegas: 18 people provided testimony
c) **Submitted to the agency written statements.**
   Two written statement were submitted to the agency.

4. If provided, the name, telephone number, business address, business telephone number, e-mail address and name of entity represented for individuals described in Item 3.

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

5. 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.

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health requested input from stakeholders, owners, and officers that are likely to be affected by the proposed regulation. A Small Business Impact Questionnaire (SBIQ) and a copy of the proposed regulation were sent to all Medical Marijuana Establishments on December 18, 2015 via the program's Listserv email distribution lists.

The questions on the SBIQ 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 Response:

Summary of Comments Received

16 Responses were received out of the 2,884 SBIQs send out (281 of those to MMEs)
Small Business Impact Questionnaires distributed;

- **7 Laboratories**
- **4 Cultivation/Production,**
- **2 Production**
- **1 Dispensaries.**

2 responses did not directly respond to the SBIQ

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?
12 – Yes 1 – Not Sure 1 – No	2 – Yes 1 – Not Sure 11 – No	11 – Yes 3 – No	3 – Yes 11 - No
Yes, **Section 6. "Production Run" defined NRS 453A., NRS 453A.370** "Allowing a production run size to be "of any quantity" has a significant effect on the number of samples we expect to see from a producer, (Example given, see PDF from MM Lab Inc.). The original regulations stated that every 5 lbs. of flower and 15 lbs. of leaf/trim had to be tested, and business models were designed based on that income. While we understand that it makes much more sense to fully test the products after extraction instead of plants destined for extraction, the unlimited production size run dramatically reduces the number of potential samples and will have a significant impact on the expected income and the ability to cover operating costs and capital investment, (Example	No	Yes, **Section 52, #7** Laboratories have repeated DPBH to officially declare a daily dose to set the metal content limits in terms of concentration. The proposed regulations still list the limits as ug/daily dose. Without a daily dose defined, the labs have no basis to pass or fail a product based on what they measure (concentration). With it defined as a daily dose, that is patient-dependent, not product dependent. The labs cannot be	No, "For the most part, it clarifies the uncertainty that has been out there on some items, but some areas still need clarification."

given, see PDF file from MM Lab Inc.). Laboratory operating costs are extremely high from salaries for highly qualified employees, very high capital investment, and very expensive operating supplies. The potential loss of income from these changes may drive labs out of business. **Section 33: NAC 453A.414, 7: Effective July 1, 2016, a MME shall utilize the Seed of Sale Inventory Program….** "The Seed of Sale Inventory Program contractor's user fees have not been established, and so the direct financial impact is unknown. However, it was noted in the RFP for this system that the state declared they will not pay for the product, and the cost will be covered by fees to the MMEs. In addition, laboratories have been spending significant amounts of money implementing their own Laboratory Information Management Systems, and forcing an interface to the Seed of Sale Inventory System with no explanation of the requirements or the interface may require laboratories to spend thousands of dollars in modifications to comply. **Section 50: NAC 453A.654** "The new table does not list residual solvents for any of the extracts. If this is not a mistake, then this will impact laboratories through loss of income since this was in the original regulations. Exact amount lost depends on the production batch size		expected to define this for every customer that could purchase the product. While it was discussed at an ILAC meeting to set the dosage to 5 grams, this has not been implemented anywhere as a written policy. This leaves the labs open to potential lawsuits if they use the 5 grams/day dosage to pass a sample, and the state will not back them up. For reference, Washington lists the limits for metals at a daily dose of 5 grams. The passing limits (metal, pesticides, etc.) for extractions need to be defined. Are they the same as for raw cannabis or should it take into account that patients should be taking less of an extract and be adjusted for that? Without clear guidance, the labs have no basis to pass or fail these	

determined in Section 6. Using the same calculations as above ($100/test, 20 vs. 1 test, 5 days/week, 52 weeks), it could be $494,000/year. With the additional testing required on the extractions, the minimum sample size should be 4 grams or 1%, whichever is more. Otherwise, the labs will not have enough material to perform all tests to the required degree of accuracy. **Section 61: Research and Development of Usable Marijuana** "While the proposed regulations allow for R&D work on raw cannabis, it does not allow for R&D work on extracts or other infused products. A producer should be able to create test products and allow the labs to guide them on potency and homogeneity. Not allowing the labs to support this in a cost effective manner (i.e., limited testing) will result in loss of income to the labs. Not allowing patients to directly submit samples to the laboratories for testing represents a loss of business. We are currently turning away requests from patients at least once a week. Patients are interested in knowing the profiles of their home-grown products to be able to compare against what is available in the marketplace and what they will need to purchase when they are no longer allowed to grow their own product."		products."	

