



February 21, 2020

VIA HAND DELIVERY

Kathyleen M. Kunkel, Cabinet Secretary
New Mexico Department of Health
Office of the Secretary
1190 St. Francis Drive, Suite N4100
Santa Fe, NM 87502

Re: *Medical Cannabis Program Rule Amendments Public Hearing*

Dear Secretary Kunkel:

Enclosed is the Report and Recommendation of Hearing Officer pertaining to the above-referenced public hearing. The official file for the hearing, which contains the exhibits that were entered into the hearing record, was sent to you on January 30, 2020 with my Report on the reciprocity rule. Since that date, a February 29, 2020 letter to me from Chris Woodward has been added as Exhibit 31. It is enclosed with this letter and should be inserted into the Exhibit Binder for the second hearing, dated January 16, 2020.

Thank you for the opportunity to serve as a Hearing Officer in this matter.

Very truly yours,

UTTON & KERY, P.A.

A handwritten signature in black ink, appearing to read "Craig T. Erickson".

By: CRAIG T. ERICKSON

CTE:tm
Enclosures

Copy (w/enclosures): Chris D. Woodward, Esq.

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**NEW MEXICO DEPARTMENT OF HEALTH
MEDICAL CANNABIS PROGRAM RULE PROMULGATION HEARING**

Public Hearing: Proposed Repeal and Replace and Amendments to Medical Cannabis Program Rules

Actions in Question: Rule Promulgation Hearing for Proposed Amendments to 7.34.2.7 NMAC (“Advisory Board Responsibilities and Duties”); Amendments to 7.34.3.7 NMAC (“Registry Identification Cards”); and to Repeal and Replace 7.34.4 NMAC (“Licensing Requirements for Producers, Couriers, Manufacturers”).

Hearing Dates: November 22, 2019 and January 16, 2020

Report Date: February 21, 2020

REPORT OF HEARING OFFICER

A Public Hearing was held on Friday, November 22, 2019 at 10:30 a.m., and continued on January 16, 2020, at the Harold Runnels Building Auditorium in Santa Fe, New Mexico for the purpose of considering the Department of Health (“DOH” or “the Department”) Medical Cannabis Program’s (“MCP” or “the Program”) proposed amendments to Parts 7.34.2 NMAC (“Advisory Board Responsibilities and Duties”); 7.34.3 NMAC (“Registry Identification Cards”); and to repeal and replace 7.34.4 NMAC (“Licensing Requirements for Producers, Couriers, Manufacturers”). Craig T. Erickson, Esq., who was appointed as hearing officer to preside at the Public Hearing by DOH Cabinet Secretary Kathyleen M. Kunkel on October 7, 2019, presided over this rulemaking hearing. The DOH was represented by Chris Woodward, Assistant General Counsel, and Dominick V. Zurlo, Ph.D., MCP Program Director.

This report does not address 7.34.4.28 NMAC (“Reciprocity”); 7.34.4.7(CCC) NMAC (“Reciprocal limit”); or 7.34.4.7(DDD) NMAC (“Reciprocal participant”), which were addressed in the Hearing Officer's January 30, 2020 Report of Hearing Officer on Proposed Rule on Reciprocity. Individuals who were present at the Public Hearing on November 22, 2019 were:

1. Robert Candelaria
2. Aaron Randle
3. Kathleen O’Dea
4. Robert Romero
5. [REDACTED]
6. Rubon Aguilar
7. Ben Lewinger
8. Caity Maple
9. Brooke Duverger
10. Donnie Romero

11. Carlos R. Gonzales
12. Robert Jackson
[REDACTED]
14. David Muscarella
15. Chris Thompson
16. Taylor Trodden
17. Alex Spra____ [illegible]
18. Jennifer Merryman
19. Leigh Jenke
20. Lynn Ambrosino
21. Cory Duor_____ [illegible]
22. Tim Van Rixel
23. Erica Rowland
24. Erik Briones
25. Ryan Gomez
26. Sheri Vallejos
27. Len Goodman
28. Eli Goodman
29. Jaylene Kost
30. Josh Alderete
31. Tyler Heeman [Hydro Lyfe]
[REDACTED]
34. Tara Hedricks
35. Andy Lyman
[REDACTED]
37. Cade Guerrero [Santa Fe Reporter]
38. Gloria Montoya
39. Rosa Estrada
40. William Ford
41. Roger Burton
42. Christopher Castillo
43. Nicole Morales
44. Sharon Jaramillo
45. Ishmael Mondragon

The sign-in sheet for the Public Hearing is provided with this Report and marked as DOH Exhibit No. 15. Some names, as indicated by blanks and question marks in the names above, were partially illegible.

Individuals who were present at the Public Hearing on January 16, 2020 were:

1. Joel Krukar
2. Jake White
3. Scott Till____ [illegible]
4. Mark Santiago

[REDACTED]
6. Grace White

- [REDACTED]
8. Ariel McDougal
9. Len Goodman
10. Ben Lewinger
11. Don Romero
12. Chad Lozano
13. Les Hopkins
14. Kenn Maxwell
15. James Franzen
16. Amanda Fratz ___ [illegible]

[REDACTED]
19. Seth Nocklman

- [REDACTED]
21. Erica Rowland
22. Dan M Field [illegible]

- [REDACTED]
24. L. Adam White
25. Ishmael Mondragon
26. Jalen Kost
27. Josh Alderete
28. Amy Milder
29. C ___ G ___ [illegible]
30. John Murray

- [REDACTED]
32. Sam Thomas
33. Eli Goodman
34. Scott McMillan
35. Billy Garcia
36. Cece McMillen
37. Andy Lyman

- [REDACTED]
39. Duke Rodriquez
40. Leigh Jenke
41. Kathleen O'Dea
42. Robert Stranahan
43. Eric Baade
44. Sharlyn S ___ [illegible]
45. Walter Torres
46. Robert Romero
47. David Lara
48. Victor Zupian

The sign-in sheet for the Public Hearing on January 16, 2020 is provided with this Report and marked as DOH Exhibit No. 30. Some names, as indicated by blanks and question marks in the names above, were partially illegible.

The proceedings were electronically recorded, and the recording was monitored by Chris Woodward. The original recording is in the possession of the DOH, Office of General Counsel.

SUMMARY OF PROCEEDINGS—November 22, 2019

Preliminary Matters

The Hearing Officer opened the proceeding by introducing himself and the others on the podium, Mr. Woodward and Mr. Vigil. The Hearing Officer stated as follows:

The Hearing Officer welcomed the audience to the Public Hearing and informed them that the hearing was on proposed amendments to Parts 7.34.2.7 NMAC; 7.34.3.7 NMAC; and the proposal to repeal and replace 7.34.4 NMAC.

The Hearing Officer further stated that the proceeding was being held in accordance with NMSA 1978, § 9-7-6(E). He also requested that anyone present at the hearing who had not yet signed the attendance sheet at the entrance to the auditorium should make the effort to do so.

In his opening remarks, the Hearing Officer explained that Dr. Zurlo would be offering comments that summarize that proposed amendments to the rules, and the proposal to repeal and replace 7.34.4 NMAC. The Hearing Officer further stated that Mr. Woodward would then read the titles of the DOH's exhibits into the record. He further explained that members of the public who chose to would be given the opportunity to make public comment. Each individual who offered public comment would be allowed three minutes, with a warning when the speak had 15 seconds remaining, in order to make their public comments. All individuals who offered public comments complied reasonably with the time requirements.

The hearing then progressed as follows.

Dr. Zurlo began his remarks by thanking everyone at the rulemaking hearing for making the effort to attend the hearing, particularly in light of a two-hour snow delay. He stated that there would be a second hearing in this process, that will be scheduled in January, so that the Department can take the comments and feedback offered on November 22, 2019, make revisions as necessary, and then move forward to hear additional comments from the public and from concerned individuals. The reason for this process is so that the Department can get the best rules possible for the program in order to be able to help patients as much as the Department possibly can.

As a brief summary of some of the highlights of the proposed changes to the rules, Dr. Zurlo offered the following comments:

- In 7.34.4.10, the DOH has proposed various revisions and additions to the requirements for testing of dried usable cannabis and cannabis-derived products. The proposed testing standards include new tables that specify action levels for microbiological, mycotoxin, and residual solvent testing.
- New requirements are proposed for testing for the presence of heavy metals, certain pesticides, and moisture content.
- The microbiological testing requirements are based on Section 2023 of the United States Pharmacopeia which is referenced in the current version of the rule.
- The mycotoxin testing requirements are consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories.
- Residual solvent testing requirements are also consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories. These standards are based in part on standards adopted in Oregon and based on discussions between the DOH and commercial laboratory operators in Colorado.
- Potency testing requirements for mandatory reporting are essentially unchanged from current requirements. However, the rule includes certain additional cannabinoids for which testing is optional.
- The testing requirements for heavy metals are newly created. They are based in part on a review of standards in other states, including California, Washington, Nevada, and Oregon.
- Pesticide testing requirements are also a new addition to the rule. The listed pesticides were selected partly with reference to Colorado's regulations. Identified action levels are borrowed primarily from regulations of the Oregon Health Authority.
- Minimum test sample sizes are based on the U.S. Pharmacopeia standards for dried botanicals and botanical extracts.
- In 7.34.4.14(C) NMAC, the proposal includes new material that prohibits certain additives including polyethylene glycol, polypropylene glycol, vitamin E acetate, and medium chain triglycerides in products that are intended to be consumed by inhalation, such as vaping cartridges. This relates to a recent outbreak of severe lung injuries sustained by individuals across the country from vaping cannabinoids and/or nicotine products. Although the cause of these injuries is not yet known, there have been indications that the identified additives may be the source, and various states have taken measures to limit the presence of these substances in vaping products. More information on this topic is available on the Department's website at <http://nmhealth.org/about/erd/eheb/vri> and the CDC website at <http://www.cdc.gov/lunginjury>. This rule also proposes to prohibit manufacturers and

non-profit producers from adding nicotine, caffeine, or any other addictive substance to a cannabis product. Naturally occurring substances are not an issue.

- In 7.34.4.15 NMAC, the proposed revisions to the general manufacturing requirements for LNPPs and manufacturers include various additional items, including requirements that manufacturing be conducted in a manner that does not allow cross-contamination from chemical or biological hazards; that manufacturing not occur within 300 feet of a school, church, or daycare center (consistent with the statutory 300-foot requirement described previously in these rules); that persons involved in handling cannabis and cannabis derived products wash their hands before putting on gloves and after removing gloves; that walls and ceilings remain free of water damage, and that insulation not be exposed; that chemicals used in extractions be intended for such usage and be of food or medical grade; that weighing devices be registered and calibrated in accordance with requirements of the Department of Agriculture; that any manufacture of cannabis derived product for a personal production license holder be recorded in an electronic tracking system specified by the Department; and that employees not be under the influence of drugs or alcohol in the warehouse.
- In 7.34.4.17 NMAC, the proposed revisions provided that laboratory application material requirements be amended to include documented proof of initial demonstrations of capability (in accordance with the rule); proof that buildings are not located at all times during their work and present the card to law enforcement upon requests; and include theft and break-in reporting requirements.
- In 7.34.4.26 [now Section 27]¹ NMAC, the proposed revisions include a new section that identifies the application and operational requirements for cannabis consumption areas. SB406 (in 2019) amended the statute to create cannabis consumption areas that are occupied on licensed premises in accordance with NMDOH rules. The Department has proposed to allow cannabis consumption areas to be operated at licensed nonprofit producers' approved dispensary locations. Pursuant to NMSA 1978, §26-2B-6.1, access to cannabis consumption areas must be restricted to qualified patients and their primary caregivers, cannabis consumption cannot be visible from any public place or from outside the cannabis consumption area, and qualified patients who consume cannabis on the premises must have a designated driver or other means of transportation consistent with applicable law (a patient cannot drive a motor vehicle from a cannabis consumption area while under the influence of cannabis.)

Dr. Zurlo closed by stating that those are the main summaries and main points from the Department related to the proposed rules.

¹ In the interim between November 22, 2019 and January 16, 2020, the DOH revised the proposed regulations resulting in some changes in Section numbers. Thus, the reference to "7.34.4.26 [now Section 27] NMAC" reflects that change.

Mr. Woodward offered the Department's exhibits into the record, and the exhibits were admitted by the Hearing Officer into the record.² The exhibits are as follows:

DOH Exhibit No. 1: Notice of Public Hearing

DOH Exhibit No. 2: 7.34.2.7 NMAC Proposed Amendments [clean version]

DOH Exhibit No. 3: 7.34.3.7 NMAC Proposed Amendments [clean version]

DOH Exhibit No. 4: 7.34.4 NMAC Proposed Repeal and Replacement [clean version]

DOH Exhibit No. 5: 7.34.4 NMAC Proposed Repeal and Replacement (w/ Technical Revisions Redlined). Mr. Woodward stating that the Department discovery some formatting issues with this set of rules, which were corrected in red-line. Another issue was the incorrect designations for micrograms as "mg" which would incorrectly refer to milligrams. A correction was made to the discussion of cannabinoid testing where a table referred to mandatory when the reference should have been to optional testing.

DOH Exhibit No. 6: 7.34.2.7 NMAC Proposed Amendments-Redlined Comparison Version

DOH Exhibit No. 7: 7.34.3.7 NMAC Proposed Amendments-Redlined Comparison Version

DOH Exhibit No. 8: 7.34.4 NMAC Proposed Repeal and Replacement-Redlined Comparison Version (Includes Technical Revisions)

DOH Exhibit No. 9: Summary of Proposed Amendments

DOH Exhibit No. 10: Letter Appointing Hearing Officer

DOH Exhibit No. 11: Affidavit of Notice to the Public

DOH Exhibit No 12: Affidavit of Publication in NM Register

DOH Exhibit No. 13: Affidavit of Publication in Albuquerque Journal

DOH Exhibit No. 14: Public Comments

DOH Exhibit No. 15: Sign-in Sheets from Public Hearing³

² Please note that references to NMAC section numbers in the section of this Report that addresses the November 22, 2019 public hearing maintain the references to section number as they were at that time, to maintain consistency with the electronic record and the exhibit numbers for each hearing.

³ The sign-in sheets were not available when Mr. Woodward read the exhibit titles into the record. They were added by the Hearing Officer later when they were available.

The DOH's Exhibits were all accepted into the record.

Public Comments

The following is a summary of the public comments offered into the record at the November 22, 2019 Public Hearing.

The Comments of Kathleen O'Dea

Ms. O'Dea is the owner and director of Scepter Lab, one of two licensed medical cannabis testing labs in New Mexico. She stated that the two labs were called to a meeting by the Department last September. When they met, they were given the opportunity to comment on proposed rules that were distributed to them. They were asked to submit written comments. She stated both labs did that on October 4. She stated that she believes that was before the rules were published. She stated that she is not sure whether either of those sets of comments have made it into the record. Consequently, she stated that she would like to read her comments into the record.

Reading from her written comments, Ms. O'Dea stated that Scepter Lab had conducted testing on over 50,000 medical cannabis samples since November 2014. They began testing when there were only seven other laboratories in the country. They have watched state after state implement rules without any input from scientists and without any empirical data showing that such testing standards are necessary.

Although some of the Department's proposed testing requirements will provide a measure of protection to public health, some of the proposed testing requirements do nothing to advance public health, and will increase the cost of patient medicine, and will encourage manipulation of samples by the growers. More rules, or more stringent rules, will not insure a safe product. Without controlling sample submission, more testing will not insure more patient safety.

They do not believe and of their customers are doctoring samples, they have seen in the past that practice occur. When they do see it, they decline to do business with those individuals. For example, the new testing requirements cannot stop a production facility from using a pesticide not on the list in order to pass the pesticide test or circumvent the list. It will also not do anything to ensure patient safety if the Department decides to impose a secret shopping test. According to her understanding, a secret shopping test is when the laboratory tests a sample, and then the Department goes back to the dispensary and samples a sample in a bag in the dispensary that carries the testing results.

Ms. O'Dea stated that cannabis is a biological material that can vary over 30% from the top of the plant to the bottom of the plant. Ms. O'Dea then concluded her remarks as her time ran out.

The Comments of Patricia McKay

Ms. McKay is a native Albuquerquean, born and raised, who is a holder of a PPL license. She is a retired healthcare practitioner. One of her concerns with PPLs is the issue of how much they are allowed to hold in their harvest. She has an indoor grow, and, in the summers, may have an outdoor grow.

In her indoor grow, she only grows at the most three plants. Recently, she had 9.2 ounces come off of one plant. It is her understanding that they are allowed to hold 8 ounces. As a PPL person, she is not sure how much weight was on the other two plants. However, she believes that she had a pound off this harvest.

She stated that she would like the Department to revisit the amount a PPL can hold. She only grew three plants and the plant limit is 16 plants.

Also, with regard to the plant count, for the licensed producers, there is still an inadequate supply in many parts of the state, especially the rural areas. She advocated for the small independent business licenses that should be opened up to serve these areas. It would help these areas. There is a glut of dispensaries in Albuquerque. There is no dispensary in Cedar Crest. There is only one or maybe two in Los Lunas. Also, the cost of cannabis in rural areas is exorbitant.

The cost of cannabis in Albuquerque is also going up. She no longer sees \$7.00 a gram.

She also asked the Department to revisit the producers having to pay over 500% more for their licenses. She said, "this is ridiculous, this is New Mexico."

The Comments of Ben Lewinger

Mr. Lewinger is the Executive Director and duly appointed representative of the New Mexico Medical Cannabis Chamber of Commerce ("NMCCC"). They are a membership organization representing producers, manufacturers, and cannabis related businesses. They submitted written comments that were voted on by their membership.

Mr. Lewinger first thanked and recognized the DOH for the hard work that goes into consistently trying to improve the Medical Cannabis Program. He recognizes that this is not an easy undertaking.

He discussed two specific areas that are addressed in the letters they submitted: labelling and testing requirements. He stated that above all NMCCC members are dedicated to the safe cultivation and production of medicine. They feel that labeling is a very important component, but the labeling regulations are simply unrealistic for what needs to go on a vast number of products that are sold as medicine. They recommend drug fact sheets similar to what is used in pharmacies. A doctor prescribes a drug and a patient then buys the drug from a pharmacy, and the patient gets a drug fact sheet from the pharmacy that has all the information necessary on it, included in the bag the product is placed in or stapling it to the bag.

The NMCCC recommends that something along those lines be implemented that is consistent with what we have along with added warnings to make sure people understand it is a THC product, so that patients have more than the bare minimum in the label but including everything else, the cannabinoids testing and the drug sheet, but not necessarily affixed to the product.

The testing requirements are the biggest concern for the members of the NMCCC. They are dedicated to safe medicine and empowering the patients by knowing what goes into their medicine. Testing is part of that. However, they feel that the proposed rule changes on testing are unnecessary and excessive. In short, the minimum amount of testing that is required per batch would put supply at risk and represents four to five times more than what the approved facilities say that they need, and then creates a problem with the wastage in those testing facilities.

Mr. Lewinger also asked whether the DOH has thought about or analyzed the cost to patients of the new testing requirements. One of their members working with independent manufacturers estimates an additional \$4,000,000.00 per manufacturer for testing yearly. They estimate that that would result in a cost of \$5.00 to \$8.00 additional per gram for manufactured products, which is unacceptable.

The Comments of Caity Maple

Ms. Maple appeared on behalf of Natural RX. She started by thanking the Department for its time and effort in this process. She stated that overall they believe that implementing common sense testing and legal requirements is in the interest of the public. It protects the integrity of the program and is the right thing to do. With that said, she did express some questions and concerns regarding the proposed regulations.

She noted that there are a bunch of smaller items that were submitted with their written comments, so she won't belabor them. However, she did want to touch on their overarching concerns. She started with a couple of questions:

- 1) Are the two licensed labs actually able to perform these tests? She noted that the Department had had some conversations with the labs. From what she is hearing, that may not be the case for most of the tests. Do the labs have the capacity to handle the increased sampling and testing? She understands that at least one of the labs is at capacity and that has been a challenge for some producers. For Natural RX there is only one lab that can do the tests, and she has questions about whether there is capacity there.
- 2) They would also like to note that the sampling batches are very large, and the frequency of sampling is very onerous. They believe that in general the regulations will result in increased cost to the patients, which may in turn fuel illicit product growth. She said we should be mindful of threading the needle between safety and sensibility as these regulations may have the unintended consequence of pushing

patients to the black market. Some products are not tested at all, so finding that balance is really important.

The Comments of Patricia Monaghan

Ms. Monaghan is an attorney and the focus of her practice is medical cannabis law. She is the chair of the State Bar Cannabis Law Section. There is also a specialization in cannabis law coming.

Ms. Monaghan wanted to give a big, big thanks to the DOH and the State for the program for the fabulous job they are doing. She recognizes that the DOH has been doing a lot of work, because this is the first time the Lynn and Erin Compassionate Use Act ("LECUA") has been amended.

A big picture issue for her is the requirement of nonprofit status. She still disagrees with that. She does not think it is consistent with the statute.

She also agrees with the NMCCC on the issues of labeling and testing, especially the sampling size. She recognized that she is not a scientist or expert, but she said that Kathleen O'Dea is very good, and she supports her comments.

She further stated that she knows that there has been a decrease in cost, but she would like it to go even lower. Costs should be lowered, and accessibility of the product should be increased. She stated that there is an excellent chart by the economist at UNM, Sarah Stith, and it shows that as product access goes up the price stays the same. As the number of producers goes up, the price goes down. More licenses are needed. She also likes the idea of co-ops.

The Comments of Jennifer Merryman

Ms. Merryman is the owner of Mountain Top Extracts. She said that she would like to go deeper into the data on the sampling that is being required of 23 grams. In a gross analysis, she called her lab, and asked how many tests they are doing. She said in an average of three months there are 26 tests per month and 312 tests per year. She stated that these are very conservative figures—a best case scenario for them. She stated that this average is a total of 7,136 grams per year.

She stated that, for independent manufacturers, that means those costs skyrocket. Those costs get loaded directly on to patients. It also takes a precious commodity off the market – 7,136 grams of medicine that could go into the community and not to unnecessary lab sampling. She stated that the two labs authorized by DOH have concurred on this point.

She stated that Mountain Top Extracts is just one independent manufacturer. There are 14 other independent manufacturers, and 32 or 34 LNPPs who also have some form of manufacturing at their places of business. When you look at those numbers, she comes up with a loss, just with the independent manufacturers of 146,000 grams of product lost a year. She said that this town is a half gram sample site so that is over 300,000 half gram products that could be

in the patients' hands. Those costs, because of the additional costs of the medicine due to pesticide testing and heavy metals testing, will cause an increase from about \$250.00 to \$700.00 or \$1000.00. When they are performing that many lab tests, that adds about. With lab tests and the loss of medicine to the market, she came up with one-half million dollars that the state could be recovering and the patients are losing. This is a no win, no win situation.

Ms. Merryman stated that she understands that the DOH is looking to Pharmacopeia for guidelines and definitions, but perhaps we could look at common sense. She urged talking with the manufacturers and the Cannabis Chamber of Commerce. They are all willing to work with the Department to provide data to determine what this really looks like for patients and the costs that will be put on patients.

The Comments of Erica Rowland

Ms. Rowland is a part owner in Seven Clover, one of the current LNPPs. She stated that she was at the hearing, not necessarily as a producer, but that she was appearing to represent more of the patients. She stated that she is concerned that the patients who grow medical cannabis do not have access to manufacturers. She raised the question: who are we to decide what a patient needs? If they are growing a certain strain at their home, and that is the concentrate that they need, how are they supposed to acquire that derivative?

She stated that the State needs to consider a patient manufacturing license. This could potentially be wrapped up into a co-op, or craft grows. As a producer, you do have the golden ticket. As a patient, you do not have the golden ticket, and you have to think about it every single day. She would like the patients to be able to have a consumption lounge with family members allowed. She does not believe the producers should have the only consumption lounges.

She said that the patients will be forced to (a) buy their product, (b) potentially pay a fee, (c) not have food, not have their friends there, not have the stigma removed, not have any sort of social, recreational, ambiance or environment, that we are all trying to achieve. She urged that that stigma be removed.

Ms. Rowland offered the option of a patient's manufacturing license, which she said would be responsible. It would follow the same guidelines as the current manufacturers, but give the patients access to small amounts of harvest to large amounts, and to all the different derivatives they need. She believes that patients need more access to the program they support. Patients fund the program. They pay for the taxes and pay for the testing. She asked how do we know we are not encouraging black market manufacturing and not allowing patients to have a safe place to go?