Yes; It is impossible to predict the extent of the negative financial impact given the current status of the analytical science of cannabis and the costs associated with the development of the, as of yet nonexistent, proposed tests and software implementation.	No	Yes, I believe there will be significant adverse negative impact on the medicinal cannabis industry in Nevada. I believe, for the reasons outlined in the attached letter, the negative adverse impact will be significant although I'm unable to predict how severe that adverse financial impact will be.	No
Yes; Section 6: "Production Run" Allowing a production run size to be "of a quantity" has a significant effect on the number of samples we expect to see from a producer. The original regulations stated that every 5 lbs of flower and 15 lbs of leaf/trim had to be tested, and business models were designed based on that income. If a producer were to process 100 lbs of flower in a two week period to make about 10-20 lbs of an extract, this used to represent 20 samples of flower. Now, it represents 1 sample. If testing for extracts is around $840/sample, this represents a loss of 19 x $840 = $15,960/bi-weekly of income and $414,960 annually. <u>Section 33: "Seed of Sale Inventory"</u>	No	Yes; Section 52, (7) Despite repeated requests to DPBH to officially declare a daily dose, there is still nothing defined to set a metals concentration. While it was discussed at an ILAC meeting to set the dosage to 5 grams/day, this has not been implemented anywhere as a written policy.	No

The Seed of Sale Inventory Program contractor's user fees have not been established. However, it was noted in the RFP for this system that the state declared they will not pay for any of this and the cost will be covered by fees to the MMEs. The Seed of Sale Inventory System may require the laboratories to spend thousands of dollars in modifications to comply.			
Yes; Section 6, Same Comments as RSR Analytical Laboratory; math is a little different. $400/sample, loss of 19 x $700 = $13,300/day of income, 5 days/week, 52 weeks, this represents 5 x 52 x $7,600 = $3,458,000 in lost revenue over 1 year Section 33, Same as RSR Analytical Lab. Section 50, $494,000 in lost revenue over 1 year Section 61, Loss of income, loss of business	No	Yes; Section 52, #7, Same Comments as RSR Analytical Laboratory	No
Yes; Concur with Ace Analytical Laboratories on all comments.	No	Yes; Concur with Ace Analytical Laboratories on all comments.	No
Yes; Section 8, 10 (We propose to raise the 10mg single dose to 50 with Physician endorsement.	Yes; Better information to patients, readable information label will have very small font	Yes; too much information on small label; Less Sales, less choice for patients	Yes, better patient education

Yes; (1) When the individual strain is cultivated batch sizes must be increased to 10 lbs. or higher. (2) In cannabis is going to be sent to a MIP, the final product should be tested instead of multiple times before the final product. Section 10, Total amount of active THC needs to be higher than 100mg, high as 500mg. NRS 453A.654, Add random sampling of pesticide residue analysis to protect patients by reducing the cost of testing. NRS 453A.654 Remove addition of Herbicides and Growth regulators from being tested every batch and have them tested randomly instead of every batch. NRS 453A.720 Instead of putting an email into NAC, just say email Division	No; Maintain Section 50 NAC 453A.654 #2	Yes	No
Yes; Section 27 Yearly Renewal fee for all agent cards, Estimated Cost: 13 x $75.00 = $975.00 Section 28 Additional inspection fees, Estimated cost: Unknown Section 33f Concentrated cannabis is ill defined, all infused products are made with concentrated cannabis, Estimated Cost: Unknown. Section 34 #2 Only 10oz. allowed per delivery run for	No	Yes; The repetitive fees and additional costs to smaller establishments increase operating expenses, ultimately the costs involved will increase prices to the Medical Cannabis Patients.	Yes; Accuracy in record keeping will keep Medical Cannabis consistent.

Dispensaries, meaning more delivery runs. Increased vehicle and staff costs, Estimated Cost: Unknown. Section 59 #2b 1, 2, 3, and 4 Home Medical Cannabis Patient grows will NOT have a large impact on profit for MME's. MME's intent is to assist Medical Cannabis Patients who cannot or do not want to grow and produce their own medicine, Estimated Cost: Minimal financial hardship to MME's.			
Yes; Section 28.2b; By requiring an increased frequency for inspections of cultivation facilities, the proposed regulation will make it less likely that cultivation MME's will work with production MME's to bring consumer products to market. Estimated Cost: $130,000 per year (10 lbs. of cultivation MME material processed per week, $250 per pound added to the purchase cost due to potential increase in inspections). Section 33.1.a.4 Tracking total THC in milligrams in inventory is a very cumbersome and inexact process. In the case of cultivators, there will be an unknown inventory of THC in all of the plants in flower which have not yet been harvested, processed, and tested. Estimated Cost: $19,500 per year (One half time employee (20 hours/week), $15/hour with	No	No	No

30% burdens). Section 33.2c This addition to the regulations can be interpreted to read that concentrated cannabis can only be sold by production MME's to dispensaries and not to other production MME's. There have already been negotiations underway to sell concentrated cannabis products to licensed production MME's with a primary focus of producing edibles and not extracting concentrates. Regulation might not allow for those transactions to take place. Estimated Cost: $75,000/year (Projected gross revenue lost based on recent negotiations). Section 50.3 Costs of production will increase by requiring all production MME final products to be subjected a more rigorous suite of testing. Estimated Cost: $93,000/year (3 lab tests/wk, $600 cost increase in each lab test) Section 60 Production MME's should be allowed R&D Quarantine rights for product development. Estimated Cost: $62,400/year (2 R&D lab tests/week, $600 cost increase for each lab test if no R&D protocols are put into place).			
Will be meeting with MME colleagues who are part of Nevada Growers and Producers Association before February 6th to discuss and present unified		Yes, Section 10, Having product contain such a small amount of THC, patients will	Yes, Section 50 #2, Will help reduce the costs of testing and ultimately the cost of medicine for the

set of comments and feedback at the Public Forum.		chose alternative dosage forms such as smoking flower, vaporizing, or smoking concentrates. The cost alone for patients will be exorbitant, and the burden of such an extreme daily regimen is very troubling. <u>Section 29 #5,</u> How are outside contractors who have no contact with cannabis plants/products or involvement with cultivation, manufacturing or sales; are they supposed to have an agent card? <u>Section 34 #7</u>, DPBH will develop its own Seed of Sale tracking system and API; does the DPBH feel that this is a good idea at such an early stage in the industry? <u>Section 50 #2</u>, This is an extremely positive step in the correct direction, however current laboratory testing	patients. We believe this reduce is cost, and hopefully future reductions in laboratory testing, will create an influx in the number of patients utilizing the medical marijuana dispensaries. <u>Section 61</u>, Testing through state licensed third party laboratories is extremely beneficial to the MMEs as a whole.

		requirements still are not adequate for the diversified extraction methodologies. With the current testing schedule this would result in a minimum of 3 tests, and even more testing if recombination takes place. At roughly $800 per mandated test we are looking at an increase of $2400, and more for any additional processes. A simple solution would be to require testing at the final stage of the product, rather than at the various points in the production cycle. Also, the wording of the section creates a substantial issue. By phrasing it as “usable marijuana” and “dry flower or trim”, the Division is not allowing for the production of fresh harvested, fresh frozen, or fresh juiced cannabis products.	

		Section 56 (1)(b), Setting a 10,000mg maximum THC is problematic for severe medical cannabis patients, such as those undergoing treatment for cancer. Also, the focus on THC is arbitrary.	
Yes; Adverse Economic Impact: Under the current NAC and NRS codes, there exist no legal frame work to legally receive a medical marijuana or medical marijuana product from a patient and test it. We strongly feel patients should have the same rights to have their products tested for a nominal fee to ensure safety and dosing concerns, as long as it follows all the same guidelines set forth for an MME, such as chain of custody, etc. No Adverse Economic Impact: Section 50, Regarding extraction of Marijuana and required quantity for testing. We feel 2 grams is an insufficient quality to perform all the required quality assurance tests. We think 6 grams is a necessary amount to perform all required tests if trim bypasses current tests and those tests are then performed on the extract. Section 52 #7, Metals limits,	No	No	No

Daily dose needs to be defined, We have heard from the state that it is 5 grams, please add this to the NAC.			
Yes; Section 41 #2, I am appalled the State is trying to make it mandatory that we use PLASTIC for packaging. If you want to regulate what is used for packaging, a solution could be to screen the proposed packaging materials a production, cultivation, and dispensary establishments decides to use prior to them becoming operational and work it out on a case-by-case basis.	Yes; Section 50 #2, This is beneficial to us because testing the marijuana plant material in addition to testing the extracted cannabis oil would be redundant, not cost effective, and wasteful.	Yes; Section 56 (b), Must not exceed a maximum of 10,000mg THC per patient for 14-day period. WOW! Again, this is absurd for a medical patient. That is less than 1 gram/day. In CO, a patient is allowed to obtain 2 ounces a day. Section 10 (a) & (c), This is change may be recreationally relevant, but not medically. There are some severe ailments that call for concentrated cannabis (e.g. 250 mg-350 mg+) per serving.	Yes; Section 61, Please add: it would be nice to see in the regulation or have the ability to as a cultivation and production facility owner the ability to run blind and double blind samples for R&D with multiple laboratories with the intention of transparency and holding everyone accountable on all sides of getting cannabis medicine into the patients hands.
Yes; Section 6.2, loss of $2 million in gross income. Section 27.2, $2000 in renewal fee above that charged to cultivators. Laboratories should not be made to pay more than cultivators.	No; While the addition of R&D testing is welcome, it is still well below that which was calculated when financial projections were created in 2014	Yes; Section 52.7, Leaves the interpretation of heavy metal limits up to the reader; the proposed changes make no mention of the 5g	No; This legislation leaves too many questions either unanswered or ambiguously answered.