The Comments of Erik Briones

Erik Briones represents Minerva Canna, Inc. He stated that he was going to pass on the opportunity to make an oral comment. However, he submitted a written comment.

The Comments of Len Goodman

Mr. Goodman is the CEO of Best Days, one of the 34 LNPPs. He stated that he is the oldest, both personally and chronologically, of the producers. He was one of the first four producers licensed in 2009, when Dominick Zurlo was still at the Department. Mr. Goodman stated that it was great working with Dr. Zurlo in the early days, and nice to see him back with the Medical Cannabis Program.

Mr. Goodman stated he does not want to deal with the trees; he just wanted to address the forest of what is going on. Plenty of written comment has been submitted by the Chamber, by labs, and by other people. He has looked at most of those materials and agrees with most of them.

He received his first license, which was for New MexiCann, in November 2009. By the spring of 2010, he was able to meet with Dr. Vigil, who was then the Secretary of the DOH with two gentlemen from Las Cruces, who introduced testing for the industry. Within three or four months of being in business, he realized the absolute need for patient care we need health and safety. However, that did not go anywhere. Three or four months later, he ran into Jeremy Apland (sp?) and he, with Mr. Goodman's support, set up a lab. Mr. Apland was a pharmacist who formed the first testing lab in New Mexico. It was approved by the Department and for quite a while it was the only functioning testing lab. They committed to testing every one of their products on every harvest. Eventually, that became part of the rules and testing became mandatory.

Mr. Goodman stated that he had two primary concerns. One is patient care and the other is product safety. He said that he is all for testing. The difficulties he sees are where there is unnecessary testing, which some of this is, and which will not serve any real function, and could be accomplished in other ways. Some of the reports detail that.

He said that the proposed testing requirements will raise pricing for patients. As costs for the patients go up, they have got to turn elsewhere. He noted that he is a patient as well. However, he does not have to turn elsewhere. He has his own grow. He stated that this reduces the patient's ability to purchase sufficient medicine because of price, and forces them into the black market, where they can get it cheaper and at higher risk. Mr. Goodman stated that this is a major concern.

Mr. Goodman said there are other ways to address heavy metals. Pesticides need to be looked at carefully. He agrees with the size and quantity of sampling being way too high and unnecessary. This will take product out of the patients' hands and also raise costs. He has a significant concern about the 1000 or 10,000 CFUs. They passed at 1000. They do not have a problem with that. But if those are living cultures, and he does not have an objection to that, but if they are randomly tested those CFUs continue to grow. With a 10,000 level, it allows for a certain amount of growth and still have safety.

Finally, Mr. Goodman stated that he concurs with the written comments that have been turned in.

The Comments of Tyler Heeman

Mr. Heeman is with Hydro Lyfe Grow Supply. He consults with a lot of LNPPS and PPLs, many of whom were present at the hearing.

He had a couple of comments on the testing. He acknowledged that he does not know a lot about the testing, nor is he an expert in that area. However, he urged the Department to keep in mind that constricting the LNPPs further and further will only reduce the access to medicine and the patients, especially in rural areas of the state, as it gets more and more expensive.

Mr. Heeman also stated that he wanted to make sure the Department protects the PPLs. This is really where the medicine is being produced in our state. A lot of patients cannot afford access to dispensaries, so growing it themselves is the only option they have, again especially in rural communities.

He urged that the Department take some recommendations from the working group that just took place. He suggested expanding not just the plant counts for the current dispensaries but expanding the number of licenses as well. This would allow many people in rural areas to be a part of the program.

The Comments of Scott E. Ransom

Mr. Ransom is a New Mexico Cannabis Patients' Alliance officer. He is also a University of New Mexico cannabis research team member. He is also a United States Army combat veteran. He stated that he would like to speak for the 22 veterans who lost their lives today and every day for the past year to preventable suicides. He stated that these tragic deaths as a result of suicide usually involve harmful and dangerous prescription drugs pushed on them by the Veteran Hospital Administration. They also involve unhealthy practices with alcohol consumption.

Cannabis for veterans is a safer and more healthful alternative treatment for those conditions Veterans are suffering from. He stated that we have failed veterans and a drastic and immediate change is required, and a solution to this emergency. He proposes an emergency general fund to build specific micro-licenses to provide medication for veterans at no cost. Veterans receive medication through the V.A. Pharmacy at no cost to them and this should be a universal standard.

The Lynn and Erin Compassionate Use Act has the ability to license nonprofit producers to provide for veterans who are in need but no producers have taken advantage of this ability in the history of the Medical Cannabis Program. The DOH has failed to create any program for the sick and dying, and the patients who cannot afford their medication but need it the most. If the

federal government fails to adhere to their responsibilities, it is the duty and moral responsibility of the State to provide for our veterans.

The proposed micro-license will require immediate funding. However, it has potential to be completely self-sustaining if they were able to wholesale to already established licensed producers who might have shortages, or in rural areas where there is little to no access. Mr. Ransom's current mission is to provide our veterans with immediate alternative medication treatment programs centered around the individual patient in an effort to lower the suicide rate of veterans.

While attending UNM, Mr. Ransom stated that he helped develop a scientific research center lead by Dr. Vigil regarding combat veterans' cannabis usage. The purpose of the study was to assess combat veteran' prescription and alcohol usage before and after enrollment into the Medical Cannabis Program. The study's data clearly showed the more cannabis a veteran used, the less alcohol and the less prescription drugs were being consumed. More research must be done in this area. Unfortunately, he stated, we do not have the funding. In the federal university system, we do not have funding, and it's a shame we do not take care of that.

He closed by stating please help him in his mission to end this preventable 22 suicides a day. He stated that cannabis has saved this veteran's life, and it is now his duty to share this with the world starting in this great state of New Mexico, which he is honored to call his home. He stated: "God bless you guys; God bless our nation's veterans. Thank you so much for your time and your careful consideration on this matter. It means the world to me. God bless America."

The Comments of Zeke Shortes

Mr. Shortes is with Sacred Garden. He thanked the Medical Cannabis Program and expressed his appreciation for everyone who works so hard in the Program. He also stated that he hoped we could to a point where every member of the Medical Cannabis Program is looking out for patients.

Mr. Shortes stated that he is also a patient and was appearing to make public comment as a patient.

He stated that he looked at the new testing requirements and what the cost would be to Sacred Garden, and, therefore, to patients. The additional testing would cost \$250,000.00 a year for Sacred Garden. He stated they would also waste an additional \$100,000.00 in product. That number is the difference between the grams they are submitting now, and the grams that this testing will require him to submit. He stated that those are very real numbers. What that means is an extra \$0.40 per gram for patients. He stated that that is a very conservative number as well.

With the increase in relicensing fees, between 33 and 100% that occurred this year, those are all costs to patients. As a producer, they are already required to pay an exorbitant amount of state and federal tax that ordinary businesses do not have to pay. They are already at a disadvantage to being efficient and being able to produce medicine at the least cost possible.

They agree with extra testing requirements such as pesticides. He does not think that heavy metals are an issue. The producers in the working group with the DOH expressed that, and their recommendation was to see if it is an issue by doing some random testing for heavy metals. He stated that it is a very expensive test. If it's not a problem, he said, then why are we worrying about it?

Also, he stated that the testing limits on some of the items has been expressed by a couple of other people as way too high. The Harvard Medical Group said that yeast and mold, for example, are safe up to 100,000 CFUs. In this state we have 1,000 CFUs as the rule. He stated that what that means is that they have to throw away a lot of good medicine and that does not make a lot of sense.

Lastly, he stated that the "nonprofit thing is bunk." He stated that "federally" the producers are not allowed to be nonprofit producers; "it is illegal." Thus, he said, "why put us in this tangle between state and federal laws."

The Comments of Larry Love

Mr. Love is a patient and patient advocate. He stated that he wanted to welcome Dominick Zurlo back and said that Dr. Zurlo was the first director and manager of the Program and he was actually for the Program. He thanked him for coming back. He said: "We've had a hell of an 8 or 9 years."

He stated that he disagrees about the heavy metals. He thinks it needs to be tested. Cannabis and hemp draw heavy metals out of the soil and medium that they are in. As a patient, he wants clean medicine, with testing for heavy metals and pesticides. He thanked the Program very much.

The Comments of William Ford

Mr. Ford also thanked the Program very much. He is the managing director of Reynold Greenleaf & Associates. He is also the chairman of R. Greenleaf Organics. He stated that his organization represents R. Greenleaf Organics, and other organizations.

He stated that he applauds the New Mexico Department of Health, and he welcomed back Dr. Zurlo to the Program. He stated that the intent of the proposed rules is "fantastic." He stated that we need more protection for patients, we need better testing, we need better labeling. He said we have been able to put this all together and implement it in many different states. He stated that he has been blessed to have been part of that process.

Unfortunately, we he looks at New Mexico, the one thing that we'll hear over and over today is that there has been an absence of interaction between he DOH and the producers, manufacturers, patients, and all the other stakeholders in the Program. He wanted us to focus on that point.

He further stated that unfortunately he stands before us today as a member of Reynold Greenleaf & Associates and tell us that in their opinion the proposed rules are not developed far enough, with enough scrutiny and enough due diligence to be promulgated. He encouraged us to look at all of the written comments and see the theme. The theme is that we will not have success and we won't be able to protect patients in the medical program without having that interaction, without having meetings, without having a dialogue between the industry and the regulator. He stated that is really important, and it is one of the reasons that Dr. Zurlo is back in the Program.

Mr. Ford stated that he knows that early on that was something that was fostered by the Department. He stated he would like to see a return to that. Unfortunately, he said, Dr. Zurlo has only just recently returned to the Program. The proposed regulations were presented as proposed but did not allow them to enough time and enough avenues of feedback to make a difference. He thinks we need to go back and readdress all of these issues. They are all very important. They support all of them, but he thinks there is a better way to do it.

The Closing Comments of the Hearing Officer

The Hearing Officer closed the proceeding by thanking everyone who participated in the public hearing and in the process. He stated that the new rules would not be effective until 30 days after they are filed with the state Department of Health.

The Closing Comments of Dominick Zurlo

Dr. Zurlo also thanked everyone for their comments. He stated that he also thanked Mr. Ford for his comments and wanted to express his thanks for the comment and the theme regarding having communication between the Department and the entire community related to medical cannabis is something that the Department is committed to increasing. He stated that one of the things that he has been doing is inviting various community members to small group meetings in order to hear what the concerns are so that they can improve the Program. He stated that they want to have the best program in the world. He stated that anyone who would like to be invited to these meetings could provide him with their contact information. He will ensure that they get invited to one of those meeting that they will continue to have over the next several months. He said that there would be another hearing in the middle of January.

SUMMARY OF PROCEEDINGS—January 16, 2020

The Hearing Officer opened the second hearing on this rulemaking process on January 16, 2020 by welcoming the public to the hearing, and announcing that this was continuation of the hearing held on November 22, 2019, involving the proposed repeal and replacement of the licensing requirements found in 7.34.4 NMAC and amendments to 7.34.2.7 NMAC and 7.34.3.7 NMAC, the definitions sections for Parts 2 and 3 of the Medical Cannabis rules.

Dr. Zurlo then offered a brief summary of the statue of the rulemaking process. He stated that the Department had posted on the DOH website, in the rules section, a summary of the proposed changes that were addressed in the first hearing and the changes that had been made by

the Department following the first hearing. He highlighted, in general, some of the changes that had been made, as follows:

- He noted the correction of several typos, such as in Part 4, Subsection 10(C)(5) in Table 5, the correction of references to measurements as parts per billion to parts per million. He stated that they also made various corrections throughout the tables to make sure that they indicated the correct designations with regard to testing and limits on testing, including the amounts of samples and the grams that are required. Changes were also made to clarify amounts needed for flower and for concentrate. This was designed to make it clear for the reader that the same amounts were not required for testing for flowering bud and testing for concentrates.
- Clarification was also made with regard to batch size and other testing aspects.
- Dr. Zurlo also noted that a lot of public comment was received with regard to various aspects of the proposed rules, including the rule related to the 300-foot distance, and that was clarified within the proposed rule.
- In addition, Dr. Zurlo stated that the Medical Cannabis Advisory Board met on December 20, 2019 and reviewed the portion of the rule on reciprocity. The Board ensured that the amount of cannabis for reciprocal patients was considered adequate for those individuals. At that time, the Board considered this, and voted to approve the proposed rule.

Mr. Woodward then introduced the additional exhibits from the Department for the continuation of this rulemaking hearing process. He introduced the exhibits as follows:

- Mr. Woodward noted that Exhibits 1 through 15 had already been accepted into evidence at the first hearing on November 22, 2019.
- Exhibit 16 is the Notice of Public Hearing for the hearing on January 16, 2020, which was published in the New Mexico Register and the Albuquerque Journal.
- Exhibits 17 and 18 are two different versions of the proposed amendments to 7.34.2.7 NMAC, as revised since the time of the previous hearing. Exhibit 17 is the clean, non-marked up version and Exhibit 18 is a marked-up version that shows all the edits that have been made to 7.34.2.7 NMAC.
- Mr. Woodward noted that all of the exhibits are available online on the Department's website.
- Exhibits 19 and 20 are the proposed amendments to 7.34.3.7 NMAC, with Exhibit 19 being the clean version and Exhibit 20 being the marked-up version that shows all of the changes.
- Exhibit 21 is the clean version of the proposed repeal and replacement of 7.34.4 NMAC.

- Exhibit 22 is a marked-up version of 7.34.4 NMAC that incorporates all of the proposed changes, including the ones proposed at the previous hearing.
- Exhibits 23 and 24 are also the proposed repeal and replacement of 7.34.4 NMAC. These exhibits include certain corrections that primarily are typos and formatting issues, as well as numbering issues. Exhibit 23 is the clean version that incorporates all of the proposed changes to 7.34.4 NMAC. Exhibit 24 shows certain changes tracked, which just includes the changes made in Exhibit 21.
- Exhibit 25 is the Summary of Medical Cannabis Program Rule Amendments for Public Hearing January 16, 2020, which addresses the changes made since the previous hearing. This is the document that Dr. Zurlo was referring to earlier. It includes a description of the changes that have been made in response to public comment. It also includes the DOH response to various comments that were made at the prior hearing and written comments.
- Exhibit 26 is the Affidavit of Notice to the Public, completed by a paralegal in the Office of General Counsel for the DOH. It attests to the various forms of notice that were given for this hearing in accordance with the requirements of the State Rules Act.
- Exhibit 27 is the Affidavit of Publication of the Notice in the New Mexico Register.
- Exhibit 28 is the Affidavit of Publication of the Notice in the Albuquerque Journal.
- Exhibit 29 the public comments that were submitted for the January 16, 2020 hearing. These are also posted in the DOH website.
- Mr. Woodward stated that written comments provided to the DOH during the hearing would be accepted as well, but the record would close after the hearing.

Mr. Woodward requested that Exhibits 15 through 29 be admitted into the record. The Hearing Officer admitted the Exhibits. The Sign-In Sheets were made available to the Hearing Officer after the hearing and were made part of the record as Exhibit 30 by the Hearing Officer. On February 18, 2020, the Hearing Officer received a letter from Chris Woodward, Esq., in response to some of the comments from the public. It has been designated as Exhibit 31.

Ms. Sundberg then described the rules for offering public comment. She stated that each speaker would be allowed 5 minutes, and she would give a warning 15 seconds before that time elapsed for each speaker.

Public Comments

The following is a summary of the public comments offered into the record at the January 16, 2020 Public Hearing.

The Comments of Joel Krukar

Mr. Krukar represents Mountain Top Extracts. He appeared to comment on the _____ [unintelligible on recording] requirements. He stated he had just found out that it had been drastically reduced and said thank you for that.

The Comments of Jake White

Mr. White represents Reynold Greenleaf and Associates. He manages two licensed growers and a laboratory. He offered a couple of comments from the cultivator's standpoint. The 72-hour rule for holding and destruction of usable cannabis. He said it is a rule that will pigeonhole growers and cultivators. He could lead contamination issues to other areas of the farm. He said that growers need to be able to cull contaminants out of the system before the pathogen has the ability to spread.

He also commented on heavy metals testing. From his standpoint, where they grow indoors and use controlled inputs, he finds heavy metals testing to be unnecessary. He thinks it will lead to a tremendous increase in testing cost. He said he has spoken to Kathleen O'Dea, and the costs will just be passed on to patients needlessly. He said he is curious if there is a middle ground could be to do assurance testing periodically.

Mr. White also stated that if we can do a quick turnaround to get reciprocity to patients from out of state, he would like to see if we could do a quicker turnaround with patients in the state than the four-week turnaround we see now.

He also stated that he was very happy to hear that Dr. Zurlo has been going around to get more public input. He thinks it is very important. He suggested doing that prior to additional rules being written. He thinks there is a lot a great input from patients, manufacturers, laboratories, and producers in the community. He really thinks more information would be a great idea before writing more rules. He suggested turning the focus to consistent and meaningful enforcement of the current rules that we have. He thinks we would then have a much stronger program than all the rules proposed here.

The Comments of Sarah Dolk

Ms. Dolk has been a patient enrolled in the Medical Cannabis Program since 2013. She has been advocating for patients since then and was a participant in the SB495 memorial task force on affordability and accessibility, created by Senator Ortiz y Pino in 2018. She has been pushing for better testing for medical cannabis for many years. She is pleased that the program is finally taking patients more seriously. However, she thinks the rules seem to be a bit overzealous. She wishes more time was put into the formation of these rules instead of mixing up what had already been established in other states.

She stated that many patients want to see testing for pesticides, molds, and heavy metals in medical cannabis. She said she is no different, but she is concerned about the high cost of the testing being passed on to the patient. She does not see how it is not going to be passed on to the

patients. After speaking with Kathleen O'Dea, she is worried about it. She worries about patients who cannot afford the medicine at the prices charged now.

She thinks the way to manage costs is, if the costs are between \$500 and \$600 a batch, that someone in the Department figure out what is being spent now, how much is going to be spent, and deduct that from the licensing fees for the producers. She suggests that the cost of the testing should proportionally reduce the cost of the licensing fees, and not be passed on to the patients.

Ms. Dolk also stated that as an employee of one of the newer cannabis producers, she got to see first how the cost of things like testing affects the opening of new cannabis businesses. The previous license holders had quite a few years to establish themselves before testing was even required. The new businesses coming on are going to really struggle unless they have a lot of money backing them, which means corporations, which are already descending on us "like a bunch of flies to a pile of poo."

The Comments of Ishmael Mondragon

Mr. Mondragon is the educational coordinator for Cannabis New Mexico Staffing and the Cannabis Training Center. He stated he appeared at the hearing as an advocate, educator and a patient. He recommends that some type of cannabis education and training be imposed as part of the application requirements and the licensing standards for LNPPs, manufacturers, testing labs, and couriers. At this time, the training would be done by a responsible vendor program. These would be private educators overseen by the DOH whose curriculum would be a minimum of 10 hours that would cover patient safety, workplace safety, and a baseline knowledge of the New Mexico Medical Cannabis Program. At this time, according to the regulations, this is supposed to be done by the cannabis business or by a third-party resource. However, to ensure that training is being done, implementing responsible training programs, into the application process and the process for obtaining an MCP license, his proposal would ensure compliance with the State.

Mr. Mondragon stated that all you need now is your state and federal background check. He asserts that by implementing third party vendor training, you would have a state and federally approved individual working in the industry and you would have an individual who is educated and trained yearly. He asserted that as we move toward approval of recreational cannabis, we need to maintain the integrity of medical cannabis program through education.

The Comments of Eli Goodman

Eli Goodman is a representative of Best Days. He thanked the DOH for having successfully run the MCP for close to 10 years. He noted that over the course of 10 years, he is not aware of that many incidents that have affected patient safety. He thinks that the testing as it has been quite productive. He said that there should be a fair amount of data as to where the complications may be. He said that health and safety is paramount to everybody. He said increased costs for testing can be problematic, "because inevitably they do end up at the

counter,” and become a burden for the patient. As the burden increases, more patients may move to obtain medicine from an unregulated source. That, he stated, is a safety and health issue.

Mr. Goodman commented on the requirement for heavy metals testing. He stated that heavy metals are a concern and no one wants them ingested in any format. The question is what is appropriate testing? If it is an indoor facility, it has inputs that can be tested and set, and if there is a protocol to turn it into the Department it should not be retested until that protocol changes. He believes that soil and water are the only two places in which metal can enter into the plant. Testing the plant is not necessary. Testing the soil and water does seem to be necessary. He raised a question about what an appropriate schedule for that testing should be. Should it be annual testing? Or every time a protocol changes? Putting the cost into each individual plant seems unnecessary and will impact the patient. Eventually, there will be a safety issue if the costs are too high.

Mr. Goodman stated that the same thing applies for testing edibles. He said that cannabis oil has already been sterilized at the point of extraction, its already been tested, and it is now simply a food ingredient. He asserts that no further testing is required.

As to colony form units and mold, he stated that we currently stand at 1,000 CFUs. He said that many states stand at 10,000. He asked if there is any empirical data that says which standard is safer. He also asked if there is a difficulty in states that go to 10,000. His concern with CFUs is that something passes at 1,000 and then it is shelved for three months before someone finishes selling that lot. Do those units continue to colonize, and, if so, and random sampling comes in, will there be failures throughout the state, and how much cannabis is no longer going to be usable? Is there a way to go to 10,000 units in the initial test or after a period of time for development based upon other states health and safety? He feels that all of the data should be available, with 10 years of experience. What are the health and safety risks that we have actually experienced? Or are we just building regulations and rules that are stringent but have no support.

As to mycotoxins, Mr. Goodman stated that the mold that is the most problematic is aspergillus.

He closed by thanking the Department and said that things are going well.

The Comments of Ben Lewinger

Mr. Lewinger is the executive director of the New Mexico Cannabis Chamber of Commerce. He stated that the NMCCC is an industry association representing producers, manufacturers, and a growing number of cannabis adjacent businesses. He thanked the DOH, recognizing that this is not an easy process. He noted that the Department was sincerely taking some of the concerns and suggestions of the industry to heart in the newly proposed revisions to the regulations.

Mr. Lewinger stated that the industry and NMCCC membership are concerned about patient safety first. To echo Eli Goodman, the testing requirements seem onerous, unnecessary,

and still raised a concern that the patients will be driven to the illicit market. He estimates a \$5 to \$8 increase per gram because of the testing requirements to the cost of raw flower medicine. Batch testing for heavy metals seems unnecessary. There are inputs in soil and water and it does not seem that every single batch should need to be tested. The degree of microbial testing does not seem to be realistic compared to the testing required in other states. He is also concerned about unnecessary testing for mycotoxins, when there are really only a few that we should be concerned about.

He noted that it appeared that the Department paid special attention to the questions and concerns for labeling. They appreciate that. Their recommendation was to include, like at any pharmacy, instructions that comes with the packaging rather than on the label. They will review these changes and see if they seem realistic, but he stated that it seems like the Department is on the right track.

Mr. Lewinger stated that they are still concerned about the new requirements for destruction. He encouraged the Department to work with the industry to understand what is feasible and what is practical. He said that they have members who tried to follow the letter of the law for destruction and wastage from the last round of rulemaking and the requirements were simply not realistic and not possible to follow.

Finally, he commented that there is a lot of historical and industrial knowledge in this room, and he thanked the Department for being a good partner and he hoped it would continue to do so in future rulemaking.

The Comments of Don Romero

Mr. Romero stated he was representing Pharma [?] Quality Concentrates. He stated he wanted to address the death warning on vaping products. He believes that, from a federal level, the CDC has already found that THC was not the cause of the issues. He stated that as a state we have any regulated products that were involved in any of the death cases. Also, he asserted that the warning is supposed to have an expiration date on it, so he said they did not have to put it on their products anymore. He believes that the issue has been resolved and removing the death label would be the right thing to do for THC was not the culprit, and to this day has not been found to have killed anyone.

He believes also that the amount testing being required needs to be reconsidered. He asserted that statistically a lot of this stuff is not ever found in cannabis or cannabis-derived products. Specifically, he said that some of the mycotoxins cannot even grow on cannabis. He believes that a proper guidance document needs to be established to refer to on what actually needs to be tested for these products.

The Comments of Chad Lozano

Mr. Lozano is from New Mexico Cannabis Patients Advocacy Association. He addressed the issue of LNPPs being the only ones allowed to have cannabis consumption areas. He advocated for cannabis consumption areas anywhere and everywhere. He wants them near

military bases because there are military spouses who are medical cannabis patients. They cannot use medical cannabis on a military post because that is a federal crime. He said that if they have to drive hours or 25 minutes away from the base, it's not worth it. He urged that cannabis consumption areas be allowed in rural areas as well. He stated such areas could also act as a vendor for cannabis products, which would help with the problem of access. He mentioned that having such a location close to El Paso for example would help with access for patients from Texas.

Mr. Lozano also commented on testing. He said that the NMDA needs to take the samples and give them to the producers to take to the testing facilities. He raised a concern about manipulation of the product before it gets to the facility; he said there have been a lot of reports of that happening. He said that testing is important, but if it gets manipulated before it gets to the lab then it does not mean anything. That is why he is proposing that we should have the NMDA take the sample but give it to the LNPP so that they can give it to the testing facility. He said this would be the same thing that is done with hemp right now.

He also stated that if the state was allowed to do the testing that might bring down some costs. He thinks that the state has a lab.

The Comments of Kenn Maxwell

Mr. Maxwell stated that he wanted to speak about some very necessary changes that need to be made in the Medical Cannabis Program. He first referred to the "landlord clause." He stated that that violates his HIPAA rights in making him divulge his medical information to his landlord. He said it is a small infringement but it is still an infringement. He said his landlord is not bound by HIPAA, so they can tell anyone they want about his medical grow, which becomes a safety issue. It makes his landlord an accomplice to a federal crime.

Second, he talked about the licensing process, and the "ridiculous costs" that are in the regulations. He noted that we are the 49th poorest state in the Union, and the fees are not paid by the dispensaries but are passed on to the low-income patients who have nowhere else to turn. He urged that coop and micro-distributors be allowed. Licenses for such businesses need to be opened up and made affordable to help dispensaries with their overhead costs across the board. He notes that this stimulates small economy and helps patient growth. It makes sure that both the medical and recreational markets are always supplied with medicine.

He argued that the DOH has had twelve years to regulate one plant and all we have seen is an increase in shortages and costs and low-quality medicine. He argued that the DOH should take care of the store fronts and the kitchens and let the New Mexico Department of Agriculture ("NMDA") take care of anything to do with the plant licenses, since that is exactly what the NMDA does. He said that the NM DOH is understaffed and undereducated. He urged that the NMDA should do the plant testing since that is what they are designed to do. He also noted that the NM Pesticide Control Act gives the NMDA sole jurisdiction over any pesticide. Why is this plant special? Is it because it has medicinal properties? He said the cinnamon and turmeric have medicinal properties too, and they are still regulated by the NMDA.

The Comments of Zeke Shortes

Zeke Shortes is the founder of Sacred Garden. He is also a patient. He thanked all the MCP staff. He acknowledged that this process is not easy and is probably pretty thankless most of the time. He also thanked the Department for taking more time to look at this whole pesticide issue. He said it is really important and it can be very costly, so given that we have the poorest patient population in the country, we have to be especially sensitive to this issue.

Mr. Shortes stated that he thought of a way to solve this problem. He noted that the MCP has started collecting more money. He said the he would love to do the testing and have the MCP pay for it. He said it seems like a good solution if you want safer medicine.

The Comments of Tony Martinez

Mr. Martinez is from R. Greenleaf Organics. He also thanked all of us for taking the time to hear their concerns—the concerns of the patients and the cannabis business community. He stated that he is also a medical cannabis patient and patient advocate. As such, he does not want to see increases in production costs that the proposed regulations will cause. The costs will get passed along to the patients at the counter in the form of higher prices; higher prices for flower, higher prices for concentrates, and for edibles. He said that many think this is an inevitable reality so they were not hear today as a medical cannabis business professional. As a partner with DOH, their mission is to supply a safe supply of cannabis. He asked that the DOH please consider the unintended consequences of overregulation.

He urged the use of industry professionals as a resource to develop regulations that serve the collective mission of delivering safe medicine to patients in New Mexico. He also stated that together we can collectively achieve the Governor's mandate to further develop and maintain a well-functioning medical cannabis, but also a responsible adult use market and the 11,000+ jobs that it runs.

He thanked the Department again and said that he has a lot of respect for the regulators who inspect his facility. He said that there is a communication issue with identifying the top problems and coming up with solutions together that solve these problems. He also thinks the Chamber is a great resource because they represent a third of the medical cannabis producer licenses, as well as management companies like his that are not directly licensed, but work through other licenses. He said there are many organizations that are above board organizations that have nothing to hide and would love to have the DOH look over their shoulder as they try to find ways to work together to find ways to solve these issues.

He also commented on the wastage clause, which says that they need to have authorization to give this product over once they have blended to down to a facility to receive it. He does not know how that would work but in his head he thinks how hard to would be to sell Waste Management on giving a certificate of destruction. He does not really see that happening, unless there are disposal facilities, with people who are accustomed to this with clear chain of custody.

He closed by echoing the comments of others who said they are there to be a resource.

The Comments of Josh McCurdy

Mr. McCurdy is part of the Advocate Alliance. He is a board member for the Advocate Alliance and been a medical cannabis patient for almost seven years. He said he has been coming to these meetings for a while and is looking positive change this year.

He spoke about testing. He said that there is no amount of testing that will make their medicine safe unless the DOH makes some rules for sanitation procedures. He said he can't tell us how many times he has heard stories about microwave or ozone stories he has heard from employees or licensed non-profits. Full spectrum testing should be done so that it is cost effective and consistent.

The Comments of Erica Rowland

Erica Rowland stated that she appeared to speak because of her opposition to only LNPPs being the only agents to allow consumption of cannabis. She does not believe that this increases access for the patients. She does not believe that it is fair, and it monopolizes cannabis. She thinks it is unnecessary. It forces a patient to buy their medicine and be in their environment and a lot of patients are not comfortable in that environment.

As an entrepreneur and a business owner, she has a license but her business partners will not allow her access, and she asks how is she able to open a consumption lounge. If the patients want to have their own lounge, they should be allowed to have their own lounge.

She is concerned about owners getting paid in cash and having a lot of cash on property. Employees walk out with that cash. It is extremely dangerous.

She is also concerned that employees of LNPPs do not have a reporting platform. They do not have an HR department that is safe for them. If they see something illegal or dangerous happening, if they report it to the top of the LNPP, they are removed. There is no safe place to report. There is the DOH hotline but that is not exactly where they feel safe. She believes that maybe the entire Department should have its own human resource center that covers hiring and firing—"all of that."

She also spoke about on-site testing. She argued that should absolutely be put in place.

She also urged allowing micro-grows to provide more access for patients.

The Comments of Tricia Monaghan

Ms. Monaghan thanked the Department and welcomed back Dr. Zurlo. Ms. Monaghan also identified herself as a medical cannabis patient and has been since 2009. She is also a medical cannabis lawyer.

She focused her comments on access and quality. That is what the patients need and deserve. She said that New Mexico has done a great job.

She distributed a handout that contained graphs that were generated by Sarah Stith, an economist from the University of New Mexico. She stated that the graph on the first page shows that the number of plants harvested during 2014 to 2019, and it shows the price per gram of the product during that time. She notes that the price does not change much, but it goes down as new producers arrive. Further, it shows that as plant count goes up, the price goes down.

Her second point is that we should get rid of vertical integration. She said that there needs to be many businesses. She also submitted an article from the Miami New Times in which the cultivation of marijuana was discussed with a headline stating two bills could dismantle Florida's medical marijuana cartel. It states that in Florida companies such as Phillip Morris cultivate and process, package, and sell tobacco cigarettes, but for some reason medical marijuana refuses to act in exactly that way. Same story here. Florida legislation requires medical marijuana industry to be vertically integrated. That's how we are. Florida Governor Ron DeSantis has likened vertical integration to a cartel. In July, a Tallahassee appellate court, issued a ruling saying that the system is unconstitutional. The issue will be heard by the Florida Supreme Court. However, if the courts don't dismantle the system, lawmakers might do so first. Two bills have been introduced in Florida to take care of the problem, to get rid of the monopolistic practices and encourage diversity.

Ms. Monaghan argued that we need to do the same and also look at the micro-licenses, and not have the LNPPs do it all. She does like to liken it to the American beer industry. American beer used to be horrible. Now, we have Elevated IPA. It's competition. People should be able to specialize and just grow if they are a really good grower and don't want to sell. Or, just open a shop and just do that. She also advocated for preference to people with minorities.

The Comments of Larry Love

Mr. Love is a medical cannabis patient. He is also an advocate for medical cannabis patients and an advocate for the program. He said that new rules need to be put in place in certain areas because patients really want good clean medicine. For future new rules, he proposes that, since we have a 10-year-old program, he would like to see the LNPPs analyzed every three years for their product. How much they are growing. How good the product is. If they are not up to it, their licenses should be taken away.

He said that there are many licensees out there right now who are treading water and not producing very much. He said: "You can look at the statistics on that." Analyzing the quality of the medicine and letting the clean medicine rising to the top is what should be done. He supports micro-licenses. He also supports coops. He said that are some really good patient growers out there. He urged letting them sell their own production. The LNPPs are not creating enough medicine.

The Comments of Kylie Safa

Ms. Safa is the Chief Operating Officer for Ultra Health. She is also a medical cannabis patient. She submitted written comments for the last hearing and written comments for the January 2020 hearing. She stated she would briefly go over each point to provide a general overview of their comments.

First, she raised a concern about the timing of this rulemaking given the upcoming legislative session and the potential for legalization coming down the line.

Her next comment relates to the Definitions in 7.34.3.7 NMAC. She stated that the statute has a “bunch” of definitions contained in the statute that do not match the definitions in the proposed rules. She also stated that the definitions for “cannabis establishment,” “cannabis product,” “cannabis testing facility,” “hemp,” “license,” “licensee,” “produce,” and other definitions that are in the statute are not reflected in the proposed rules. She recommended that the definitions be the same in the rules as written in the statute.

She then discussed 7.34.4.8(Z) [now Subsection X] NMAC, referring to geographical regions, is unclear whether there is a restriction as to producers in a geographical region to new licenses or is it only for current licenses. She said there is a little vagueness there and she would like clarification.

She discussed 7.34.4.9 NMAC—Minimum Standards for Production. She said that they agree that cannabis businesses should strive for high levels of quality control and technical advancement. The level of restriction and vagueness in this section could lead to some absurd results. For example, there is a phrase that says “equipment, implements, and fixtures that are used for the production of cannabis shall be used exclusively for the production of cannabis.” [Subsection 9(A)(2)]. She said that could be construed to mean a microwave could not be allowed because it is not used for the production of cannabis. She thinks there needs to be a list of things that must only be used for the production of cannabis.

Ms. Safa next referred to 7.34.4.9(A)(12) [now Subsection 11] NMAC, which requires that “floors, walls, and ceilings . . . are constructed in such a manner that they are washable, wipeable, and non-absorbent and can be kept clean and in good repair.” She said that this requirement is simply unworkable because many producers grow medical cannabis outside or in green houses, where obviously soil is absorbent. She said there needs to be a distinction for what is required for those who are producing consistent with agricultural standards and those who are manufacturing need to be consistent with manufacturing standards.

Ms. Safa next turned to 7.34.4.9(A)(3) NMAC, which prohibits the cultivation of hemp with medical cannabis plants. She argued that hemp is under the authority and regulation of another department. She thinks the DOH is overreaching there in what they are allowed to regulate. Also, she thinks hemp can be used in the MCP to increase that much needed and much sought after high-CBD product. Thus, she argued that it seems logical that cannabis producers could produce both hemp and medical cannabis.

Ms. Safa next addressed 7.34.4.10 NMAC, referring to testing. She said that she had not had a chance to go over all of the changes in detail so for now she is going to assume that many of them still have the issues that were present in the last hearing. There is some impossibility of testing. There is a lot of research regarding whether you can meet these standards because of how strict they are. However, she is not sure on what the details are on this issue yet, but as of now they seem pretty difficult to reach. Also, as far as she knows, DOH has not consulted the Medical Advisory Board on what standards of testing should be.

She said they support state tested reliable medicine. They do want to bring attention to the increased costs and decreased supply. She said there needs to be some kind of clarity there to keep the costs down.

She referred again to 7.34.4.10 NMAC. She discussed what constitutes a repeat failure. Is it 2 failures or 450? There needs to be some clarity there.

Her last comment was on "additives" and "addictive" in reference to 7.34.4.14 (C) NMAC. She said there should be a specific list, because technically sugar is addictive.

The Comments of Duke Rodriguez

Mr. Rodriguez is from Ultra Health. He said he was going to keep his comments more narrow and stay away from all the rules. They appreciate all the work the Department has done. He said they have not had time to reconcile all the changes for the January 16 hearing.

He stated that the number of changes is pretty significant and he is concerned that they are not allowed enough time to absorb the changes, especially in light of the fact that the Governor has called for legalization of marijuana. He stated that in the draft legalization bill, effective July 1, the Department is totally removed from the Medical Cannabis Program. He stated that it would be wise to watch the process and see what happens in the next 35 days. If DOH is removed, it will be handed over to RLD, which will have to promulgate a bunch of whole new regulations and make this all moot. He said it seems wise to wait because if the legislation passes the involvement of the DOH will be only, strictly, the registry.

Going forward, he is concerned that a lot they have asked to be addressed has not been addressed, for example, the use of LNPPs. In the current draft rules, the DOH has identified LNPPs 78 times, and only identified cannabis producers twice. He said that the statute was changed last spring and there is no such thing as a licensed non-profit producer. There was no such a thing in the past and there is not today. He said the Department wants to promulgate this myth, of these non-profits producers that do not exist in the statute. There are licensed cannabis producers and they have very distinctive powers to produce, possess, distribute, dispense, and manufacture. He said it is not a mandate of vertical integration. A producer can do any one of the five, or all of them. He would like to make sure that continues and is reaffirmed in the regulations, because it is specifically what the statute says.

Mr. Rodriguez discussed the issue of seedlings and mature plants, and the issue of PPLs having a license to grow mature plants. He said that under the regulation they are limited to four

mature plants flowering, and 12 seedlings. He said this is an impossibility and absurd outcome because that would mean every PPL could never have a plant in vegetative state. That would not work. He argued that instead of these extensive changes and overwriting of the current regulations, why don't we just fix the problems we know existed, let the legislature do its work and see if in fact DOH will continue to have a role going forward.

Mr. Rodriguez next turned to the issue of residency. He said that the issue of residency has been well-addressed. He is a card holder in New Mexico, California, and Arizona. He said the courts have ruled that residency is allowed for any person. The regulation change does not reflect that. He said that even yesterday the Governor said that she might call for a change in the statute, but until that change is made, the law is the law. The regulations should reflect the current law.

He returned to the issue of seedlings. He said let's go back and look at that plant count one more time. He said that we all know from a practical standpoint why prices are not going down. It's because we don't have enough material out there. There is not enough material to meet all the needs. He asked why don't we go back and reevaluate the 1750 plant count, and treat that as only a limit for mature, flowering plants. Seedlings and everything else should not be counted. He thinks that would go for a long way to resolve some of these problems.

Mr. Rodriguez stated that he believes that the Department continues to move in the right direction. He welcomed Dr. Zurlo and said he has done a great job since he got back.

The Comments of Leigh Jenke

Ms. Jenke is also a representative of Ultra Health. She wanted to respond to a couple of issues that she heard people speaking about at the hearing.

She first addressed the issue of patient limits. She said patients should be able to buy what they want. New Mexico has a limit of 8 oz. for 90 days. All other medical cannabis states allow their patients to buy 1 to 3 oz. a day. If you consider 8 oz. for roughly 3 months, and other people can hit that within a week, it does not seem quite fair to the patients of New Mexico. She further stated that each qualifying condition is unique so that is akin to having diabetes. She said that she takes more or possibly less insulin than other diabetes patients. She said it is not up to the State to decide how much insulin she can take. That should be left up to the patient, and their qualifying condition, and how much they need, and, possibly, their doctor.

She further stated that usually limits are set for addictive substances, such as opiates. Cannabis is a very viable alternative to opiate substances which people are now turning to. This is a substance that does not kill people.

Ms. Jenke next addressed vertical integration. She noted that this is also addressed in the statute. Vertical integration covers training, cultivation, manufacturing, distribution, and in every other industry, like grocery stores, pharmacies, Wal-Mart, and other health care industries, they are all vertically integrated. She hears a lot of people talking about pricing of medications. When you allow vertical integration, that typically hits price point. That allows them to make

products that they know patients want and they can typically provide it to patients at a lower price than having to go through a middle-man.

She also addressed the issue of plant count. She asked that we just let them grow what they need to grow based upon patient demands. They are currently are at roughly 80,000 card holders. That number is ever increasing. It does not make sense to have to keep promulgating rules constantly to keep up with increasing patient consumption and demand. As the card count and demand increases or decreases, she asked that we allow them to be able to keep up with that demand.

The Comments of Robert Stranahan

Mr. Stranahan is the chief legal counsel for the Harvest Foundation. He stated that one of the things that he thinks has been an ongoing theme in the hearing is that they would like to create a regulatory structure that allows for safe and cost-effective medicine to the patients. However, we are looking at increasing the regulatory demands that can only drive up costs. He said that when you are talking about sample sizes for testing, there should be a better give and take with the DOH to determine how that testing should be done and what volume should be tested. He said that the 25-gram proposal just does not make sense from a cost standpoint.

He argues that are other ways that we can increase the testing and the effectiveness without creating a financial crunch on the producers. He said that volume alone does not fix any problems that are perceived. He would like a more expansive review on what other ways that we could bring in testing changes that might be more cost effective and also more effective from an oversight standpoint.

The Comments of Aaron Newell

Mr. Newell stated that he represents himself. He is a card holder. He had four topics he wanted to talk about.

First, he said that the Program testing in our state is horrendous. He said that the test samples can easily be manipulated by growers in private business. His said samples should be selected by the State or a third-party representative.

Also, he argued that complete testing is a must. Heavy metals, pesticides and complete microbiology panels must be done. This is needed for the safety and health of our patients.

He said that every LNPP should be randomly evaluated in surprise visits to ensure that all protocols and SOPs and the state requirements are being complied with.

His second topic was that licenses should be opened up or micro-licenses should be allowed. This goes along with the adequate supply issues. He believes there should be an overage of supply here rather than an adequate supply. Opening the licenses or micro-licenses or third-party cultivators would be a big step which would allow small craft growers or PPL growers to go buy their access medicine through an authorized location for patients to purchase.

He next argued that with the plant count going up the quality has significantly gone down. Out of the entire state there are only two shops worth his dollar and time; one is Sandia Botanicals and the other is Harvest Foundation. All the other ten LNPPs in our state produce poor quality product or poor quality at a high price. He said this forces people to go to the black market to find better medicine. He asked that we please open up the licenses and save our program.

Mr. Newell's third topic was the consumption sites. He said that they should not be limited to LNPPs, especially in the southern part of New Mexico, where locations are scarce and few and far between. He said: "If I don't buy my medicine there, why would I go there to mix." Patients should have options and availability to choose their locations that is neutral and comfortable, and away from retail locations. He said it is almost like they are being forced to buy an LNPP's medicine in order to be able to consume at these sites.

His last topic was the three-month limit. He stated that it needs to be removed. He mentioned that his condition may be different than that of someone else and might require more than his three-month limit. You have patients who buy their whole three-month limit at one time. He recommended the rule in California which recommend that all patients need something different. The limit here forces people to go to the black market. Most patients reach their three-month limit in a month, leaving them without medication for two months, or forcing them to the streets.

The Comments of Larry Love

Mr. Love raised the question of whether, if legalization passed, the DOH will lose the Medical Cannabis Program. He said that does not make any sense. DOH stands for "Department of Health." This would be a bad thing.

Andrea Sundberg asked if anyone else would like to speak. No one took advantage of that opportunity.

The Hearing Office then thanked all the participants who offered public comments and stated that he would be working on a report to the Secretary and closed the hearing.

Dr. Zurlo also reminded people that he has been working with small groups so that every one's voice can be heard. He let people know that they can let him know.

ANALYSIS AND RECOMMENDATIONS

Guidance in determining whether a rule adopted by an administrative agency will be upheld can be found in *New Mexico Mining Ass'n v. New Mexico Mining Com'n*, 1996-NMCA-098, 122 N.M. 332, which states as follows:

Rules adopted by an administrative agency will be upheld if they are in *harmony* with the agency's express statutory authority or *spring from those powers that*

may be fairly implied therefrom. [Citations omitted.] Similarly, regulations adopted by an agency are presumed to be valid if they are shown to be *reasonably consistent* with the statutory purposes of the agency. [Citation omitted.] [Emphasis added.]

See also *Rio Grande Chapter of Sierra Club v. New Mexico Mining Com'n*, 2003-NMSC-005, 133 N.M. 97 at ¶ 25.

In addition:

"The court will confer a heightened degree of deference to legal questions that implicate special agency expertise or the determination of fundamental policies within the scope of the agency's statutory function."

Id., quoting *Morningstar Water Users Ass'n v. N.M. Pub. Util. Comm'n*, 120 N.M. 579, 583 (1995).

The Hearing Officer addresses each of the current group of proposed amendments to the Medical Use of Cannabis Rules as follows:

7.34.2 NMAC – ADVISORY BOARD RESPONSIBILITIES AND DUTIES

7.34.2.7 NMAC – Amendments to DEFINITIONS

The proposed amendments to the Definitions in 7.34.2.7 NMAC are identical to the proposed changes in 7.34.3.7 NMAC and 7.34.4.7 NMAC. Consequently, the comments in this subsection apply to all three sets of proposed amendments to Definitions.

The proposed changes to Definitions in 7.34.2.7 NMAC are as follows:

The definition of “**Adequate supply**” in 7.34.2.7(B) NMAC is modified to more closely reflect the statutory definition.⁴

Recommendation: There were no public comments directed specifically to this rule. The proposed rule is in harmony with the Department's express statutory authority. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Applicant**” in 7.34.4.7(F) NMAC is not proposed for amendment in this rulemaking process. However, Jason Marks provided a written comment on this rule. See Exhibit 14, Written Comments of Jason Marks at 10. Mr. Marks argues that this definition is only needed and used with respect to patients and caregivers. He argues that it creates ambiguity to include producer applicants in the definition. *Id.* There were no other comments on this proposed rule.

⁴ See Exhibit 25, *DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing* January 16, 2020 at 1.

Recommendation: This rule was previously promulgated in another rulemaking process and was not revised in this rulemaking process. The proposed rule does not appear to be ambiguous. The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Approved laboratory**” at 7.34.2.7(G) NMAC has been struck in favor of adding a definition for “**laboratory**” at 7.34.4.7(Y) NMAC, which references the statutory definition of “**cannabis testing facility**” in the statute at NMSA 1978, § 26-2B-3(I). This provision was added to the statute by SB406 (2019).⁵

Recommendation: There were no public comments on this amendment. The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Approved Entity**” at 7.34.2.7(G) NMAC was added to distinguish manufacturers, laboratories, and couriers from licensed producers. All these entities are licensed by the Department, but references in the rules to “licenses” generally refer to producer licenses.

Recommendation: There were no public comments on this amendment. The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Batch**” at 7.34.2.7(H) NMAC has been revised to remove the reference to the word “homogenous” in response to public comment, and substituted with text proposed in public comment to identify a “batch” as having come from the same cultivation area at the same time, and having been subject to the same agricultural practices (including pesticides).

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Cannabis consumption area**” at 7.34.2.7(J) NMAC has been added to reflect the addition of the statutory definition of “cannabis consumption area” from SB406(2019). See NMSA 1978, § 26-2B-3(C). There were several comments from individual members of the public seeking a broader definition of “cannabis consumption area,” not limited

⁵ See Exhibit No. 9 for the *DOH Summary of Proposed Rule Amendments*, dated November 22, 2019.

to LNPPs. Some commenters wanted a much broader definition, including one who sought a rule that would allow cannabis consumption areas anywhere and everywhere.

Recommendation: The proposed rule as written is consistent with the express language of the statute. The proposed definition of “cannabis consumption area” mirrors the definition of “cannabis consumption” found in NMSA 1978, § 26-2B-3(C). Further, the creation of cannabis consumption areas is a new component to the Medical Cannabis Program, just being introduced for the first time. It should be kept narrow in scope for the time being. The Hearing Officer recommends that the Secretary adopt this amendment.

The definition of “**Cannabis establishment**” in 7.34.2.4(L) NMAC has been included as an added statutory definition, based upon public comment. *See* Exhibit 25.