Section 33.7, It may cost each laboratory up to $15,000 per year to purchase and successfully interface their existing Laboratory Information Management System with this as-of-yet unknown Seed of Sale Program. Section 50, If the elimination of residual solvent testing is not in error, this would represent a large loss for the business. Assuming that each test would earn the laboratory $150 in gross revenue, 100 samples/week for 50 weeks/year would represent $750,000/year in lost revenue.	that included unlimited R&D as well as testing of patient medicine.	daily dose that was agreed upon at the ILAC meetings. Such ambiguities will leave the state and MME vulnerable to legal action.	

Any persons interested in obtaining a copy of the summary may email, call, or mail in a request to Marilyn Gray at the Division of Public and Behavioral Health, Medical Marijuana Program, 4150 Technology Way, Suite 106, Carson City, NV 89706, (775) 684-3487, medicalmarijuana@health.nv.gov. The Small Business Impact Statement has been posted on the Division's website: http://dpbh.nv.gov/Reg/MME/MME_-_Home/ where it may be viewed and downloaded.

6. If the regulation was adopted without changing any part of the proposed regulations, a summary of the reasons for adopting the regulation without change.

From December 17, 2015, to August 29, 2016, The Division revised the proposed regulations three times pursuant to comments received from the Small Business Impact Questionnaire, discussion at the Industry Stakeholders meeting, Public Workshop, and Legislative Counsel Bureau regulations analyst. The only remaining change from the adoption hearing pertained to Section 20 as outlined in the Errata that was also adopted at the public hearing.

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

Anticipated effects on the business:

Adverse Effects: Concerns from laboratories indicated there was a loss of income with the additional language added to the "Production Run" definition to include "of any quantity". After

several meetings, MMP staff changed the language to read "Of a quantity no more than 15lbs. of usable marijuana"; which will decrease laboratories expected loss of income by 95%. With the language added to Section 61, "Research and Development" of the proposed regulation, laboratories will be able to compensate their 5% income loss, which concludes the economic impact for laboratories will have a neutral effect. Medical Marijuana Laboratories also indicated an adverse economic impact with the proposed regulation language adding daily inventory recording. MMP staff deleted language excluding laboratory implementation of the required inventory control system, which will alleviate some adverse economic impact on labs.
Additional concerns stated from Medical Marijuana Establishments regarded renewal fees. However, the renewal fees are set by NRS 453A.344; the MMP cannot increase nor decrease the set fees.
Lastly, Medical Marijuana Establishments expressed an adverse economic impact with residual solvent testing omitted from list of required marijuana or marijuana products tested. This was a mistake made by DPBH and residual solvents will be added back to the table of required testing.

Beneficial Effects: The regulations provide the required structure and oversight of the industry, and will clarify security requirements and tracking of product from seed to sale. This contributes to the transparency of the industry, should enhance the image of the industry and inspire public confidence in the state government's ability to safeguard the health and safety interests of all Nevadans.

Immediate Effects: Medical Marijuana Establishments can now participate in Research & Development (R&D) activities. This will not only foster innovation and the development of new products throughout the industry, but also will provide additional revenue streams for Medical Marijuana Establishments.

Long Term Effects: The proposed regulations provide long-term growth opportunities for the industry in terms of Research and Development (R&D) efforts. The industry will have the ability to innovate and pioneer new and improved products and bring more effective medicine into the market. R&D represents an additional revenue stream for MME laboratories and provides them an opportunity to grow with the rest of the industry.

Anticipated effects on the public:

Adverse Effects: None anticipated

Beneficial Effects: Increased public safety by controlling the product from seed to sale. All products must be tested by independent certified medical marijuana testing laboratories. Patients will know with confidence what is in the products they are purchasing. Excess program revenues are transferred to the State Distributive School Account.

Immediate Effects: Increased public safety, protection and improvement of the health and safety of medical marijuana cardholders.

Long Term Effects: The proposed regulations force more transparency of operations among MME operators. In the long run, this added transparency should enhance public safety by reducing opportunities for product diversion into the black and grey markets.

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

No change in program enforcement costs is anticipated. The regulation will be enforced as a regular part of the ongoing Medical Marijuana Program operations and does not represent an additional expenditure of staff time and effort.

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

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

10. 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.

11. 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.

The proposed regulations do not impose a new fee or increase existing fees.