Recommendation: The proposed rule is consistent with the express language of the statute. The Hearing Officer recommends that the proposed rule be adopted.

The definition of “**CBD**” at 7.34.2.7(M) NMAC is a new definition added to the regulations. It replaces the definition of “**Cannabinoid**(“**CBD**”) previously found in 7.34.2.7(I) NMAC.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**CBDA**” at 7.34.2.7(N) NMAC is a new definition added to the regulations.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Courier**” at 7.34.2.7(P) NMAC was revised to cross-reference the statutory definition of “cannabis courier” found at NMSA 1978, §26-2B-3(D).

Ultra Health argues in its written comments that this definition does not match or track the statutory definition. It argues that “cannabis courier” in the statute is a person “licensed” by DOH, but in the regulation is a person “approved” by the Department. *See* Exhibit 14.

Ultra Health also argue that different definitions for the same terms, as set forth in the statute and in the regulations, sows confusion among medical cannabis businesses and patients, which, Ultra Health states, cannot serve two masters—the statute and the regulation. Ultra Health argues it is beneficial to the business-DOH relationship to ensure that regulations match the statutory language. Ultra Health argues that consistent definitions eliminates confusion, and is legally proper. While Ultra Health acknowledges that courts give some deference to an agency's

interpretation of a statute, if the statute is clear and unambiguous, and not within the agency's expertise, courts should afford little if any deference on issues of statutory construction, citing *Marbob Energy Corp. v. New Mexico Oil Conservation Commission*, 2009-NMSC-013, ¶ 6-7, 206 P.3d 135. Ultra Health also argues that “[w]hen a statute and a regulation conflict, the statute prevails, citing *Gallegos v. State Bd. of Education*, 1997-NMCA-040, ¶ 23, 123 N.M. 362.

Recommendation: The distinction between the words "licensed" and "approved" is not a significant one. It is not a difference that creates ambiguity; there can be little question that to be "approved" as a courier, one must be licensed. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

The definition of “**Diversio**n” at 7.34.2.7(S) NMAC is a new definition added to the rules. Jason Marks provided a written comment on 7.34.4.7(S) NMAC (which is identical to the same definition in Part 2 of the rules) and also commented on 7.34.4.7(X) NMAC—the definition of “**Inversio**n” (also a new definition) at the same time. He argued that both definitions are overly broad and make the definitions less useful. See Exhibit 14, Written Comments of Jason Marks at 10. He also argued that the definitions are potentially subject to void for vagueness challenges if a transfer of cannabis that is unlawful (that is, in violation of the rules) is a “diversion” or “inversion.” He argues that the DOH should narrow these definitions to pertain to transfer from or to persons who are not licensed entities.

Recommendation: There were no other public comments in opposition to this amendment. The proposed definitions do not appear to be overly board or vague. The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Dried usable cannabis**” at 7.34.2.7(T) NMAC is a new definition added to the rules.

Recommendation: There were no public comments in opposition to this amendment. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

The definition of “**Hemp**” at 7.34.2.7(V) NMAC is an added statutory definition, as a consequence of public comment. See Exhibit 25.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Inversio**n” at 7.34.2.7(X) NMAC is a new definition added to the rules.

Recommendation: See the discussion of the definition of "Diversion" above. There were no public comments in opposition to this amendment. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

The definition of "**Laboratory**" at 7.34.2.7(Y) NMAC is a new definition added to cross-reference the definition of "**cannabis testing facility**" in the statute at NMSA 1978, § 26-2B-3(I), which was added in SB406 (2019).

Recommendation: There were no public comments in opposition to this amendment. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

The definitions of "**License**" at what were formerly 7.34.2.7(S) NMAC and "**Licensure**" at 7.34.2.7(U) NMAC were removed in recognition that "**approved entities**" are effectively licensed by the DOH, as expressed in statutory amendments in SB406 (2019), as codified in NMSA 1978, § 26-2B-3(D), (F), and (I), which identified "cannabis couriers", "cannabis manufacturers", and "cannabis testing facilities" as persons "licensed" by the Department.

Recommendation: There were no public comments in opposition to this amendment. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

The definition of "**Manufacture**" at 7.34.2.7(DD) NMAC has been modified to more closely reflect the statutory definition, as a consequence of public comment. *See Exhibit 25.*

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of "**Manufacturer**" at 7.34.2.7(EE) NMAC has been amended to cross-reference the statutory definition of "cannabis manufacturer" which was added to the statute in SB406 (2019), and codified at NMSA 1978, § 26-2B-3 (F).

Ultra Health argues in its written comments that this definition does not match or track the statutory definition. It argues that "cannabis manufacturer" in the statute is an entity "licensed" by DOH, but in the regulation is a person "approved" by the Department. *See Exhibit 14.*

Recommendation: The distinction between the words "licensed" and "approved" is not a significant one. It is not a difference that creates ambiguity; there can be little question that to be "approved" as a manufacturer, one must be licensed. This proposed amendment to the rules is in harmony with the DOH's express statutory authority. The Hearing Officer recommends that the Secretary adopt this amendment.

7.34.4.7(EF) NMAC, the definition of “**Medical cannabis program manager**” has been revised to reflect that the word “director” has been used as the title of the person who administers the Medical Cannabis Program, in response to public comment. See Exhibit 14, Written Comments of Jason Marks at 10.

Recommendation: The Hearing Officer recommends that the Secretary adopt this revision.

Jason Marks also offers a written comment 7.34.4.7(FG) [now Subsection “II”] NMAC, the definition of “**Medical director.**” He states that the LECUA requires that the Department issue patient registrations upon a practitioner’s certification. He states it would be unlawful for the medical director to exercise the power provided in this definition. This rule is not the subject of this rulemaking process and was previously promulgated.”

The foregoing proposed rule is not in conflict with the statute. The proposed rule is in harmony with the Department’s express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

Jason Marks also offers a written comment 7.34.4.7(HH) [now Subsection “RR”] NMAC, the definition of “**Petitioner.**” He states that it would exceed statutory authority for the DOH to exclude petitions for covered conditions from persons who are not residents. This rule is not the subject of this rulemaking process and was previously promulgated.”

The foregoing proposed rule is not in conflict with the statute. The proposed rule is in harmony with the Department’s express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Permanent structure**” at 7.34.2.7(OO) NMAC is an added, new definition. The expression “permanent structure” is used in new text, discussed below, that modifies a passage concerning the cleaning of surfaces in buildings operated by LNPPs. This change was made in response to public comment. See Exhibit 25.

Recommendation: The proposed rule is in harmony with the Department’s express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of “**Pesticide**” at 7.34.2.4(QQ) NMSA has been added to cross-reference the term “pesticide” as defined by the New Mexico Pesticide Control Act, NMSA 1978, § 76-4-3, et seq.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of **"Produce"** at 7.34.4.7 (YY) NMAC is an added statutory definition, based upon public comment. *See* Exhibit 25.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of **"Recall"** at 7.34.4.7 (BBB) NMAC is an added definition, based upon public comment. *See* Exhibit 25.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of **"THCA"** at 7.34.2.7(NNN) NMAC is a new definition added to the regulations.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of **"Testing"** at 7.34.2.7(QQQ) is amended for clarification.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

The definition of **"Wastage"** at 7.34.2.7(TTT) NMAC is a new definition added to the regulations.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.3 NMAC – REGISTRY IDENTIFICATION CARDS

7.34.3.7 NMAC – Amendments to DEFINITIONS

The proposed changes to Definitions in 7.34.3.7 NMAC are identical to the changes in 7.34.2.7 NMAC. The proposed changes to 7.34.3.7 NMAC are discussed above in the analysis for the proposed revisions to 7.34.2 NMAC.

Recommendation: The Hearing Officer recommends that the Secretary adopt the proposed changes to the Definitions in Part 3 in the same manner as set forth in the Recommendations related to the Definition in Part 2 above.

7.34.4 NMAC – LICENSING REQUIREMENTS FOR PRODUCERS, PRODUCTION FACILITIES AND DISTRIBUTION

7.34.4.1 NMAC through 7.34.4.6 NMAC are unchanged in these proposed rules, and should be adopted by the Secretary in this repeal and replace promulgation proceeding.

7.34.4.7 NMAC – Amendments to DEFINITIONS

The proposed changes to Definitions in 7.34.4.7 NMAC are identical to the changes in 7.34.2.7 NMAC and 7.34.4.7 NMAC. The proposed changes in 7.34.4.7 NMAC are discussed above in the analysis of 7.34.2 NMAC.

Recommendation: The Hearing Officer recommends that the Secretary adopt the proposed changes to the Definitions in Part 4 in the same manner as set forth in the Recommendations related to the Definition in Part 2 above. Furthermore, since this proceeding seeks to repeal and replace Part 4 of 7.34 NMAC, the Hearing Officer recommends that the Secretary adopt all of the proposed definitions in Section 7 of 7.34.4 NMAC.

7.34.4.8 NMAC – Producer Licensing: General Provisions

7.34.4.8.(A) – The department may license two classes of producers

Written Comment of Jason Marks – November 22, 2019

Jason Marks is an attorney who states that he represents more than one-quarter of all the entities holding medical cannabis production licenses. *See* Exhibit 14, written comments of Jason Marks at 1. He argues that the Department may not restrict producers to non-profit corporations. *Id.* at 2-3. Other commenters made several comments at the public hearings regarding the requirement that producers be non-profit corporations.

Recommendation: 7.34.4.8(A) NMAC was the subject of a prior rulemaking process and is not part of the current rulemaking process. The Department has proposed no changes or amendments to this subsection of the rule. The Hearing Officer recommends no changes to the rule restricting producers to non-profit corporations at this time.

7.34.4.8(D)(3) NMAC – Processing of production applications

DOH Summary of Proposed Rule Changes – November 22, 2019

The reference to “a non-profit producer” is replaced in the subsection on processing of production applications with “[a]n applicant” in recognition of the fact that this passage concerns applicants whose applications are not yet approved. *See* Exhibit 9.

Recommendation: The proposed rule is in harmony with the Department's express statutory authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.8(F) NMAC – Production and distribution of medical cannabis by a licensed non-profit producer; use of couriers

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

This rule is proposed for revision by adding “grandfathering” text from the statute, in response to public comment. *See* Exhibit 25. The new text would allow an LNPP to continue operating at a location that is within 300 feet of a school, church, or daycare center if the producer’s location existed at the location prior to the establishment of the school, church, or daycare center within the 300-foot boundary. *Id.* In order to be consistent, the Department has proposed identical text in the passages of the rule that apply the 300-foot standard to locations of manufacturers, laboratories, and couriers. *Id.*

The Department notes that one commenter argues that the New Mexico legislature did not extend the 300-foot rule to production facilities, but only to “distribution” locations. The commenter also argued that the 300-foot provision should not apply to laboratory or manufacturer locations. In response, the Department states that it considers the production of cannabis and the manufacture of cannabis-derived products to be part of the distribution chain, and that the 300-foot requirement, as applied to production and manufacturing facilities, there falls within the statutory provision at NMSA 1978, § 26-2B-7(A)(6)(b). *Id.*

Further, the Department argues that the 300-foot requirement, as applied to LNPP production facilities, manufacturer locations, and laboratory locations, is an appropriate standard and can be required by the Department consistent with its statutory authority to identify requirements for the licensure of producers, manufacturers, and laboratories, pursuant to NMSA 1978, §26-2B-7(A)(5). *Id.*

The Department also notes that it has proposed, consistent with the exception that was recently included in the statute at NMSA 1978, § 26-2B-7(A)(6)(b), to include the “grandfathering” provision that would allow any such licensee to continue operating at a location that falls within the 300-foot distance, provided that the school, church, or daycare center was

established within the 300-foot boundary after the licensee became licensed to operate at the location. *Id.*

Written Comments of Jason Marks – January 16, 2020

Mr. Marks comments in his January 16, 2020 are largely identical to his comments in his November 22, 2019 written comments. However, with respect to 7.34.4.8(F) NMAC, he raised an additional argument. He responds to the Department's argument that the location limits in LECUA should be interpreted in the same manner as provided by the state's Liquor Control Act, NMSA 1978, § 60-3A-1, et seq. He argues that the Liquor Control Act only imposes location limits upon the sale of alcoholic beverages within 300 feet of any church or school, not on the production of alcohol within those limits.

Recommendation: The statute, at NMSA 1978, § 26-2B-7(A)(6)(a) and (b) addresses both "production facilities" and "distribution of cannabis" in requiring the Department to establish rules in order to "develop a distribution system for the Medical Cannabis Program." Thus, "production" and "distribution" fall generally within the requirement of "develop a distribution system." For the reasons stated by the Department, summarized above, the Hearing Officer recommends that the Secretary find that the proposed rule in harmony with the express authority given to the agency under the statute and is reasonably consistent with the purposes of the statute, and recommends adoption of the proposed rule.

7.34.4.8(G)(4) NMAC – Verification of application information

Written Comments of Jason Marks – November 22, 2019

Jason Marks offers written comments on this proposed rule, and other similar statements in the rules, as listed below. *See* Exhibit 14, written comments of Jason Marks at 1. He argues that the Department may not reserve the power to promulgate ad hoc rules and may only promulgate rules through a formal rulemaking process with notice and comment and publishing such rules in the Register and the Administrative Code. He argues that seven of the rules in 7.34.4. NMAC violate these principles without going through notice and comment, or publication. He argues that the defective rules include the following:

- 7.34.4.8(G)(4) NMAC “requiring additional information as the department deems necessary”;
- 7.34.4.8(O)(14) NMAC “such other policies or procedures as the department may require”;
- 7.34.4.14(B)(25) NMAC “such other materials as the department may require”;
- 7.34.4.17(D)(1) NMAC “such other materials as the department may require”;
- 7.34.4.22(I)(3) NMAC “such other information as the department may reasonably request”;
- 7.34.4.26(B)(12) NMAC “such additional information or materials as the department may require”;
- 7.34.4.29(B)(3) NMAC “such additional information as the department may request.”

Mr. Marks argues that the foregoing rules violate NMSA 1978, § 9-7-6(C) because they would allow the Department to enact rules without a public hearing on the proposed action before the Secretary or a designated hearing officer. He urges the Hearing Officer to strike the rules. He argues that 7.34.4.8(O)(14) NMAC is the most egregious of the rules, claiming that the Department purports therein to reserve unlimited power to impose new regulations on LNPPs without going through rulemaking. *Id.* at 2.

The foregoing is fundamentally flawed because it fails to recognize that six of the foregoing seven rules are not new rules that are part of the current rulemaking process, but are rules that were promulgated in prior rulemaking processes, with notice and comment, and were published in the Register and the Administrative Code. The only one of the foregoing rules that is in a new rule and part of this current rulemaking process is 7.34.4.26(B)(12) NMAC. The rest of the rules have already been properly promulgated and the Hearing Officer recommends no changes to the foregoing rules at this time. 7.34.4.26(B)(12) is addressed below.

7.34.4.8(I) NMAC – Criminal history screening requirements

DOH Summary of Proposed Rule Changes – November 22, 2019

The reference to “qualified patients” in the subsection on criminal history screening requirements is removed to clarify that a qualified patient is not ordinarily subject to criminal history screening under DOH rules. A qualified patient who is an employee, contractor, or board member, etc., of a non-profit producer, manufacturer, courier, or laboratory, will, however, be subject to criminal history screening in that capacity.

Recommendation: There was no public comment on this proposed rule. The proposed rule is reasonably consistent with the express language of the statute, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(K) NMAC – Limitation on number of production facilities

DOH Summary of Proposed Rule Changes – November 22, 2019

Existing text in the subsection on limitation on number of production facilities is struck to remove old reference to 150 plants, and to allow licensed non-profit producers to request an additional production facility, to be granted or denied at the Department’s discretion, irrespective of the number of plants that the producer is approved to grow. *See* Exhibit 9.

Written Comment of Jason Marks – November 22, 2019

Jason Marks offers written comment on 7.34.4.8(A)(2) and 8(K) NMAC (“Limitation on number of production facilities”). *See* Exhibit 14, written comments of Jason Marks at 10. He states that the DOH reasonably licenses multiple production facilities under a single license. He also states that concurrent operation of an indoor and an outdoor grow is common and desirable. He argues that Subsection 8(A)(2) of the rule should state “one or more facilities” and not imply a restriction to “facility” for clarity. He also suggests that in Subsection 8(K) the rules should not

restrict production to one facility, nor allow facilities at the Department's "discretion," which he asserts is arbitrary. He argues that Subsection 8(A)(2) should be rewritten to state "A producer shall conduct its operations only at the physical locations approved by the department, which facilities shall be reasonably necessary to supply the cannabis needs of the patients served by the producers, and whose numbers and locations shall not unreasonably burden the department's ability to monitor production activities."

Recommendation: The revised version of 7.34.4.8(K) NMAC is in harmony with, springs from, or is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(M) NMAC – Destruction of usable cannabis and cannabis plants

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on destruction of usable cannabis is amended to specific that destruction of both cannabis and cannabis plants must be documented in accordance with the rule. *See Exhibit 9.*

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The Department notes that one commenter suggested that the proposed 120-day retention of cannabis destruction is too burdensome, and that digital storage is too costly. The Department states that it finds the proposed 120-day retention period to be reasonable and appropriate to accomplish the Department's objectives. It also argues that, upon information and belief, digital storage is relatively inexpensive, and should by no means be cost prohibitive. *See Exhibit 25.*

Recommendation: The Hearing Officer agrees with the statements of the Department in support of the proposed rule. The proposed rule is in harmony with, springs from, or is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(O)(13) NMAC – Non-profit producer policies and procedures

DOH Summary of Proposed Rule Changes – November 16, 2019

The subsection on non-profit producer policies and procedures has an added requirement that the producer submit an attestation that it will prohibit its employees and contracts from being under the influence of drugs or alcohol in the workplace. *See Exhibit 9.*

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The Department responds to a commenter who criticized the proposal to prohibit employees of licenses from being under the influence of drugs while at work, and who suggested that employees should be allowed to use cannabis at work. See Exhibit 25. The Department responds by stating that allowing employees to be under the influence of drugs or alcohol while at work would pose obvious health and safety risks, and states that it does not intend to allow it.

Recommendation: 7.34.4.8(O)(13) NMAC is in harmony with, springs from, or is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(P) NMAC – Retention of training documentation

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on the retention of training documentation is amended to strike requirements for tender of employee training documentation to the Department. Department access to materials is specified elsewhere in the rule, including the section regarding monitoring (currently 7.34.4.23 NMAC).

Recommendation: 7.34.4.8(P) NMAC is in harmony with, springs from, or is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(Q)(2) NMAC – Licensure periods

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on licensing periods is clarified regarding the licensure period for personal production licenses.

Recommendation: 7.34.4.8(Q)(2) NMAC is in harmony with, springs from, or is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(Q)(3) NMAC – Licensure periods

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on licensing periods is also revised to include a requirement the LNPP employees carry their Department-issued employee I.D. card at all times during their work and present the card to law enforcement upon request.

The Department added a provision to this subsection of the rule to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on an LNPP's licensed premises. *See* Exhibit 9. A similar requirement was included in section regarding each of the other cannabis establishments. *Id.*

Recommendation: 7.34.4.8(Q)(3) NMAC is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(R)(2) NMAC – Amended license

DOH Summary of Proposed Rule Changes – November 22, 2019

The Department added text to this subsection of the rule to specify that the MCP will identify materials that remain to be submitted for completion of an incomplete LNPP application for amended licensure, and that the LNPP will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete. *See* Exhibit 14.

Written Comment of Jason Marks — November 22, 2019

Mr. Marks included written comments on 7.34.4.8(R)(2) NMAC [now Section 8(R)(1)-(3)] and 7.34.4.17(J)(1) NMAC which, respectively, require that a producer or laboratory file an application for an amended license upon “any physical modification or addition to the facility.” *See* Exhibit 14, written comments of Jason Marks at 4-5.

The language he addresses in 7.34.4.17(J)(1) NMAC is part of a new rule relating to amended licenses for approved testing laboratories.

Mr. Marks argues that the language of the rule related to “physical modification or addition to the facility” in 7.34.4.8(R)(1)(b) NMAC is arbitrary, overly broad, and bears no relation to legitimate regulatory concerns. He argues that the rule would require a licensee to go through a costly and time-consuming amendment process any time it adds lighting, changes flooring or surfaces, reconfigures a back office or break room, or makes any number of possible physical modifications that have no effect on security or regulatory concerns. *Id.* at 4.

Mr. Marks argues that the regulations should be re-written to require amendment only for physical modification that add or remove space or areas where cannabis is dispensed, stored, or produced, or modifications which change the location of external doors; or which materially change the security system. *Id.*

Mr. Marks also argues against the requirement in 7.34.4.8(R)(1)(b) NMCA and 7.34.4.17(J)(1) for an amended license when a change in ownership of facilities occurs. He argues that transfers in building ownership by a third-party landlord of a cannabis business has no regulatory importance and should not be required. He further argues that he assumes this requirement comes from concerns about disclosure of the identify of related parties to cannabis businesses. If so, he argues, the Department should develop a rule to focus on circumstances with which it is actually interested and eliminate rules that burden licensees. He also argues that licensees should not be required to disclose all persons with indirect interest in facility ownership, whose identities may not even be known to them. *Id.* at 5.

Finally, Mr. Marks argues that Subsections 8(R)(1) and 17(J)(1) of the rules are excessive and burdensome in requiring amended licenses for changes in LNPP directors. He argues that directors resign without notice or must be replaced immediately for other reasons. He also notes that the rules already require background checks and issuance of an employee card for new directors. He suggests that the Department's additional needs to know about director changes could be satisfied by a notice requirement. *Id.*

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The Department does not believe that the amendment of an LNPP's license be required whenever the membership of the LNPPs board of directors changes names is too onerous, as asserted by some of the commenters. The Department believes this information is valuable and important for purposes of tracking the management of a licensed producer. *See* Exhibit 25.

The Department also disputes public comments which argue that amendment of a license should only be required for modification to a producer's facility when the modifications add or remove space to areas where cannabis is dispensed, stored, or produced, etc. *Id.* The Department asserts that this approach would be too restrictive, and states that it is interested not only in the size and location of producer locations, but in how producer operations are conducted.

The Department further responds to comments about amendment to licensure being required for any change in ownership of a facility. *Id.* It notes that commenters have suggested that an LNPP that rental property should not be required to report changes in ownership of that property, and that LNPPs should not have to disclose the identities of persons who have only an indirect interest in facility ownership. The Department states that it believes that recording the ownership of premises occupied by an LNPP is important, irrespective of whether an LNPP leases the property.

Recommendation: The Department has provided an adequate justification and reasonable bases for this proposed rule. The Hearing Officer recommends that the Secretary find that the

proposed rule is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(R)(1)(c) NMAC – Amended license

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on amended licenses is revised to include a reference to an LNPP manufacturing plan. *See* Exhibit 9.

Recommendation: There was no comment on this proposed revision and is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(U) NMAC – Automatic expiration of licenses

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on automatic expiration of licenses is amended to strike existing text regarding closure of LNPP operations, which is proposed to be replaced by a new rule 7.34.4.32 NMAC, “Closure of a Non-Profit Producer or an Approved Entity.” *See* Exhibit 9.

Recommendation: There was no comment on this proposed revision and is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(V) NMAC – Display of license

DOH Summary of Proposed Rule Changes – November 22, 2019

The subsection on display of licenses is amended to specify that the LNPP license must be maintained at both production locations and dispensary locations. *See* Exhibit 9.

Recommendation: There was no comment on this proposed revision and is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(W)(4) NMAC – Fees applicable to applicants and licensees

DOH Summary of Proposed Rule Changes — November 22, 2019

The subsection on fees applicable to applicants and licensees is amended to specify that a licensure fee that is paid by a newly-licensed LNPP for initial licensure will be pro-rated based on the amount of time that remains in the licensure period. *See Exhibit 9.*

Recommendation: There was no comment on this proposed revision and is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(X) NMAC – Geographic requirements for initial licenses

Written Comments of Ultra Health – January 16, 2020

Ultra Health responds to this proposed rule by stating that it believes that the DOH certainly expresses the right sentiment with this proposed regulation, but it asserts that the rule as proposed is ambiguous. *See Exhibit 29.* It states that it is not clear whether the rule applies to new applicants for a license or applicants for re-licensure. It argues that if the rule applies to already-licensed entities who are going through re-licensure processes, this criterion could result in closure of smaller producers and could disrupt production and patient access.

Ultra Health also asserts that the placement of the proposed rule is odd because 7.34.4.8(F) NMAC already sets out “factors considered” in “determining the number of licenses” and which entities should be licensed. Ultra Health suggests that if DOH is concerned about applicants’ commitments to underserved areas, it could add this criterion as a factor considered in granting license applications in the first place.

The Department included a provision here that the Department may require that an LNPP operate dispensaries in certain geographical locations as a precondition of initial licensure. This provision was modified to apply to initial licensure, in response to public comment. *See Exhibit 9.*

Recommendation: This proposed rule, as revised to clarify that the rule applies to initial licensures, is reasonably consistent with the Department's statutory authority to promulgate rules, and should be adopted by the Secretary.

7.34.4.8(Z) NMAC – Reporting of theft to department

DOH Summary of Proposed Rule Changes – November 22, 2019

This new subsection is added to establish theft and break-in notification requirements for LNPPs. *See Exhibit 9.*

Recommendation: The Department has provided an adequate justification and reasonable basis for this proposed rule. The Hearing Officer recommends that the Secretary find that the proposed rule is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.8(AA) NMAC – Closure of applications period

DOH Summary of Proposed Rule Changes – November 22, 2019

This new subsection is added to clarify that the applications period for LNPP licensure may be opened and closed by the Department, and includes similar text in section regarding manufacturers, laboratories, and couriers. *See Exhibit 9.*

Recommendation: The Department has provided an adequate justification and reasonable basis for this proposed rule. The Hearing Officer recommends that the Secretary find that the proposed rule is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9 NMAC – Non-Profit Producers; Minimum Standards for Production of Cannabis

DOH Summary of Proposed Rule Changes – November 22, 2019

This is a proposed new section that identifies minimum standards (primarily hygiene standards) for the production of cannabis by a licensed non-profit producer. The requirements largely duplicate existing requirements that apply to the manufacturers of cannabis-derived products. *See Exhibit 9.*

7.34.4.9(A)(1) NMAC – General Requirements

Written Comments of Ultra Health – November 22, 2019

Ultra Health offers written comments on 7.34.4.9 NMAC. *See Exhibit 14.* Ultra Health supports the sentiment of the proposed rule but argues that it is vague and will result in unworkable standards. It argues that the “level of strictness” in the proposed rule is “positively draconian” and may drive smaller producers out of business due to the cost of compliance. Subsection 9(A)(1) requires compliance with zoning, occupancy, licensing, and building codes. Ultra Health argues that many producers rent their premises and have little control over building codes. It argues that as tenants, they should not be responsible for incurring the cost of renovating buildings which are rented premises.

Recommendation: The requirement that producers comply with the requirements of zoning, occupancy, licensing, and building codes does not appear to be an unusual or unreasonable requirement for producers, and no argument is offered for why they should be exempt from the types of codes businesses typically must follow. This proposed rule appears to be reasonably

consistent with the statutory purposes of the agency, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9(A)(2) NMAC – General Requirements

Written Comments of Ultra Health – November 22, 2019

Ultra Health argues that the provision in Subsection 9(A)(2) which requires that “all equipment, implements, and fixtures shall be used exclusively for the production of cannabis” means that a microwave in an employee breakroom could be disallowed, and the computer to run BioTrack would be disallowed. *See* Exhibit 14.

Ultra Health also claims that there are “vagaries that produce absurd results.” *Id.* It states that the requirement that all “equipment, implements, and fixtures shall be used exclusively for the production of cannabis” would require that a microwave in an employee break room would be disallowed, and the computer that is used to run BioTrack is disallowed. Another provision required production to be conducted in a manner that does not allow cross-contamination from chemical or biological hazards” without a precise definition of hazards. Ultra Health argues that such innocuous substances as water or oxygen can quickly become hazards under specific conditions. *Id.*

Written Comments of Natural Rx – November 22, 2019

Brooke Duverger from Natural Rx commented on 7.34.4.9(A)(2) NMAC. She stated that this proposed rule raises a concern because there are many items in their facilities that are not used solely for that purpose, including computers, equipment in employee break rooms, and other items commonly found in the workplace. She recommended revising the rule to allow for such items. *See* Exhibit 14, written comments from Natural Rx at 1.

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This subsection of the rule was revised to clarify that equipment, implements, and fixtures that are used for the production of cannabis shall be used exclusively for that purpose. *See* Exhibit 25. The Department included this edit in response to public comment.

Recommendation: As revised, this proposed rule is reasonably consistent with the agency's statutory purposes, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9(A)(3) NMAC – General Requirements

Written Comments of Ultra Health – November 22, 2019

Ultra Health also offers written comments on 7.34.4.9(A)(3) NMAC. This provision requires that producers ensure “that no cannabis plants other than those grown pursuant to the non-

profit producer's production license from the department are grown on the premises of the non-profit producer, including but not limited to hemp plants." See Exhibit 14.

Ultra Health argues that Subsection 9(A)(3) effectively prohibits a producer from co-housing medical cannabis and industrial hemp plants on the same campus. It argues that the word "premises" is vague. Ultra Health asks whether the term is defined by an address to the property, by who owns which parcel of the addressed property, by fences, or by walls?

Ultra Health also argues that this subsection exceeds the statutory authority of the Department by claiming power to regulate hemp. It argues that regulatory authority over hemp was given by the Legislature to the Department of Agriculture at NMSA 1978, § 76-42-2, and that the Legislature has given the DOH no authority to regulate hemp.

Ultra Health argues that it obtained a writ of mandamus from the 13th Judicial District Court in D-1329-CV-2018-01854 that held that the DOH may not place location restrictions on dispensaries other than the 300-foot rule, which requires placement of production facilities no closer than 300 feet from any school, church, or daycare center.

Ultra Health states, however, that it would not oppose a regulation that required some kind of segregation of hemp and medical cannabis within a premises or campus, such as with walls, fences, and signage.

Written Comments of Ultra Health – January 16, 2020

These comments echo the comments Ultra Health made in their November 22, 2019 written statement.

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This subsection of the rule was revised by replacing a reference to "premises" with the phrase "licensed property." This revision was made in response to public comment seeking clarification. See Exhibit 25.

The Department also removed the reference to manufacturing being conducted indoors. This provision is more appropriate for the manufacturing section and is contained within Section 15(A)(3). *Id.*

Recommendation: As revised, this proposed rule is reasonably consistent with the agency's statutory purposes, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9(A)(4) NMAC – General requirements

Written Comments of Ultra Health – November 22, 2019

Ultra Health argues that Subsection 9(A)(4), which requires that “production is conducted in a manner that does not allow cross-contamination from chemical or biological hazards” lacks a precise definition of “hazards.” *See* Exhibit 14. Ultra Health argues that such innocuous substances as water and oxygen can quickly become hazards under certain conditions.

Written Comments of Natural Rx – November 22, 2019

Ms. Duverger from Natural Rx commented on 7.34.4.9(A)(4) NMAC—“that production is conducted in a manner that does not allow cross-contamination from chemical or biological hazards.” She stated that this is a goal that they support but it is unclear what would be considered “chemical or biological hazards” under this rule. She recommends including a definition to ensure proper compliance with this rule. *Id.* at 1.

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The Department responds to a commenter who suggested that the Department define “chemical or biological hazards” at that phrase is used in Section 9. *See* Exhibit 25. The Department states that it cannot create a definition for every substance or circumstance that may present a threat, and it does not consider this phrase to be especially ambiguous. It further states that, in essence, this phrase is intended to address threat that could reasonably result in the contaminants of cannabis with other substances, whether they be chemical or biological in nature. *Id.*

Recommendation: The proposed rule is reasonably consistent with the agency's statutory purposes. It is not ambiguous, and the language used should be given their ordinary meanings, as described by the Department. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9(A)(7) NMAC – General Requirements

Written Comments of New Mexico Cannabis Chamber of Commerce—November 22, 2019

NMCCC offered written comment on Subsection 4.9(A)(7) NMAC. NMCCC states that this section contains requirements that are unclear as to how to interpret and unclear as to how DOH plans on enforcing the rule, specifically as to plumbing and handwashing. NMCCC states that handwashing should pertain to product handling and packaging, but not farming activities. [This issue is also raised in response to 7.34.4.15(A)(8) NMAC.] *See* Exhibit 14.

Recommendation: The requirements of this proposed rule are not particularly onerous or unusual. The proposed rule simply sets forth a requirement for the provision of hand-washing facilities” wherever good sanitary practices require employees to wash or sanitize their hands.” *See*

Section 9(A)(7) NMAC. This appears to be a common sense type of rule. While production facilities likely would require more frequent hand-washing, farming activities may also give rise to situations where good sanitary practices would require hand-washing. This proposed rule is in harmony with and reasonably consistent with the purposes of the statute. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.9(A)(11) NMAC – General Requirements

Written Comments of Ultra Health – November 22, 2019

Ultra Health also challenges 7.34.4.9(A)(11), which requires that “floors, walls, and ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and can be kept clean, and in good repair.” See Exhibit 14. It argues that this requirement is “unworkable” for the medical cannabis industry, which combines agricultural operation with manufacturing.

Ultra Health argues that some producers grow outdoor in soil, and soil can never be made “nonabsorbent.” It also argues that outdoor growers are incapable of having “washable” ceilings, because their ceiling is simply open sky.

It further notes that Ultra Health itself grows in greenhouses with floors made of gravel, to allow excess water to flow away. A non-absorbent floor would require that Ultra Health would have excess water that stands in pools on concrete under their gravel floors. This would take Ultra Health out of operation at significant expense.

Ultra Health argues that the DOH needs to separate growing from processing and finishing in the regulations. Growing should be subject to agricultural standards and processing and finishing should be subject to manufacturing standards.

Written Comments of Natural Rx – November 22, 2019

Ms. Duverger from Natural Rx commented on 7.34.4.9(A)(11) NMAC—“floors, walls, ceilings are constructed in such a manner that they are washable, wipeable, and non-absorbent, and kept clean, and kept in good repair.” *Id.* at 1-2. She stated that Natural Rx is committed to ensuring all of their facilities are clean and well-kept. However, she expressed a concern that this proposed rule seems better suited for a manufacturing facility as opposed to a facility for cultivation. She noted that many cultivation sites have floors, walls, and ceilings that cannot be washed or wiped. She recommended that this rule apply solely to manufacturing licenses. *Id.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

This subsection was revised to clarify that the requirement of “washable, wipeable, and non-absorbent” surfaces excludes earthen floors, and to reference “permanent structures.” See Exhibit 25. These edits were made in response to public comments.

Recommendation: As revised, this proposed rule is reasonably consistent with the agency's statutory purposes, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.9(A)(31) NMAC – General Requirements

DOH Summary of Proposed Rule Changes – November 22, 2019

This subsection was added to prohibit the combination of hemp, hemp extract, and hemp derived products with usable cannabis that is sold or distributed in the Medical Cannabis Program and identified hemp paper and hemp seed oil as exceptions. The Department proposes to prohibit the combination of hemp products with medical cannabis products to ensure quality and adherence with DOH testing requirements for all medical cannabis products sold, and to limit the potential for illegal inversion of marijuana and marijuana products that are produced outside the Medical Cannabis Program. The Department is exempting hemp seed oil from this prohibition because cannabis seeds do not contain significant quantities of THC, and therefore do not present concerns regarding inversion.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department responded to public comments expressing disagreement with the prohibition of hemp production on the same premises as medical cannabis. The Department first notes, for purposes of clarification, that the reference to “premises” has been revised to state “licensed property.” *See* Exhibit 25. It further states that the prohibition against hemp production on LNPP licensed property is based on several concerns of the agency.

The Department asserts that hemp and marijuana are both cannabis with the only distinction being the quantity of THC contained in each. *Id.* The Department asserts that it is virtually impossible to distinguish hemp and marijuana by visual inspection. New Mexico law allows hemp growers licensed by the New Mexico Department of Agriculture to grow hemp. However, cannabis that tests above the 0.3% threshold for THC is marijuana, and must be destroyed by the hemp grower, as required by the rules that govern hemp production. *See* 21.20.2.9(C) NMAC; 21.20.2.12 NMAC.

The Department states that it is concerned that LNPPs that grow hemp on property licensed for cannabis production may be inclined to convert such marijuana into medical cannabis, rather than destroying it. *Id.* The Department asserts that this practice, known as “inversion,” is not only illegal, but presents additional risks, including but not limited to subverting medical cannabis testing requirements.

The Department states that it intends to prohibit the production of hemp on LNPPs' licensed premises to limit the risk of inversion and to provide greater clarity to Department employees and law enforcement who visit LNPP grow locations regarding the plants and plant material that falls within an LNPP's licensed grow operations. *Id.*

Recommendation: As revised, this proposed rule is reasonably consistent with the agency's statutory purposes, and the Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.10 NMAC – Testing of Usable Cannabis

DOH Summary of Proposed Rule Changes – November 22, 2019

In this section, the Department proposes various revisions and additions to the requirements for testing of dried usable cannabis and cannabis-derived products. The proposed testing standards include new tables that specify action levels for microbiological, mycotoxin, and residual solvent testing.

New requirements are proposed for testing for the presence of heavy metals, certain pesticides, and moisture content. The microbiological testing requirements are based on Section 2023 of the United States Pharmacopeia which is referenced in the current version of the rule. The mycotoxin testing requirements are consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories.

Residual solvent testing requirements are also consistent with past guidance provided by the Department to LNPPs, manufacturers, and laboratories. These standards are based in part on standards adopted in Oregon and based on discussions between NM DOH and commercial laboratory operators in Colorado.

Potency testing requirements for mandatory reporting are essentially unchanged from current requirements. However, the rule includes certain additional cannabinoids for which testing is optional.

The testing requirements for heavy metals are newly created. They are based in part on a review of standards in other states, including California, Washington, Nevada, and Oregon.

Pesticide testing requirements are also a new addition to the rule. The listed pesticides were selected partly with reference to Colorado's regulations. Identified action levels are borrowed primarily from regulations of the Oregon Health Authority.

Minimum test sample sizes are based on the U.S. Pharmacopeia standards for dried botanicals and botanical extracts.

Written Comments of Ultra Health -- November 22, 2019

Ultra Health submitted written comments regarding the testing requirements in the proposed rules. Ultra Health states that it supports the "sentiment" of the proposed testing rule, but it has "serious reservations with the rule based upon potentially devastating effects." See Exhibit 14, Ultra Health's written comments at 5-9.

Ultra Health asserts that the rule requires much more testing than is currently required. It asserts that there are one-and-one-half laboratories in New Mexico that handle medical cannabis. The reference to “half” a laboratory is the fact that Scepter Laboratory is located in Santa Fe and the other laboratory is Rio Grande Analytics in Las Cruces. Ultra Health states that in its experience, when couriers travel with medical cannabis to Las Cruces, federal Immigration and Customs Enforcement Agents often taken the cannabis and never return it. *Id.* at 4. If Scepter Lab shuts down, either entirely or partially, producers will have to rely on a laboratory in Las Cruces, which will result in a high likelihood of federal agents confiscating medical cannabis which has been sent to Las Cruces for testing.

Ultra Health also asserts that the proposed testing rule sets much more stringent requirements than the current rule, and it does not know if the laboratories are capable of testing to the level of specificity required in the proposed rule. It also may require new and expensive testing equipment, which the labs do not have.

Ultra Health also raises a concern about whether the labs can handle the volume of testing required under the proposed rule. It estimates that it will be requirement to submit 2,000 – 3,000 samples for testing per month. Prior to the increased plant limitation of 1,750, it was doing 400 test samples per month.

Ultra Health recognizes that 7.34.10(A) NMAC provides that DOH may waive testing if labs are not able to perform the tests. However, it argues that that should not be the only basis for waiving the requirements of the rule. Ultra Health argues that consideration should be given to waiving the rule where the lab has the ability to perform the test, but it (1) may take too long; or (2) it may cost too much, resulting in delayed product or product that is too expensive for patients. Ultra Health argues that could result in a product that does not ensure “beneficial use,” as required by the Compassionate Use Act.

Ultra Health asserts that the DOH does not know if the producers will be able to meet the standards for testing required by the proposed rule. It raises the question: If 95% of the products fail the testing requirements, is that acceptable to the DOH and patients? If 10% fail, is that acceptable?

Ultra Health advocates for the DOH to adopt a pilot program to test the test in order to determine whether the standards in the proposed rule are workable. It argues that the testing requirements in the proposed rules are more stringent than those of California and Colorado. It also argues that more stringent test requirements in California and Colorado have resulted in higher costs, which are passed on to the consumer, which in turn has caused consumers to go to the black market. Ultra Health argues that these issues could be examined in a pilot program.

Ultra Health also argues that the DOH failed to consult the Medical Advisory Board about the new testing requirements. The Medical Advisory Board is created by statute, at NMSA 1978 § 26-2B-6. Ultra Health recognizes that the statute does not explicitly require that the DOH consult the Board regarding testing requirements but argues it would “seem strange” not to consult the Board. It argues that it would be arbitrary, capricious and absurd for DOH to promulgate rules for safety standards for medical cannabis without consulting the Board. Ultra Health argues that the

failure to consult the Board indicates that the proposed standards are “simply plucked from the air, rather than being the product of scientific consensus.” *Id.* at 7.

Ultra Health further argues that the DOH has failed to consider how the new testing standards will affect supply. It argues that the required sampling size will be impacted by the new rule, because the new rule requires batch testing and “off-the-shelf” testing. *See, id.* at 7 and 7.34.4.10(C)(6). It estimates that the new testing requirements will require one-half pound of material for testing from every five-pound batch, and the test destroys the cannabis. Ultra Health argues that this will result in 10% of harvested cannabis being consumed by testing alone—and this material will not go to patients. Ultra Health asserts that when the DOH calculated patient demand, it did so without calculating amounts lost to failed tests. This, it asserts, will result in decreased supply, higher prices, and more patients being driven to the black market. *Id.* at 8.

Finally, Ultra Health argues that the new testing standards will result in producers closing their businesses or selling licenses. It argues that some producers “do not have the wherewithal to achieve more stringent standards.” *Id.* at 8. It argues that the costs of improving techniques will be very high, and lack of access to capital will impair instituting capital improvements. Current licensees may look to out-of-states interests to buy licenses, resulting in a bidding war that “does not serve the interests of New Mexico patients.” *Id.*

Ultra Health argues that producers already have a litany of challenges for their businesses to survive, including “punitively high licensing fees demanded by DOH”; “punitive tax treatment that results in very large tax burdens”; lack of access to capital because of restrictive federal laws; constant competitive from the black market; and high production costs due to high energy and water costs. “On top of this, DOH add stringent testing standards that could result in failure rates as high as 95%.” *Id.*

Written Comments of Jason Marks—November 22, 2019

Jason Marks also submitted written comments on the proposed rules related to testing requirements. *See Exhibit 14, Written Comments of Jason Marks at 5-10.*

Mr. Marks argues that the rules specifying when testing is required are “ambiguous and unworkable.” *Id.* at 5. He states that 7.34.4.10 NMAC appears to require testing before any transfers of cannabis can occur, and expressly requires testing of dried cannabis before it is manufactured into a CDP. He argues that it is wasteful and of no benefit to require testing of dried cannabis which is destined for extraction, and states that the regulatory needs are met by testing the extract or other resulting CDPs prior to distribution to patients. He argues that the rule should be rewritten in that manner, and that licensees should be permitted to transfer untested cannabis on a wholesale basis between themselves, and licensees should not be required to test dried cannabis that will be used to make an extract.

Mr. Marks further argues that microbiological testing requirements and action levels in the proposed rule are excessive. *Id.* at 5. He argues that the specified action levels for microbiologicals exceed what some other states require. He states this results in unnecessary costs for production activities and remediation. He also argues that the recommendations from the

Cannabis Safety Institute white paper should be adopted. *Id.* He states that these recommendations comport with the experience of Scepter Labs with respect to samples which have failed microbiological screening. He further argues as follows:

- Cannabis should be tested for *Aspergillus flavus*, *A. fumigatus*, *A. niger*, and *A. terreus*. He argues that these species are responsible for the vast majority of cases of invasive pulmonary aspergillosis and are the only pathogens that present a clear and certain danger in cannabis. *Id.* at 5-6.
- Cannabis should be tested for total generic *E. coli* and samples with levels greater than 100 cfu/gram should be rejected. *Id.* at 6. He argues that significant levels of *E. coli* are strong evidence of problems with growing or processing and is accepted as the optimal indicator organism for possible fecal contamination.
- Cannabis should be tested for *Salmonella*. *Id.*
- Testing cannabis for total yeast and mold is unnecessary and unjustified. *Id.* He argues that testing for yeast and mold result in detection of only a small fraction of the fungal species in the environment and do not correlate with the presence of a pathogenic species.

Mr. Marks argues that routine mycotoxin testing should be eliminated. *Id.* He argues that Scepter Lab, as of the Fall of 2019, had conducted 15,649 mycotoxin tests on medical cannabis samples since the requirement was implemented in New Mexico, at a cost of \$704,205.00 to producers, without registering a single positive result. He asserts that there has not been single positive mycotoxin test result in any New Mexico cannabis laboratory. He further asserts that Confident Cannabis, a cannabis laboratory software platform, states that only about 100 positive results for mycotoxins have occurred across all of its client laboratories, and none have occurred in dry climates like New Mexico.

Mr. Marks also asserts that Kathleen O'Dea from Scepter Lab has concluded that mycotoxins are rarely found in cannabis because the material does not support the growth of the organisms that produce mycotoxins or the production of mycotoxins. *Id.* at 6-7.

For the foregoing reasons, Mr. Marks asserts that the requirement for routine mycotoxin testing is arbitrary and capricious and not supported by a reasonable assessment of risks, at very material expense.

Mr. Marks also asserts that routine heavy metal testing is unjustified. *Id.* at 7. He states that the Cannabis Safety Institute only recommends heavy metal testing where cannabis is grown outdoors on land where there has been historical use of arsenic based pesticides that has accumulated in this soil. He notes that arsenic based pesticides are band in the U.S. He argues that medical cannabis in New Mexico is cultivated either indoors in media from commercial products, or outdoors in media in containers, not in native soil—at least to his knowledge. He argues that it is not possible for cannabis grown in commercial media to become contaminated with heavy metals. Thus, he claims it is arbitrary and unjustified to require routine heavy metal testing, which imposes significant expense on laboratories and producers in the absence of any plausible

risk. He further claims that Scepter estimates that the cost of the equipment necessary to implement heavy metal testing is well in excess of \$100,000.00 to purchase, and \$30,000.00 to lease.

Mr. Marks suggests that a reasonable rule to protect patients from heavy metal contamination in cannabis products would be a rule that targets soil, not cannabis, focusing on any producer who grows in native soil.

Mr. Marks argues that the rules that require testing for pesticides should be refined. *Id.* at 7. He argues that the DOH regulations permit the use of any licensed pesticide but require testing for only 13 substances. He argues that this is both “too many and too few.” *Id.* He argues it is too many insofar as it is wasteful to require testing for substances that have not been used in the cultivation of a particular batch of cannabis, and too few when the rules allow the use of substances that will not be tested for.

He also argues that the equipment and supplies necessary to implement testing for pesticides are expensive. *Id.* at 8. The equipment costs \$450,000.00, and Scepter estimates it will have to charge \$250.00 per sample to cover the cost.

Mr. Marks argues that the Department should withdraw the pesticide testing rule and convene a work group of patients, producers and testing laboratories to arrive at a workable rule.

Mr. Marks next argues that requiring specific testing technologies and samples is unjustified. *Id.* at 8. He argues that the requirements found in Table 7 (Minimum Test Sample Size) of the proposed rule are arbitrary and unjustified and would result in unnecessary costs. He argues that laboratories should be permitted to use any technology that can demonstrate sufficient testing accuracy.

Mr. Marks argues that Scepter Lab currently uses the ELISA method for detecting mycotoxins, and that this method of testing is fully validated for use in cannabis testing. *Id.* He states that the ELISA method also generates numerical data that matches with HPLC. He notes that other states allow for the use of ELISA.

He also argues that the Department should not mandate specific sample quantities in the rule. *Id.* He argues that sample size should be determined by the laboratory’s determination of the size of a sample necessary to provide complete and reliable results. Anything in excess of that is an unnecessary expense to producers and will increase the costs to the patients.

Mr. Marks next argues that “quality assurance testing” is of limited value. *Id.* at 8-9. He argues that the results of the testing required by 7.34.4.12 NMAC are not indicative of the testing accuracy of laboratories which may have tested a sample from the batch which is being examined by the Department. He argues that such results are not indicative of anything other than how that one sample tests. He also argues that cannabis plants can differ by as much as 30% from the top of the plant to the bottom. Further, he states that portions of a harvest may be exposed to different conditions during drying, curing, and other processing which also introduce nonconformity.

Mr. Marks also argues that end-product testing is unjustified. *Id.* at 9. He states that the Cannabis Safety Institute recommends against end-product testing of cannabis edibles and recommends instead requiring production under sanitary conditions (which the Department requires elsewhere in the rules.) He argues that the Cannabis Safety Institute has found that cannabis is the least likely component to be the source of contamination in any food product. *Id.*

Mr. Marks further argues that repeat “initial demonstrations of capability” are unjustified. *Id.* at 9-10. He states that proposed rule 7.34.4.19(F) NMAC requires an Initial Demonstration Capability (IDC) whenever a laboratory is initially approved for a platform, or when equipment is moved, or a new instrument is installed. He also notes that 7.34.4.17(C)(17) NMAC requires documentation of IDCs with renewal examinations. Mr. Marks claims that this rule should be eliminated because, he asserts, there is no benefit to requiring the resubmission of documentation for a previous IDC with renewal, assuming that the rule is requesting resubmittal. He states that if the rule is requesting a new IDC, that is inconsistent with the IDC rules at 7.34.4.19(F) and is arbitrary and unjustified. *Id.* at 9.

Mr. Marks argues that the phrase “Initial Demonstration of Capability” means just that— an initial demonstration. *Id.* He argues that if a laboratory is not changing its parameters for performing testing using a particular platform, there is no reason to require another initial demonstration. He also argues that it is unjustified for the Department to require a new IDC whenever equipment is relocated. *Id.* at 10. He argues this requirement results in unnecessary expense in time and materials.

Written Comments of NMCCC – November 22, 2019

NMCCC offered written comment on 7.34.4.10 NMAC as well. *See* Exhibit 14, Written Comments of NMCCC at 1-3. NMCCC states that it shares the goal of cultivating, manufacturing, and selling medicine that is safe for the end user. Overall, it states, the proposed changes to the testing requirements are largely unnecessary, excessive, and would be cost prohibitive to patients. NMCCC raised a concern that this could force more patients to the illicit market. NMCCC also argues that in New Mexico, plant count limits and comparatively few cultivators and manufacturers make for small batches, which have a disproportionate effect on the costs per gram to patients.

NMCCC asserts that one of the labs estimates that the new testing requirements will result in an additional batch increase of over \$700.00 for a full panel of testing. It further asserts that this will result in an increased testing cost of nearly \$4,000,000.00 per year for independent manufacturers. NMCCC also claims that in addition to lost revenue to the state from unnecessary wastage, patients would pay an additional \$5 to \$8 per gram of manufactured product. *Id.* at 2.

NMCCC notes that the rule on staggered implementation for testing is important because neither of the approved labs are currently capable of testing for pesticides or heavy metals. *Id.* NMCCC states that it does not believe that heavy metal testing is a necessary batch test. *Id.* It argues that heavy metals in dried usable cannabis would come from the material that the cannabis was grown in, or water used in the production of cannabis. NMCCC recommends testing of the soil

or material that cannabis is grown in, and the water used in that process, rather than testing all batches. *Id.* at 2-3.

NMCCC also argues that requirements for the same testing on manufactured products where there is no possibility of a different test result on dried usable cannabis should be removed. It argues that this redundancy would do nothing but increase patient costs. *Id.* at 2.

NMCCC further states that flower and trim be delivered to manufacturers with disclosures for all testing performed, and with a statement regarding pesticide use. *Id.*

As to microbiological testing, NMCCC supports testing for four types of *Aspergillus*, total generic *E. coli*, and salmonella. It is against testing for total yeast and mold because the only pathogenic mold that could appear on cannabis is *Aspergillus*. *Id.*

NMCCC argues against testing for mycotoxins, asserting that tens of thousands of tests by both state-approved laboratories have never produced a positive test result for mycotoxins. *Id.* It also argues that if mycotoxins were not present in a test of dried usable cannabis, they would not be present in the manufactured product from that batch; thus, a second test is unwarranted. *Id.*

NMCCC argues that the rule on random testing of finished cannabis derived product—7.34.4.10(C)(3) NMAC, puts an “unfair onus” on producers and manufacturers that is not seen in any other industry. It argues that food inspectors inspect food and the Department should do the same. *Id.*

NMCCC states that perhaps the greatest area of concern it has with the proposed rules is found in 7.34.4.10(C)(9) NMAC in Table 7. NMCCC claims that both testing facilities attest that the proposed sample sizes are far too large, creating a logistical challenge for test facilities to handle significantly more waste. *Id.* NMCCC also asserts the sampling sizes would potentially hurt supply for patients, with the increased in sample size for manufactured products potentially at 1% of dried cannabis, and up to 20% of concentrate per batch. *Id.*

Written Comments from Natural Rx – November 22, 2019

Brooke Duverger from Natural Rx offered written comments on 7.34.4.10 NMAC, the rule on testing of cannabis. *See* Exhibit 14. She stated that Natural Rx appreciates the staggered implementation to allow flexibility and time, however, she has the following concerns:

- She raises the question whether the two licensed labs in New Mexico are actually able to perform the tests.
- She raises a concern about one lab being south of the federal checkpoint, resulting in frequent confiscation and destruction of cannabis, raising a question about whether the other lab has the capacity to conduct increased sampling and testing.
- She asserts that the sample and batch sizes are much too large, and states it is unclear whether labs need to use that much.

- She asserts that the sampling and random testing frequency is onerous and will result in a significant percentage of product being used for those purposes, which diminishes the volume of product that will go to patients.
- The new testing requirements, she asserts, will “drastically” increase costs to patients, which may be cost-prohibitive and lead to greater use of illicit markets.
- She suggests that the Department consider alternative remediation options for flower.

Id. at 2.

Brooke Duverger stated that Natural Rx believes that implementing common-sense testing and labeling requirements for medical cannabis is in the interest of public safety, protects the integrity of the program, and is generally the right thing to do. *See* Exhibit 14, written comments from Natural Rx at 1.

Written Comments of Scepter Lab – November 22, 2019

Ms. O’Dea, on behalf of Scepter Lab, submitted a November 22, 2019 letter to the Hearing Officer. *See* Exhibit 14, November 22, 2019 letter to Hearing Officer. She also provided a copy of the Jason Marks written comments, an October 4, 2019 letter to Secretary Kunkel, a November 22, 2019 letter to Andrea Sundberg, and an October 4, 2019 letter from Barry Dungan. *Id.*

Ms. O’Dea states that her overarching concern is that much of the proposed testing is unnecessary, expensive, not supported by empirical data, and will not enhance patient safety. *Id.* She argues that the other states which may have “imposed similar or identical regulations,” have done so without regard to any data which supports the need for such testing. She states: “Merely copying another state is not adequate justification for making new rules here.” *Id.*

Ms. O’Dea also argues that there are a limited number of producers in New Mexico, with plant limits, which has the effect of making the cost of testing “significantly” higher than other states. *Id.* She argues that there is “no rational, nor scientific, basis for imposing heavy metal testing, mycotoxin testing or total yeast and mold testing.” *Id.* She claims that heavy metal tests are seen in 0.11% of test results, and mycotoxins are at 0.4% of the samples nationally. She claims these are likely false positives.

Ms. O’Dea further states that producers have paid Scepter over \$704,205.00 to test 15,649 sample for mycotoxins without producing a single positive result. She argues that cannabis plant material will not support the formation of mycotoxins. She argues that the same principle applies to testing for heavy metals, with a much, much higher price tag. *Id.* Cannabis grown in indoor artificial media, she argues, will not produce heavy metals.

Ms. O’Dea included an October 4, 2019 letter to Secretary Kunkel in her written comments. *See* Exhibit 14. She notes that she is the director and owner of Scepter Lab, and her company has conducted testing on over 50,000 medical cannabis samples. She states that some of the Department’s proposed testing requirements will provide an added measure of safety to advance public health, other proposed rules “do nothing to advance public health, will increase the cost of patient medicine and could encourage manipulation of samples by the growers.” *Id.* at 1. She

further asserts that “[w]ithout control over who takes the sample and who submits it to the laboratories, the growers can simply continue to ‘doctor’ samples, substitute samples or find other ways to circumvent the passing requirements.” *Id.* She offers as an example a producer using a pesticide that is not on the list in order to pass a pesticide test and circumvent the list. She does not believe that pesticide testing will tell anything at all about the purity of the batch. *Id.*

Ms. O’Dea asserts that the most important change the Department could make to the regulations is to clamp down on and control what is submitted for testing.

She argues against adopting the rule on “Quality Assurance; random testing of products at department discretion.” She asserts that cannabis is biological material and differs by as much as 30% from the top of the plant to the bottom, or from plant to plant. She suggests that a better approach is to regulate how samples are taken and submitted to the lab, with sampling criteria.

Ms. O’Dea argues that mycotoxin testing should be eliminated entirely, as set forth above. *Id.* at 2. She also states that Scepter uses the ELISA method for detecting mycotoxins. She argues that this method is fully validated for use with cannabis and generates numerical data that matches with the HPLC. She further argues that the first steps in ELISA are procedurally identical to HPLC; the only difference is how the active material is “read” – HPLC or spectrophotometer. She argues that it would be a significant hardship for Scepter to replace their spectrophotometers, and would require months of validation on-line. She notes that other states accept the ELISA method, and states that if this rule is adopted, Scepter will have to take legal action. *Id.* at 2.

Ms. O’Dea argues that heavy metal testing should not be required, or should be “phased in.” *Id.* at 3. She argues that the Scientific Laboratory Division should be required to provide empirical data from indoor grown cannabis that establishes that heavy metals in specified thresholds actually exist before implementing a requirement for testing for heavy metals. *Id.*

Ms. O’Dea claims that it will take at least three months to bring equipment for testing heavy metals on-line, at a minimum cost of \$90,000.00 before any samples are tested. *Id.* She argues that the lease expense will add \$60.00 to the cost of the panel. Adding labor, supplies, and overhead will require a charge of at least \$150.00 per sample for this single test. She estimates the cost to producers will amount to \$1,800,000.00. She argues that when there is no showing anywhere that indoor grown cannabis is contaminated with heavy metals it is an unreasonable requirement to impose this rule, with no demonstrable health benefit.

Ms. O’Dea states that pesticides pose a health hazard to the consumer, and they are being used on cannabis. *Id.* at 4. However, she argues there are two problems with the rule on testing for pesticides. She states that there are 3,126 pesticides available, and asks the question: which ones are the most appropriate to test for? Furthermore, how do you stop growers from using a pesticide that is not the list once a list is published? *Id.*

Notwithstanding the foregoing questions, Ms. O’Dea states that the Department’s proposed list is reasonable, but the implementation date is not. Scepter would need at least three months to order an appropriate instrument for testing. She asserts that time for set up is an additional three months and would cost \$450,000.00. Scepter does not have an available lender or investor. Even

if the manufacturer extended credit, the monthly fee would be \$50,000.00. She asserts her lab would have to charge \$250 for each sample. She argues that unless the plant count were increased, there would be no way to cover the cost. *Id.*

With respect to testing for mycotoxins, Ms. O'Dea argues that end-product testing of cannabis edibles should not be required. *Id.* at 5. She asserts that the Cannabis Safety Institute does not recommend the end-produce testing of cannabis edibles. She argues that cannabis is the least likely component to be the source of contamination in any food product. The plant material is dried to a safe level before extraction, and then usually subject to a decarboxylation process that acts as a heat-kill step. She further argues that the vast majority of extraction processes are themselves sterilizing. She notes that when the extracts are added to food, the food may be mishandled or subject to temperature abuse, which may result in contamination, but asserts that these are factors that face all foods and should be regulated like all food products. She also asserts that the only pathogen of real concern is *Aspergillus*, which is not infectious by oral route. *Id.*

With respect to the proposed rule on sample size [Table 7], Ms. O'Dea states that moisture content is not the current acceptable methodology for determining quality or shelf life. *Id.* at 6. She states that water activity is the method most states require and should be adopted here. She quotes the Cannabis Safety Institute:

Water activity can be used as a marker for overall microbial levels. Plant material with high water activity will support microbial growth. Because the drying step is on piece of insurance against microbial dangers associated with cannabis, it makes sense to require that this step be complete. The majority of commercially sold cannabis is dried to water activity levels that are below the minimum threshold for any type of microbial replication. Very few bacterial or fungal species can replicate between Aw 06 and AWO.7. We recommend that all curing processes aim to produce flower material under Aw 0.6.

Ms. O'Dea states that Scepter agrees with Barry Dungan from Rio Grande Analytics, who states: "For the microbial panes (Salmonella, E. coli, RAC, RYM, EB, EC) I feel the current amount of Ig is sufficient to do the test. We currently have to do very large dilutions to accurately count colonies on petrifilm." *Id.*

Ms. O'Dea states, with regard to microbial panes, that the recommendations from the Cannabis Safety Institute white paper should be adopted, as follows:

1. Cannabis should be tested for four species of *Aspergillus*, specified in her written comments. *Id.* at 7.
2. Cannabis should be tested for total generic *E. coli*. *Id.*
3. Cannabis should be tested for *Salmonella*. *Id.*
4. There is no need to test cannabis for total yeast and mold. *Id.*

Finally, Ms. O'Dea outlines that general provisions for Department-approved testing laboratories that Scepter supports and complies with in response to 7.34.4.17 NMAC. *Id.* at 7-8.

Ms. O'Dea also attached an email from Tony Lewis. He states that his company has seen 70,000 tests for indoor flowers for mycotoxins with 75 fails or 0.11%. They have seen 1,200 tests for outdoor flower with 26 fails or a 2.15% failure rate.

As to heavy metals, Mr. Lewis states that they have seen 50,000 tests for indoor flower with 209 files or 0.41%, and 1,100 tests for outdoor flower with 60 fails or 5.48%.

Written Comments of Rio Grande Analytics, LLC – November 22, 2019

Barry Dungan is a co-owner of Rio Grande Analytics (“RGA”) and submitted written comments on behalf of his company. *See* Exhibit 14, written comments of Barry Dungan at 1. He states that the additional tests set forth in the proposed rules are “incredibly important in protecting public health but consideration must be given to laboratories to accommodate these requirements while continuing to serve an expanding number of patients.” *Id.* He asks that the Department recognize that the labs will incur extreme expenses to acquire new machinery and expand their testing facilities, and they also need to comply with other industry standards regarding hazardous materials, employee training and protection, and waste disposal. He raises a concern that without sufficient time and planning, labs may not be able to purchase and establish the equipment and protocols necessary to meet the requirements of the propose regulations. *Id.*

Mr. Dungan states that the implementation of pesticide and heavy metal testing will have a significant impact on the labs. If done properly, this testing will require three separate machines: GC-MS, LC-MS, and ICP-MS. *Id.* He states each machine will cost several hundred thousand dollars and require new waste removal systems and highly trained personnel to operate and maintain the machines. *Id.*

In light of the foregoing comments, Mr. Dungan proposes that the proposed regulations be prioritized and implemented in two separate phases. *Id.* He states that pesticide testing is the most important test not currently in use and “should be implemented first as it poses the greatest hazard to patient health.” *Id.* He suggests that establishing heavy metal testing, and possibly expanding mycotoxin and pesticide detection lists should be completed in phase two, after reliable pesticide testing has been properly established. *Id.*

Mr. Dungan proposes that his recommended Phase 1—all the changes in this proposed testing rule, excluding heavy metals should be implemented in January 2021. *Id.* He suggests that the heavy metals requirements—Phase 2—should be implemented in January 2022. *Id.* at 2.

With respect to the proposed rule on quality assurance testing and random testing, Mr. Dungan state that he agrees that some type of "secret shopper" rule should be in place to make sure that products are labeled properly and that the results for each product are available on demand. *Id.*

Mr. Dungan states that RGA is already in compliance with the rule for mycotoxin test instrumentation, 7.34.4.19(A) NMAC and 7.34.4.10(C)(2) NMAC [Table 2]. *Id.* at 2. He states that RGA uses an HPLC with a post column derivatization box and a fluorescence detector for the detection and quantification of mycotoxins. *Id.* He further states that RGA is in the process of upgrading to UPLC/MS/MS to confirm the presence or absence of mycotoxins currently required. *Id.* This will allow them to rule out false positives and expand the list of toxins as the program needs increase. *Id.* at 3. He states that the upgrades will also allow the simultaneous detection of pesticides. *Id.*

Mr. Dungan states that heavy metal testing will be the most difficult to get online. *Id.* at 3. However, he agrees that this test should be done, but it will come at a ‘huge cost’ to labs, producers, and consumers. He states the cost will amount to a \$250,000.00 investment for the needed instrumentation, and personnel will need to be identified and trained. Mr. Dungan states: “I am committed to providing these services, but you should be aware that some consideration should be given to allow remediation of certain problems that will unfortunately occur.” He thinks this type of testing should be implemented in his Phase 2.

Mr. Dungan states that the rule on pesticide testing on dried usable cannabis (i.e., flower, shake trim, etc.) is a step in the right direction for the immediate safety of MCP patients. *Id.* at 3-4. He thinks this should be the main focus of his proposed Phase 1. He acknowledges that it is difficult to make a list of pesticides, because it gives people something to avoid. However, he states that the instrumentation required to conduct the tests will detect compounds on the list, as well as flag samples that have suspicious contaminants for further analysis. He suggests that bringing this test online in Phase 1 will allow labs to report on pesticides, and not become overburdened with financing and training for heavy metals testing at the same time. *Id.* at 4.

Mr. Dungan also asks for clarification whether, in the list in Table 6, the isomers listed need to be separated and quantified independently, and, if so, the reporting level 100 ppb is for each or as a total?

Mr. Dungan agrees with the proposed rule on end-product testing. *Id.* at 4-5, although the heavy metal analysis should be in his Phase 2. He also suggests that pesticide testing should be done on concentrated cannabis derived products because of the possibility of contamination during the extraction/concentration process and the nature of the mode of ingestion of the products (i.e., vaping). *Id.* at 5.

Mr. Dungan states, with respect to the proposed rule on sample size increase, that he has a few suggestions, as follows:

- The potency analysis should be done on either LC or GC.
- Potency for products like smokable flower is best done on GC.
- Products like edibles are best run on the LC to determine the amount of the acid and neutral forms of the cannabinoids which could not be achieved on the GC.
- The client should be allowed to request which test they would like to provide to their clients based on the products they are selling and the labs should be allowed to provide both services.

Id. at 5-6.

He agrees that it is good to provide moisture count. *Id.* at 6. He agrees that 1 gram is plenty to do that test.

He does not see the need for mass spectrometry for testing for residual solvents and agrees that FID should be an accepted method of detection. *Id.* Mr. Dungan states that the current amount of 1g to do the test is sufficient for the microbial panes (Salmonella, E. coli, RAC, RYM, EB EC). *Id.*

Mr. Dungan states that they currently have to do very large dilutions to accurately count colonies on petrifilm. *Id.* He states that adding more dilution steps will add a huge waste stream of plastic bottles that are not necessary. If any panel requires more, he thinks it will be pesticide testing. He thinks that 10g minimum, if not more, should be required. He also states that, after the first year, that amount could be reduced or increased when his propose Phase 2 metals testing comes online. For heavy metals, he thinks that 50-110mg will be enough for microwave digestion, and subsequent ICP-MS analysis. He also thinks that half a gram should be plenty if confirmation testing is required with Phase 2. *Id.*

With respect to the rule on Department-Approved testing laboratories, general provisions, 7.34.4.15 NMAC [now Section 17], Mr. Dungan state that he agrees that a section for “Other methods may be approved as necessary” should be added for unexpected disposal needs that may arise and that cannot be foreseen. He also states that there has always been a requirement for, and they continue to hold, all calibration records. *Id.* at 7.

Written Comments of Minerva Canna, Inc. – November 22, 2019

Erik Briones from Minerva Canna submitted written comments for the November 22, 2019 hearing as well. He stated that Minerva Canna wholeheartedly agrees with the need for adequate testing requirements. *See* Exhibit 14, written comments of Minerva Canna at 1.

Mr. Briones states that Minerva Canna supports to some degree the need for additional testing for pesticides and heavy metals. However, he states that the frequency of the proposed testing requirements is unnecessary and financially burdensome. *Id.* He states that the additional testing requirements will carry an estimated cost of as much as \$700.00 per 5 lbs. batch of flower. This cost will be passed on to the price of the end product. *Id.*

With respect to the requirements for testing for heavy metals in the proposed rule, Mr. Briones states LNPPS do not regularly change their growing processes over long periods of time. *Id.* This includes the type of soil or soilless medium the LNPPs as, as well as types of fertilizer, water, the source of that water, and the management of pests. He argues that if an LNPP passes a heavy metal test, it's a given that they will continue to pass the same test with all things remaining constant. He recommends bi-annual testing to assume that heavy metals continue to be absent from a grow operation, rather than the proposed testing of every batch. He further suggests that if an LNPP fails a test for heavy metals, they should be tested monthly until they pass three continuous tests, and then be tested bi-annually again. *Id.*

With respect to the testing of pesticides, Mr. Briones states that he understands why the MCP will not publish a list of acceptable pesticides for use on cannabis. *Id.* He states that states that have published lists of acceptable pesticides have been besieged with problems. He does not recommend that the DOH publish a list of acceptable pesticides. *Id.*

Mr. Briones further states that all LNPPs should follow safe principles when using pesticides and use only safe pesticides that are recommended for cannabis. *Id.* at 2. He argues that they should be organic in composition and applied according to the instruction on the labels for the product. He stated that some LNPPs may violate these principles and testing should be required. *Id.*

Mr. Briones notes that many different strains of cannabis are often grown in one room in New Mexico. *Id.* He states that if an insect invades one plant, it stands to reason that it invades the entire room. He recommends that the rule require that one strain of each harvest in each room be tested for pesticides, and that random spot samples chosen by the DOH in an unannounced inspection for pesticide testing also take place. *Id.*

With respect to edibles, Mr. Briones states that edible production in New Mexico occurs in small batches; for example, 70 brownies at a time, or 100 chocolate bars. He argues it would be cost prohibitive to test every batch produced, a requirement which he says would destroy the edible market in New Mexico. *Id.*

Mr. Briones states that the current testing requirement is to test the concentrated distillate oil that is used to manufacture the edibles. *Id.* He states that this practice works well, and that if the oil tests successfully, so will the edible. However, he acknowledges that this does not ensure that an edible could not test positively for some other type of impurity acquired in the process of manufacturing. It would, he argues, be cost prohibitive to require testing on each batch, but not on a small percentage of batches. *Id.* He suggests that a reasonable testing sample could be .001% of each different item produced from the original batch, but with no redundancy in testing for pesticides or heavy metals, which would have been tested already on the distillate oil. *Id.*, see at 2-3 for an example.

In summary, Mr. Briones state that Minerva Canna supports additional testing of cannabis products to assure that clean, safe, quality medicine is provided to the patients. *Id.* at 3. However, he also states that “these proposed additional testing requirements (without further specification of which requirements, but apparently referring to the requirements he responds to above), add substantial costs to every product, are unnecessarily redundant, and needlessly burdensome. *Id.*

Written Comments That Were Submitted by Individuals Who Appeared on Their Own Behalf at the January 16, 2020 Public Hearing

There were 22 individuals who submitted written comments as individuals (not as representatives of a business or organization) at the January 16, 2020 public hearing. The Department redacted personal identification information from their written comments. The contents of those comments are summarized here as a group, as follows:

- Several of the commenters indicated their support for opening up micro business licenses to allow small businesses to enter the market to sell medical cannabis to LNPPs and directly to medical patients for medical (and potentially recreational) cannabis use. There were also recommendations for allowing craft growers.
- Several of the commenters supporting allowing third party businesses to collect and to test medical cannabis.
- Several supported increasing the scope of locations for cannabis consumption areas and not them to LNPPs to participate by approval of an application to be anywhere and everywhere.
- Concerns were raised about prices being higher than ever, and not lowered with the increased plant count.
- Concerns were raised by the potential for increased prices as a consequence of additional testing requirements.
- Concerns were raised that test samples can be manipulated by growers.
- One commenter urged allowing PPLs to test flower and help fill shelves at local dispensaries.
- One commenter criticized the state of LNPPs, asserting that they are not committed or have found ways to produce minimum quality and quantity and cost because they have a steady supply of patients who rely on them for medicine despite the quality and quantity available. The commenter asserts that by capping the number of licenses, the State has essentially protected many of the LNPPs from worrying about competition or keeping their cannabis to the status quo. The commenter further asserts that by increasing testing requirements the State will stifle and slow the growth of the “already lagging LNPPS.”
- One commenter supported pesticide and heavy metal testing in a written comment. That individual urged that the cost of testing not be passed on to “the already overburdened patient,” and asked that the State establish a testing laboratory with the cost to be shared between the State and the LNPPs. The same individual recommended that samples for testing should be done by the State.
- An individual expressed a belief that further testing by LNPP’s seems unnecessary. This person was concerned about additional costs and felt that new packaging and additional testing seem like a “great idea” for the future, but not now. This person was also concerned a shortage of product might result from these requirements.
- Taylor Trodden of the Verdes Foundation expressed concern over the new label and information sheet requirements. He states that Table 8’s sample label creates logistic

issues given the limited size of the packaging and container options in the industry, and recommended use of an information sheet attached to the patient's bag.

- Another individual submitted an email with the heading "Written Comment proposed rule revisions" [sic]. This individual expressed a concern that the new proposal for testing will create a downward spiral for patients and producers due to the costs involved with the testing. Specific concerns raised include the following: smaller producers not being able to afford the increased testing costs; a longer waiting period to complete testing and a backlog overloading the only two testing labs in NM, making producers unable to fill the LECUA requirements for a 90 day unlimited supply of cannabis; increased costs, ultimately incurred by the patients; increased costs of what is currently safe, tested cannabis, driving patients to illicit markets. This writer also suggested that the DOH could produce a list of banned substances, such as caustic substances and certain pesticides, and then establish a random testing program on whatever products they choose, with substantial sanctions if such substances are found. The writer suggests that this type of program may "quell the costs." Price caps on labs for testing are also suggested.

Written Comments of PathogenDx – January 16, 2020

PathogenDx, a testing laboratory in Arizona, submitted a written comment. See Exhibit 29. They summarize what they assert are three important general principles of cannabis contamination. *Id.* The three principles are as follows:

- 1) There is a much larger range of contamination than previously generalized, especially for fungal contaminants. They focus on *Aspergillus fumigatus*, *A. flavus*, *A. niger*, *A. Mucor*, *A. Penicillium*, and thermophilic actinomycetes.
- 2) The substantial variation in the number and nature of pathogen contamination suggest that the range of pathogenic bacteria and pathogenic fungal contamination may be much larger than previously suspected.
- 3) Total Yeast and Mold and Total Bacterial Load may be viewed as relatively useless analytical tests.

In addition, they make the following testing recommendations:

- 1) Testing for toxic bacteria, especially *E. coli* and *Salmonella*.
- 2) Testing for Aspergilli (*flavus*, *Niger*, *terreus*, *Fumigatus*) and *Penicillium* (*citrinum*, *paxillin*).
- 3) Nucleic Acid Tests should be deployed in a way that bypasses cell culture.
- 4) Additional testing recommendations may be found in PathogenDx's written comments.

Written Comments of Scepter Lab – January 16, 2020

Kathleen O’Dea from Scepter Lab said in a written comment that there is a “glaring” error in the new version of the proposed rules. *See* Exhibit 29. In particular, she stated that ethylbenzene is not the same as meta xylene, and the footnote in the table for testing solvents [Table 3 of 7.34.4.10(C)(3) NMAC] is incorrect because meta xylene and para xylene cannot be separated. She further asserts that ortho xylene can be separated from meta and para xylene, but only with great difficulty and, she claims, there would be no reason to do so. She further asserts that the action level is incorrect. She asked that these issues be corrected.

Written Comments of Ultra Health – January 16, 2020

These comments echo the written comments of Ultra Health in its November 22, 2019 written comments. *See* Exhibit 29.

Written Comments of Jason Marks – January 16, 2020

These comments largely echo the written comments of Mr. Marks in his November 22, 2019 written comments, with a few additional comments addressed below. *See* Exhibit 29.

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The Department notes that there were many public comments regarding the proposed testing standards. The testing standards include new tables that specify action levels for the various tests and propose new requirements for testing for the presence of heavy metals, certain pesticides, and moisture content. *See* Exhibit 25.

The Department responds to public comments that focused on the perceived added costs of conducting additional testing. *Id.* The Department states that it anticipates that the actual costs of testing will be substantially less than has been represented in public comments. The Department expects that the costs will be spread across many tests of many batches of cannabis, which should substantially reduce the cost per test. The Department anticipates that as production increases, the number of batches and the number of tests is expected to rise. The Department expects that there will be some increase in testing costs for producers, but it will be diluted by the volume of tests. Ultimately, the Department expects that the benefit of the additional testing, and the added assurance for patients that they are purchasing a safe product, substantially outweighs the concerns about added costs. *Id.*

The Department also responded to a concern raised by a commentator that “repeated failures” of tests may lead to disciplinary actions. The Department acknowledges the concern, but states that repeated failures may or may not raise significant public health and safety issues, and it intends to assess individual facts and circumstances in determining whether to take action against a licensee. *Id.* If the repeated failures of tests can be attributed to an LNPP’s substandard practice, repeated testing failures will more likely lead to disciplinary action. *Id.*

One commentator suggested that the Department should conduct all random sampling and testing of cannabis-derived products. *Id.* The Department responded by stating that it does not have the infrastructure or resources necessary to conduct this work, although it notes that it does have a quality assurance testing component.

The Department also responded to comments that the only necessary microbiological testing should be testing for aspergillus. The Department states that it based its testing standards on the U.S. Pharmacopeia standards for nonsterile supplements, and believes they are appropriate. *Id.* The Department also states that it is concerned that laboratories may not be able to adequately distinguish between different mold species, which is why the rule was written to address combined yeast and mold. *Id.*

The Department states, in response to a comment that the proposed action levels for microbiological testing, solvent testing, and heavy metals testing should be increased to reflect the standards established in Colorado, that it has based its testing standards on USP 2023 and it believes that those standards are appropriate. *Id.* The Department asserts that having lower action levels ensures safer, cleaner products. The Department states that the same principles apply action levels for residual solvents.

One laboratory representative offered public comment that mycotoxin testing should be eliminated because the laboratory had never detected mycotoxins, and because this was consistent with the laboratory's experience in other jurisdictions. *Id.* The Department responds that, considering that it is proposing new standards for how tests are conducted, and those standards exclude ELISA as an approved testing method, the Department believes that it is premature to remove mycotoxin testing from the rule. If the testing supports removal of this requirement in the future, then the Department will reconsider this requirement.

The Department also responds to comments that mycotoxins degrade from the heat of smoking or decarboxylation, and that mycotoxin testing is therefore unnecessary. *Id.* The Department responds by stating that even if the foregoing assertion is true, there are various methods of ingesting cannabis and patients may not be smoking or otherwise burning the product.

The Department responds to public comment that yeast and mold testing is unnecessary, but if it is continued, the action level for yeast and mold should be relaxed. The Department states that it relies upon the USP 2023 standards and deems them to be appropriate. *Id.* In fact, the Department states, the proposed yeast and mold standards are somewhat less stringent than the ones currently proposed by the USP, and thus, they represent an appropriate middle ground.

Some of the commentators argued that it is unnecessary to test for heavy metals, and some suggest that the preferred method should be the periodic testing of soil. The Department responds by stating that heavy metals can originate in soil, but they can also be found in water and water systems. *Id.* The Department notes that several LNPPs in New Mexico have established grow facilities in industrial or formerly industrial locations, which present threats of heavy metals contamination. The Department also notes that cannabis is demonstrated to be

effective at filtering metals, and thus the risk of heavy metal contamination is somewhat higher than it is in other plants. The Department further notes that processes used to concentrate THC can also increase the concentration of heavy metals in a product, just as they tend to do with pesticides and other contaminants. Finally, the Department notes that these requirements are common in other states that have medical or recreational cannabis as well.

The Department responds to a comment that it does not make sense to require testing for pesticides the producer knows they have not used. *Id.* The Department notes that this suggestion would mean that it should not rely on testing, but on the producer's word about the pesticides that they have used. The suggestion also indicates an assumption that the producer has exhaustive knowledge of the contents of every substance used in their cultivation of cannabis, which may or may not be true. The Department asserts that the proposed testing for pesticides will ensure that prohibited pesticides are not used, and, if used accidentally, will be identified in the testing process. Finally, the Department notes that the recent health concerns related to vaping THC has made clear that the burning of pesticide residue on cannabis products can pose serious health dangers.

One commentator suggested that quality assurance testing by DOH should be struck, because cannabis is a biological material that is not uniform in composition. The Department responds by stating that it recognizes that QA testing may be of greater or lesser value depending on the circumstances, but it is still important to have QA processes in place to enable the independent evaluation of testing conducted of an LNPP's or manufacturer's products. It asserts that QA testing potentially can identify deficiencies in the chain of a given testing scheme. *Id.* It can also identify deficiencies in the LNPP or manufacturer's sampling protocol. The Department asserts that this process is valuable. *Id.*

The Department notes that some commentators expressed support for random testing of finished cannabis-derived products (end product testing) by LNPPs and manufacturers, and others argue it is not justified. *Id.* The latter group argues that food products only become contaminated by improper hygiene, which can be regulated without requiring laboratory testing. The Department argues that randomized end product testing is the only mechanism to determine whether the THC content of a cannabis product is homogenous in distribution, in accordance with the proposed rule. It argues that THOC homogeneity is not assured by adherence to hygiene standards. Further, the Department argues that in proposing this rule, it took care to propose standards that would be of minimal impact to LNPPs and manufacturers. It does not believe these standards are particularly onerous, and the tests may prove valuable in identifying gaps in the tests previously conducted of dried cannabis or concentrates utilized in cannabis food products. *Id.*

The Department also responds to the comments of some commenters who state that the Department should not mandate that certain technologies be used for testing, and that ELISA is a reliable testing method. *Id.* The Department responds by stating that the requirement for use of certain technologies in testing is designed to ensure the reliability of test results, and to create more uniform standards for how the testing is conducted. The Department does not agree that ELISA is a reliable method for testing mycotoxins. It asserts that ELISA is only accurate in testing one type of mycotoxin (aflatoxin B1), and ELISA tends to undermeasure for the other

three mycotoxins. Further, it tends to over-measure for ochratoxin B and ochratoxin C, which can then be reported as false positives for ochratoxin A. The Department asserts that ELISA is “notorious” for reporting false negatives and false positives. *Id.*

One commenter suggested that the proposed remediation standards are too restrictive and the rule should allow for additional remediation processes, including using ultraviolet light. *Id.* The Department explains that the purpose in restricting the methods and circumstances in which remediation of cannabis and cannabis products can occur is to address a concern that producers and manufacturers may currently be using unreliable remediation methods. The Department finds that UV light is not efficacious and not reliable for removing microbiological contaminants. The Department states that the proposed rule allows remediation through the use of extraction and distillation methods for cannabis and cannabis products that have failed the microbiological test or the residual solvent test, which the Department finds are effective tools for the remediation of the identified contaminants. Further, the Department finds that remediation would be inappropriate for cannabis that has failed tests other than the microbiological and residual solvent tests.

A commenter offered the comment that “moisture content” is not an appropriate methodology, and that the Department should use “water activity” instead. *Id.* The Department responds by stating that it proposes testing for moisture content to ensure that LNPPs do not sell cannabis flower that contains a significant amount of water. This is because patients typically pay for cannabis flower by weight, and the evaporation of water from the product can mean a significant decrease in the weight of the product after it is sold.

The Department clarified that dried usable cannabis that is destined to be converted into a cannabis derived product is not required to be tested prior to the conversion. This edit was made in response to public comment.

Some of the specific subsections of the proposed rules in 7.34.4.10 NMAC that received public comments were summarized above. The following are additional subsections of the proposed rules on testing that received specific comments from the public. This section also includes some of the Department’s explanations for revisions to specific subsections. The Hearing Officer’s recommendation on Section 10 – Testing – follow at the end of this entire section.

7.34.4.10(C)(1) NMAC – Individual testing requirements – Microbiological test

Written Comments of Vicente Sederberg, LLP

Vicente recommends amending 7.34.4.10(C)(1)-(3) NMAC regarding the action levels for various required tests to ensure they are appropriate. In particular, Vicente states that, for microbial testing, the action limit on CFUs of combined yeast and mold are orders of magnitude lower than the action limits currently used in Colorado and internationally recognized organizations. Vicente also asserts that most of the established limits align with USP 2023 for final products except for Nutritional Supplements with Botanicals. Vicente suggest that lower action limits be adopted for the Total Aerobic Microbial Count parameter. *Id.*

For mycotoxin testing, Vicente recommends that both Method Reporting Levels and Action Levels be measured in micrograms per kilograms. *Id.* at 5.

For solvent testing, Vicente recommends that the Department mirror the solvent resident limits established in Colorado but does not provide those limits. *Id.* at 5.

For heavy metals, Vicente also recommends that both Method Reporting Levels and Action Levels be measured in micrograms per kilograms. *Id.* at 5. Vicente also appears to suggest that the Department consider adopting the rules in Colorado for heavy metals but does not expressly state that. *Id.* at 5.

For pesticide testing, Vicente recommends that both Method Reporting Levels and Action Levels be measured in micrograms per kilograms. *Id.* at 5.

7.34.4.10(C)(2) NMAC – Individual testing requirements – Mycotoxin test

The Department revised its proposed amendments to correct a typo in Table 2 headings and a footnote by changing “mg/kg” to “µg/kg”. The measure was correctly identified as parts-per-billion (ppb) in the footnote, but incorrectly indicated in the heading in the chart. *See* Exhibit 25.

7.34.4.10(C)(3) NMAC – Individual testing requirements – Residual solvent test

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The Department revised its proposed amendments to correct a typo in the headings and a footnote by changing “mg/kg” to “µg/kg”. The measure was correctly identified as parts-per-million (ppm) in the headings and footnote, but incorrectly indicated in the heading in the chart. *See* Exhibit 9. The Department also switched the positions of ortho-xylene and meta-xylene within the table so that the method for the reporting level for ortho-xylene is 100 ppm and that of meta-xylene (reported together with para-xylene) is 200 ppm. This correction was made in response to public comment. *See* Exhibit 25.

The Department also lowered action for multiple targeted resident solvent compound. The Department asserts that having lower action levels ensures safer, cleaner products, and in some ways can make laboratory analysis less expensive, insofar as labs won’t have to buy a wider range of reference materials. *See* Exhibit 25.

7.34.4.10(C)(4) NMAC – Individual testing requirements – Potency test

Written Comments of Vicente Sederberg, LLP – November 22, 2019

Vicente recommends that the “potency testing” section, 7.34.4.10(C)(4)(a) NMAC include potency testing best practices from Colorado and other states by adding the following statement: “A cannabis derived product shall not be considered homogenous if 10% of the

infused portion of the cannabis derived product contain more than 20% of the total THC contained within the entire cannabis derived product.” See Exhibit 14.

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The Department revised its proposed amendments to specify that an LNPP may test for the quantity of CBN, CBGA, CBG, CBC, and THCV, at the LNPP’s option, but is not required to test for those cannabinoids. The Department states that while this had been implied in other passages of the rule, the previous text of this subsection incorrectly indicated that testing for those substances was mandatory. See Exhibit 25.

7.34.4.10(C)(4)(a) NMAC – Homogeneity in potency

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This subsection was revised to include text that specifies that a cannabis-derived product will be deemed non-homogenous if 10% of the infused portion of the product contains more than 20% of the total THC contained in the product. This text was proposed in public comment. See Exhibit 25.

7.34.4.10(C)(5) NMAC – Individual testing requirements – Heavy metal test

Written Comments of Organa Brands – November 22, 2019

Derek Young of Organa Brands commented on the new rule related to testing for pesticides and heavy metals. He stated that “testing of pesticides and heavy metals at the producer level is absolutely necessary.” See Exhibit 14. He also states that the fact that “these weren’t required thus far is shocking considering all issues facing manufacturers.” *Id.*

7.34.4.10(C)(5) [Table 5] NMAC – Heavy Metal Testing Requirements

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The Department corrected a typo in the heading and footnote to change “mg/kg” to “µg/kg”. The measure was correctly identified as parts-per-million (ppm) in the headings and footnote, but incorrectly indicated in the heading in the chart. See Exhibit 9. The Department also lowered the method for the reporting level for arsenic from 1.0 µg/g to 0.2 µg/g. This revision was made to correct a typographical error. See Exhibit 9.

7.34.4.10(C)(6) NMAC – Individual testing requirements – Pesticide test

See comments of Organa Brands above.

7.34.4.10(C)(6) NMAC [Table 6] – Pesticide Test

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department revised its proposed amendments to correct a typo in headings and a footnote by changing “mg/kg” to “µg/kg”. The measure was correctly identified as parts-per-billion (ppb) in the footnote, but incorrectly indicated in the heading in the chart. *See Exhibit 9.*

7.34.4.10(C)(7) NMAC – Moisture content test

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department revised this proposed rule to create separate designations for “concentrated cannabis-derived products” (CCDPs) and “non-concentrated cannabis-derived products” (NCCDPs). This revision was made in response to public comments expressing concern that the rule would require 10 grams of concentrate to be sampled for microbiological testing. With this revision, the Department proposed that only 1 gram of concentrate be sampled for microbiological testing. *See Exhibit 9.* The Department also specifies in the footnote that the combined test sample sizes for CCDPs, NCCDPs, and dried useable cannabis. *See Exhibit 9.*

7.34.4.10(C)(8) NMAC – Random testing of finished cannabis derived products

Written Comments of Vicente Sederberg, LLP – November 22, 2019

Vicente recommends that this rule be revised to replace the requirement that LNPPs or manufacturers conduct random testing with the requirement that random sampling for quality control auditing should be performed by the DOH to ensure that LNPPs or manufacturers do not avoid sampling batches with suspected or potential contamination. Vicente provides suggested revised language for this rule. *See Exhibit 14.*

7.34.4.10(E)(1) NMAC – Procedures for testing; sampling and segregation

Written Comments of Organa Brands – November 22, 2019

Derek Young from Organa Brands stated in written comment that the proposed sample size for testing at 25 grams is “absolutely not possible.” He stated that there are many producers that provide small amounts of product to his company and once processed, yields could be as low as 25 grams or as high as 100. He asserts that 1 – 3 grams is standard in any other medical or recreational market. *See Exhibit 14.*

Written Comments of Vicente Sederberg, LLP – November 22, 2019

The Vicente comments recommend changing the responsibility for product sampling from LNPPs or manufacturers to an approved laboratory. Vicente asserts that giving LNPPs or manufacturers the responsibility for sampling products for testing creates a potential conflict of

interest that could result in the selection of nonrepresentative samples. *See* Exhibit 14, Vicente comments at 2-3. Vicente provides proposed language to revise the rule in this manner. *Id.*

Vicente also recommends reducing the minimum test sample size in 7.34.4.10(E)(1) NMAC for Total Aerobic Microbial Count testing from ten grams down to one gram. *Id.* at 3. Vicente argues that the minimum sample size for Total Aerobic Count testing (10g) is quite large given the colony-forming test (cfu) units established in 7.34.4.10(C) NMAC. Vicente further states that the sample size for testing indicated in AOAC 997.02 is based on the corresponding cfu. They argue that if the cfu is one gram, then the sample size should be one gram as well. *Id.*

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The Department responded to public comments regarding the proposed sampling requirements. *See* Exhibit 25. The Department notes that the commentators stated that the identified sampling sizes are too large, especially with respect to cannabis concentrates. The Department also notes that some commentators contend that the Department should not dictate sample sizes at all and should leave the decisions regarding the size of the samples to the laboratories. Other commentators expressed agreement with the proposed standards. *Id.*

The Department asserts that the sample sizes identified in the proposed rule are consistent with U.S. Pharmacopeia USP 2023 standards for nonsterile supplements, such as botanicals and extracts, and the Department considers the Pharmacopeia standards to be appropriate. Further, the Department asserts that the rules regarding sample sizes have been amended to clarify that concentrates do not require a 10-gram sample for microbiological testing, and that a one-gram sample is sufficient. The Department notes that this was one of the more prominent concerns raised in public comment. *Id.*

In response to public comments that suggested that the tests could be accomplished by laboratories using smaller sample sizes, the Department states that it attempted to identify not only quantities that are sufficient to conduct a test, but also attempted to identify sizes of samples that are sufficient to be representative of the batch from the samples were taken. Adopting smaller samples sizes, the Department asserts, would be contrary to this goal. The Department asserts that these requirements will not be wasteful, as asserted by some commentators, but necessary to assure appropriate testing, and thereby promote the health and safety of qualified patients. *Id.*

The Department also responds to one commentator, who expressed the opinion that setting sample sizes, without controlling how material is sampled, accomplishes nothing. The Department asserts that both sample sizes and sample collection methods are important, and it has for that reason proposed rule provision that address both topics. The Department notes that the procedures for testing identified at Section 10(E) include sample selection requirements that state that an LNPP and a manufacturer shall collect and submit for testing samples that are representative of the batch being tested, and authorize the Department to order that modification be made to sampling collection practices if the Department has reason to believe that samples previously taken were not representative of a batch. *Id.*

In addition, the Department responds to commentators who proposed that sampling should be done by laboratories alone, and not LNPPs or manufacturers, who may have an incentive to take non-representative samples. The Department states that it understands the concerns that have been raised, and it may revisit this proposal in the future. At this time, however, the Department does not intend to require laboratories to conduct sampling. The Department asserts that it is not yet clear what logistical impacts such a requirement would have on LNPP and manufacturer testing, or whether the existing labs would even have the resources to conduct sampling at all the current production facilities in the state. The Department notes that the proposed rule incorporates a component for quality assurance testing to be conducted by the DOH, which may aid in identifying deficiencies in producers' and manufacturers' sampling methods. *Id.*

7.34.4.10(E)(5) NMAC – Procedures for testing; disciplinary action

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

Ultra Health offers a comment on 7.34.4.10(E)(5) NMAC, which provides that “repeated failure to pass testing may result in the imposition of disciplinary action(s) by the department, consistent with this rule.” *See* Exhibit 14. Ultra Health comments that no indication is given as to what the DOH considers to be “repeated.” It argues that it plans to perform 2,000 to 3,000 tests per month. It expects that there will be repeated failures given the high numbers of tests. It asks whether two failures will subject a producer to disciplinary action.

Ultra Health argues that the producers need to know what the DOH considers to be an unacceptable number of testing failures. *Id.* at 9. It argues that cannabis plants are complex “living beings” which results in greater variability and failure rate than a product like Coca-Cola, for example. *Id.* It asks that the DOH consult with the Medical Advisory Board to develop proposals for unacceptable rates of testing failures, with special attention paid to the context of medical cannabis cultivation. *Id.*

7.34.4.10(F) NMAC – Remediation; Subsequent Testing

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection in the proposed rules was added to establish remediation standards and allow remediation of dried usable cannabis and cannabis derived products when dried cannabis has failed a microbiological test, and when cannabis derived product has failed a microbiological test or residual solvent test. An LNPP or manufacturer may not remediate cannabis or cannabis derived products that fail other tests required by the rule. The Department is not aware of a reliable, safe method to remediate dried usable cannabis for mycotoxins, solvent residue, heavy metals, or pesticides. According to the Department, upon information and belief, other states, including Colorado, have prohibited remediation of cannabis for the same reason.

Written Comments of Vincent Sederberg, LLP – November 22, 2019

The Vicente comments suggest amending this rule to include testing for heavy metals and pesticides during the post remediation re-resting phase for contaminated products that have

undergone processing and extraction to remediate the product. *See* Exhibit 14, Vicente comments at 4. Vicente proposes language in the rule to achieve that goal.

Written Comments of NMCCC – November 22, 2019

NMCCC states that 7.34.4.10(F) NMAC (the “Remediation; subsequent testing rule”) does not include other commonly accepted processes for remediation, such as UV. *See* Exhibit 14. It also argues that the language is confusing and awkwardly worded.

7.34.4.10(F)(3) NMAC – Remediation: Edible cannabis-derived product

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department revised this subsection to include text clarifying that an LNPP or manufacturer may not remediate edible cannabis-derived products such as brownies, cookies, candies and similar products. *See* Exhibit 9.

The Department provided additional information to the Hearing Officer on February 18, 2020 in response to certain public comments that were submitted for the January 16, 2020 public hearing. *See* Exhibit 31. The comments included the following:

- The Department does not believe that additional testing should be implemented through a phased-in program or via a pilot program. The Department asserts that this approach would not be useful and may prove to be detrimental.
- The Department acknowledges that there may be some delay in implementing additional testing to allow for laboratories to acquire additional testing equipment. Consequently, the Department may temporarily waive testing requirements as provided in 7.34.4.9(A) NMAC.
- Given the fact that the cost of additional testing relates to the laboratories having to acquire additional equipment, the Department argues that it does not foresee that phased in testing or a pilot program would be economically beneficial for licensees or patients. If phased-in testing were adopted, for example, the cost of the equipment would be associated with fewer tests, driving up the cost for the patients.
- The Department argues that fewer tests would not benefit public health.
- The Department is also concerned that a phased-in testing program would cause confusion for the public, because they would not know whether a product had been tested or not, and may get the false impression a product had been tested for a contaminant when it had not.

The Department also responded to public comments that testing for total yeast and mold is not beneficial. Some commenters had suggested that only certain molds (such as *Aspergillus*) are dangerous and testing for total yeast and molds is not necessary. The Department states that it recognizes that not all molds are alike, and some molds are more hazardous than others. However, the requirement for testing for total yeasts and molds is based upon standards that apply to nonsterile botanical supplements in the U.S. Pharmacopeia, and the Department believes this standard is appropriate. Further, licensed laboratories may not be able to accurately speciate

between different mold types at the present time. Testing for total yeast and mold may have limited value, but it may still be beneficial insofar as a higher quantity of total yeast and mold may present a greater likelihood of the presence of dangerous substances, and may indicate problems with a producer's growing or curing methods that could in turn increase the possibility of cannabis harboring dangerous microbiological contaminants.

Finally, the Department responds to comments related to expanding the proposed rules related to cannabis consumption areas. The Department states that some commenters asked that they be allowed to take cannabis that they have grown themselves as holders of personal production licenses to cannabis consumption areas, and they expect that LNPPs will not allow them to do that. The Department states that at this time, having LNPPs operate cannabis consumption areas makes the most sense. It suggests that most qualified patients who visit a cannabis consumption area will wish to obtain cannabis on the LNPP's premises, and LNPPs are authorized to sell it. The Department further states that creating a new designation of licensee to operate cannabis consumption areas is unnecessary and may encourage operators to effectively operate as LNPPs, thereby engaging in unlawful sales.

Recommendation:

The Department's proposed rule on Testing of Usable Cannabis, 7.34.4.10 NMAC provoked more comment than any other proposed rule in this rulemaking hearing. The comments covered a range of different perspectives, and included many of the individuals who offered public comment as individuals representing themselves (typically as registered card holders), and individuals who offered written and oral public comments on behalf of producers, manufacturers, couriers, and laboratories. Those comments have been summarized throughout this Report. *See also* Exhibits 14 and 29.

Many participants supported the additional testing requirements that are included in the proposed rules and spoke of the concerns that they have in being confident that they are getting safe medical cannabis that is free of contaminants. Many also raised concerns about the potential for increased costs as a consequence of additional testing requirements. Sarah Dolk, for example, express support for testing for pesticides, molds, and heavy metals, but is concerned about the cost of testing being passed on to the patient. Aaron Newell stated that complete testing is a must; he argued that testing for heavy metals, pesticides, and complete microbiology panels must be done.

Several participants raised concerns that test samples can be manipulated by growers.

Many individuals supported the proposals for pesticide, and heavy metal testing, but were concerned about the cost of the new requirements being passed on to the patients at the counter, when many are struggling to pay for medical cannabis at the current prices.

A variety of opinions related to the new testing requirements were expressed by individuals who work in different capacities in the medical cannabis industry including representatives of LNPPs, manufacturers, testing laboratories, and the New Mexico Cannabis Chamber of Commerce.

Zeke Shortes from Sacred Garden agrees with testing for pesticides. He does not think heavy metals are a problem and believes that there should not be required testing for that contaminant.

With respect to the participants who work or run businesses in the medical cannabis industry, there appeared to be a consensus that there should be testing for the following contaminants:

- Aspergilli (flavus, niger, terreus, fumigatus) and penicillium (citrinum, paxillin);
- Toxic bacteria, especially total generic E. coli and Salmonella;

There were substantial concerns raised by many participants from the medical cannabis industry regarding the expense and purported necessity of the proposed new testing requirement, arguing that many of the requirements are not supported by empirical data and will not enhance patient safety.

Among those who offered public comment from the industry, many argued that there is an inadequate basis for imposing testing for heavy metals, mycotoxins, or total yeast and mold counts. Substantial expenses are expected by the laboratories in acquiring equipment necessary to conduct the testing.

Participants from the industry offered substantial monetary figures for the costs of some of the testing. For example, Scepter Lab claims that producers have paid over \$700,000.00 to test over 15,000 samples for mycotoxins without producing a single positive result. Scepter argues that heavy metal testing would likely have similar results, with a much higher price tag.

Ms. O'Dea from Scepter Lab claims that the cost of additional testing to producers will amount to \$1,800,000.00. She estimates the cost in equipment for her lab will be \$450,000.00.

A written comment from Tony Lewis indicated a 0.11% failure rate for mycotoxins in indoor plants, and a 2.15% failure rate for plants grown outdoors. Mr. Lewis states that they have seen a failure rate in testing for heavy metals of 0.41% for indoor grows, and 5.48% for plants grown outdoors.

Concerns were raised about the integrity of the sampling protocols, specifically raising concerns about who takes the samples and the potential for circumventing the intention of the rule.

The proposed rule requiring specified types of testing equipment is disputed. In particular, Scepter and the NMCCC argue that the state should not specify the type of equipment

used, a reaction to the fact that Scepter uses the ELISA methodology method and the Department rejects that methodology. The Department has responded with a reasonable explanation for their disagreement with that perspective.

Many of the commenters from the industry urged that the new testing rules be phased in or that a pilot program be established to give the MCP experience with seeing how well the new testing protocols work in the real world environment. One commenter suggested starting with pesticide testing first because pesticides pose the greatest hazard to patient health. The commenter, Barry Dungan from Rio Grande Analytics, one of the testing labs, suggested this would be a step in the right direction. He also suggests testing for heavy metals should be a step taken later so that the labs do not become overburdened with financing and training for heavy metal testing at the same time.

Erik Briones from Minerva Canna, Inc. supports the need for testing for pesticides and heavy metals but asserts that the frequency of the required testing is unnecessary and financially burdensome.

Many commenters disagreed with the proposal to conduct heavy metals testing with plant samples, arguing that the issue is whether the soil or soilless medium the plants are grow in, and the water used to water the plants, are the likely source of heavy metals if they are to be found. For indoor grows, most of which do not grow in soil, they argue that it is unlikely tests results will be positive for heavy metals.

Ultra Health supports the “sentiment” of the proposed testing rule but also raises concerns about the practical implementation of the rule. In particular, Ultra Health states that New Mexico has one-and-one half laboratories that handle medical cannabis—Scepter Lab in Santa Fe, and Rio Grande Analytics in Las Cruces. The physical location of RGA presents a problem with confiscation of medical cannabis by federal officials at the checkpoint north of Las Cruces, resulting in a loss of product.

The size of the testing samples required was disputed by several of the commenters. Ultra Health also raises concerns about the volume of samples required for testing, and expects to go from 400 test samples a month to 2,000 to 3,000 samples per month. This in turn raises a concern about whether the labs can handle the increased volume. Ultra Health urges a pilot program to determine whether the new testing requirements are workable.

Jason Marks echoes the comments of Ultra Health and Scepter Lab.

The New Mexico Cannabis Chamber of Commerce offers similar statements. It estimates a \$5 to \$8 increase per gram in the cost of medical cannabis.

The Department relies upon United States Pharmacopeia for many of the test requirements that appear in the proposed rule for microbiological testing. The Department also states that the proposed mycotoxin testing requirements are consistent with past guidance provided to the Department to LNPPs, manufacturers, and laboratories. The same principle applies to residual solvent testing. These standards are based upon standards adopted in Oregon,

and on discussions with commercial laboratory operators in Colorado. The testing requirements for heavy metals are new, and based on standards from other states, such as California, Washington, Nevada, and Oregon. The new pesticide requirements are based on regulations from Colorado, and the Oregon Health Authority.

The Department summarized its responses to the public comments on new testing requirements in its *Summary of Medical Cannabis Program Rule Amendments* for the November 22, 2019 public hearing, and its *Summary of Medical Cannabis Program Rule Amendments for Public Hearing*, dated January 16, 2020. See Exhibits 9 and 25. The *Summaries* were, in turn, summarized in detail with respect to the issues related to testing requirements in these proposed rules. The Department has provided reasonable bases in response to public comments for the proposed testing rules.

The foregoing comments represent just some of the many perspectives offered by commenters who participated in the public hearings in this rulemaking process. In considering the entire range of comments, it is clear that there are many areas of disagreement and many areas of agreement with the proposed rules on testing.

In evaluating the proposed rules related to the testing of medical cannabis, the Hearing Officer is governed by principles established by the courts of New Mexico related to agency rule promulgated. The Hearing Officer is governed by the principles established by New Mexico law in considering proposed rules that implicate areas of special agency expertise or the determination of fundamental policies within the scope of the agency's statutory function. See *Rio Grande Chapter of Sierra Club, supra*, 2003-NMSC-005 at ¶ 25. These principles have particular importance in evaluating the highly technical requirements expressed in the proposed testing rules.

The Hearing Officer is obligated to assess whether the proposed rules are in harmony with the agency's express statutory authority, or spring from those powers that may fairly be implied therefore. *Id.* Further, regulations adopted by an agency are presumed to be valid if they are shown to be reasonably consistent with the statutory purposes of the agency. *Id.*

The Department has offered substantial justification for the new testing requirements. Testing is an area where deference should be given to the Department to exercise the agency's expertise. The Department has also demonstrated a willingness to take into consideration public comments, has held two public hearings in this rulemaking process, and has revised proposed rules during this process, taking into account the comments it has received. The Department has acknowledged that, given the need for laboratories to acquire new equipment, it may temporarily waive testing requirements as provided in 7.34.4.9(A) NMAC. Further, the public comments have given the Department much to continue to consider in this rulemaking process.

For the foregoing reasons, the Hearing Officer recommends that the Secretary find that 7.34.4.10 NMAC is consistent with the Department's statutory authority as expressed in 1978 NMSA, § 26-2B-2 and § 26-2B-6.1. The Hearing Officer further recommends that the Secretary adopt the proposed rule at 7.34.4.10 NMAC.

7.34.4.11 NMAC – Wastage of Cannabis: Permitted Methods

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This is a new section that proposes to include requirements specific to “wastage” (i.e., destruction) of usable cannabis and cannabis plants by an LNPP or an approved entity. It includes permitted methods of wastage and disposal, a holding period for cannabis and cannabis plants intended to be wasted, and documentation and notice requirements. *See* Exhibit 9.

Written Comments of Natural Rx – November 22, 2019

Brooke Duverger from Natural Rx offered written comments on 7.34.4.11(C) NMAC—“waste shall be held in a secure designated holding area for a minimum of 72 hours prior to being wasted.” *See* Exhibit 14, written comments of Natural Rx at 2. Ms. Duverger asserts that it is unclear what the Department means by “designated holding area.” She raised the question whether this can be a locked box or should it be a separate room on the premises? She recommends a definition be added to resolve these questions. *Id.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department responds to a public comment which asked what constitutes a “designated holding area” for purposes of the wastage section, and whether such an area could be a locked box, or whether it needed to be a separate room on the premises. The Department responds by stating that a designated holding area can be a room, a locked box, or some other form of holding area, so long as the holding area is secured. *See* Exhibit 25.

Recommendation: This proposed rule is consistent with the Department’s express statutory rulemaking authority, or springs from those powers that may fairly be implied therefrom. Furthermore, the proposed rule is reasonably consistent with the statutory purposes of the Department. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.12 NMAC – Department Testing; Quality Assurance; Randomized Testing; Complaint Procedure

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection in the proposed rules adds provisions for quality assurance testing of usable cannabis, to be conducted by the Department. *See* Exhibit 9. *See also*, discussion of quality assurance testing above in the discussion of testing requirements.

Recommendation: The proposed rule is reasonably consistent with the Department’s statutory authority. The Hearing Officer recommends that the Secretary adopt the rule.

7.34.4.13 NMAC – Use of Pesticides by Licensed Producers

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection includes a proposed revision to require that pesticides be stored in a secured area, and that pesticides be segregated from usable cannabis, cannabis plants, and products and equipment that are used in the manufacturing or production process. This is intended to avoid issues of contamination. *See* Exhibit 9.

Recommendation: The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14 NMAC – Department Approval of Manufacturers of Cannabis Derived Products; General Manufacturing Provisions

7.34.4.14(A) NMAC – Submittal of Applications

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The application requirements for manufacturers are proposed to be amended to increase the licensing application fee for manufacturers from the current \$1,000.00 to \$5,000.00. *See* Exhibit 9. The Department asserts that this fee increase is appropriate in light of the size and the revenues of licensed manufacturers under the statutory amendments that were made in SB406 (2019). The Department further asserts that, while the proposed \$5,000.00 is substantially less than the fees paid by licensed non-profit producers, the Department finds that LNPPs and manufacturers are not comparable considering that LNPPs have much higher revenues than manufacturers, and given that LNPPs, as the only entities permitted to sell cannabis or cannabis products to the public, control the market and the prices for cannabis products in a way that no one else does.

Written Comments of Organa Brands – November 22, 2019

Derek Young of Organa Brands submitted a written comment that argues against the proposed changes in licensing fees. *See* Exhibit 14. He states that the increase from \$1,000.00 to \$5,000.00 amounts to a 500% increase “without any understanding of what this increase will benefit.” *Id.* He argues that the DOH has not explained what fees that were considered from other states covered, including plant count for manufacturers and any benefits or protection this offers to current licensed and state approved manufacturers. He further argues that the increase only serves the State and not patient of the MCP or the producers and manufacturers. *Id.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

In response to public comment, the Department states that it believes the proposed fee of \$5,000 is fair and appropriate. *See* Exhibit 25. It finds the \$1,000 fee to be too small, especially given the significant cost borne by the Department in man hours committed to reviewing manufacturer’s license applications. Further, the Department asserts that the proposed fee is consistent with the fees charged in other states.

Recommendation: The Department has provided a reasonable basis for the increase in licensing fees. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(3) NMAC – Manufacturing Provisions

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed revision to the rules would require hazard analysis critical control point plans (HACCP plans) for each of the products that a manufacturer applicant intends to manufacture. *See* Exhibit 9. HACCP plans are plans that address the safety of products to be consumed, through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing distribution and consumption of the finished product.

Written Comments of Ultra Health – November 22, 2019

Ultra Health notes that 7.34.4.14(B)(3) NMAC requires a “hazard analysis critical control point plan (HACCP) for each type of product that the manufacturer wishes to manufacture.” *See* Exhibit 14. Ultra Health argues that it appears that the DOH derived this requirement from food manufacturing regulations, and it argues that HACCPs are heavily regulated by the federal FDA. *Id.* It also asserts that a recent study by the food industry found that developing an HACCP costs around \$25,000 for small establishments. *Id.*

Ultra Health argues that it is not clear that the DOH has the expertise to pass judgment on an HACCP plan. It also questions whether the DOH has employees with the expertise in HACCP plans to know if the manufacturer has submitted a genuine one or simply a “garbled collection of nonsense.” *Id.*

Ultra Health asks if the Medical Advisory Board recommended HACCPs or sees a need for them. *Id.* It also urges looking at specific targeted improvements, rather than requiring manufacturers to incur the expense of HACCPs.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department responded to a comment which criticizes the inclusion of HACCPs in the manufacturer application requirements. *See* Exhibit 25. The commenter suggested that a single HACCP would cost \$25,000.00. The Department does not agree. It argues that an HACCP is essentially a written plan which identifies biological, chemical, and physical hazards that exist in the production and distribution of a product. The Department states that it has no reason to believe the creation of these plans will be cost prohibitive. It also asserts that the plans have the potential to be very beneficial to promoting public health and safety.

Recommendation: The Department has provided a reasonable basis for the increase in licensing fees. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(4) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed revision to the rules would amend application requirements to include a detailed list of all products to be manufactured.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(8) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed revision to the rules would amend the application requirements to include a requirement that manufacturer applicants submit proof that no buildings to be used by the manufacturer are located within 300 feet of a school, church, or daycare center. *See* Exhibit 9. This 300-foot requirement is based on the statute, at NMSA 1978, § 26-2B-7.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department revised this subsection to include the grandfathering provision regarding application of the 300-foot rule to manufacturer locations. *See* Exhibit 25.

Recommendation: The Department has provided a reasonable basis for this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony

with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(13) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed revision to the rules would amend the application requirements to include a requirement for manufacturers to include submittal of documentations of successful testing of alarms and a law enforcement notification system. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(18) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed revision to the rules would amend the application requirements to include a requirement that a manufacturer applicant submit attestation that it will ensure that all persons who work at its facilities will be 18 years of age or older. *See Exhibit 9.* This is intended to limit access of minors to cannabis.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(B)(19)-(24) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

These proposed revisions to the rules would amend the application requirements for manufacturing applicants to include, among other things, submittal of an attestation that the applicant will comply with all applicable state and local zoning, occupancy, licensing, and building codes; and proof of prior approval from the NM Regulation and Licensing Department for the use of compressed gas extraction equipment. *See Exhibit 9.*

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department's statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.14(B)(25) NMAC – Application Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added an application requirement that manufacturer applications include a written statement of the days and hours that the manufacturer will operate. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(C) NMAC – Prohibited additives

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule proposes to include new material in the rule that prohibits certain additives, including polyethylene glycol, polypropylene glycol, vitamin E acetate, and medium chain triglycerides, in products that are intended to be consumed by inhalation, such as vaping cartridges. *See Exhibit 9.* This revision relates to a recent outbreak of severe lung injuries sustained by individuals across the country from vaping cannabis and/or nicotine products. The Department states that although the cause of these injuries is not yet known, there have been indication that the identified additives may be the source, and various states have taken measures to limit the presence of these substances in vaping products. The Departments also notes the presence of additional information related to vaping-related lung disease on the DOH website at <http://nmhealth.org/about/erd/eheb/vri> and the CDC website at <http://www.cdc.gov/lunginjury>.

The Department further states that this proposed subsection seeks to prohibit manufacturers and licensed non-profit producers from adding nicotine, caffeine, or any other addictive substance to a cannabis product.

Written Comment of Ultra Health – November 22, 2019

Ultra Health argues that the proposed 7.34.4.14(C) NMAC conflates “additive” with “addictive.” *See Exhibit 14.* The rule is titled “Prohibited additives” and then states that manufacturers shall not “combine nicotine, caffeine, or any other addictive substance” with cannabis. *Id.*

Ultra Health argues that the word “addictive” is not useful unless it is defined. It notes that sugar is considered an addictive substance by many medical professionals. Read broadly, this rule could result in a ban on sugar in edible cannabis products. *Id.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department revised this subsection, in response to public comment, to add an exception to the “addictive substance” requirement to exempt sugar. *See Exhibit 25.*

Recommendation: With the revision to exempt sugar from the proposed rule, the Department has provided an adequate basis for this rule and it is in harmony and reasonably consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.14(E) NMAC – Identification cards

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection proposes an additional requirement for manufacturer employees to carry their Department-issued employee I.D. card at all times during their work. *See Exhibit 9.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a manufacturer’s licensed premises. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(F) NMAC – Amended license

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection proposes an additional requirement that a manufacturer that intends to change locations, board, directors, methods of manufacturing, etc., or that intends to change its security plan, first seek amendment to their licensure. *See Exhibit 9.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added text in subsection 14(F)(2) of the rule to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete manufacturer application for amended licensure, and that the manufacturer will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete. *See Exhibit 25.*

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department's statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.14(G) NMAC – Inventory and sales equipment

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This subsection proposes to require that a manufacturer that intends to use equipment, software, and services that are specified by the Department for tracking inventory, sales, and other information, and for reporting that information to the Department. This proposed rule is modeled after a similar, existing requirement that applies to LNPPs. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(H) NMAC – Reporting theft to department

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule would establish a theft and break-in requirement for manufacturers that is identical to the proposed rule for LNPPs on the same issue, as described above. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.14(I) NMAC – Closure of applications period

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule addresses closure of the application period. It is similar to the requirement for LNPP application periods, described above. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15 NMAC – Standards for Manufacture of Cannabis-Derived Products

7.34.4.15(A) NMAC – General requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department states that this proposed rule would revise the general manufacturing requirements for LNPPs and manufacturers, including requirements that manufacturing be conducted in a manner that does not allow cross-contamination from chemical or biological hazards; that manufacturing not occur within 300 feet of a school, church, or daycare center, that persons involved in handling cannabis and cannabis derived products wash their hands before putting on gloves and after removing gloves; that walls and ceilings remain free of water damage, and that insulation not be exposed; that chemicals used in extractions be intended for such usage and be of food or medical grade; that weighing devices be registered and calibrated in accordance with requirements of the Department of Agriculture; that any manufacture of cannabis derived products for a PPL holder be recorded in an electronic tracking system specified by the Department; and that employees not be under the influence of drugs or alcohol in the workplace. *See Exhibit 9.*

Recommendation: The proposed rule is in harmony with the agency’s express statutory authority or springs from those powers or may fairly be implied from them. It is also reasonably consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.15(A)(2) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added language to this subsection to clarify that equipment, implements, and fixtures that are used for the manufacture of cannabis-derived products shall be used exclusively for that purpose. This edit was made in response to public comments. *See Exhibit 25.*

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15(A)(5) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department included the requirement here related to the grandfathering provision related to the application of the 300-foot rule to manufacturing operations. *See Exhibit 25.*

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15(A)(36) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a requirement in this subsection that the Department must be notified of any changes to the days or hours of a manufacturer's business operations. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15(A)(37) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a requirement in this subsection that manufacturer staff tasked with conducting compressed gas extraction must be appropriately trained prior to conducting extraction activities. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15(A)(38) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a requirement here, discussed above at ____, that manufacturers must not combine hemp or hemp-derived products with usable cannabis intended to be sold or distributed in the Medical Cannabis Program. *See Exhibit 25.*

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department's statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.15(A)(39) NMAC – General Requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a requirement here that cannabis and cannabis-derived products that are kept in manufacturing areas must at all times be clearly segregated from hemp and hemp-derived products. *See* Exhibit. 25.

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department’s statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.15(B) NMAC – Prohibited products

DOH Summary of Medical Cannabis Program Amendments – November 22, 2019

The proposed revisions to this rule on prohibited products state that DMSO cannot be possessed on the premises of an LNPP. The Department states that federal law restricts the use of DMSO. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.15(C) NMAC – Imprinting of certain usable cannabis products with universal THC symbol

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a requirement here that certain edible products containing THC must be imprinted with a universal THC symbol denoting THC content. This is a safety feature intended to alert consumers that a product contains THC and is a fairly common requirement in other cannabis programs. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.16 – Labeling of Usable Cannabis; Drug Information Sheets

7.34.4.16(A) NMAC –Packaging and labels not designed to appeal to children

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule would prohibit packages that contain usable cannabis from displaying product names and packages from being modeled after a brand of product that is traditional marketed toward children. *See* Exhibit A. This is intended to keep cannabis packaging from being enticing to children, who may mistake a cannabis product for candy or some other ordinary food product.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.16(B) NMAC -- Labeling requirements [Table 8 – Sample Label for Usable Cannabis Products]

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule would require that cannabis products be labeled using a standardized label format, shown in Table 8. *See* Exhibit 9. The label includes various information regarding the contents of a package, as well as laboratory analysis results. The label would also include certain warnings, including the warning regarding the vaping of THC that was included via a recent emergency rulemaking.

Written Comments of Natural Rx – November 22, 2019

Brooke Duverger from Natural Rx comments on the labeling rule—7.34.4.16 NMAC (which she designates as 7.34.4.17 NMAC) in her written comments. *See* Exhibit 14, written comments of Natural Rx at 2. She states that the proposed labeling comments are unworkable for producers, particularly the 8-point font size. She asserts that it will not allow enough room for all required information. She also asserts that the Drug Information Sheets are duplicative and wasteful. She recommends having only the THC and CBD content, testing data, warnings, and barcode on the product, and requiring producers to have all other information readily available at patient request.

Written Comments of Organa Brands – November 22, 2019

Derek Young from Organa Brands supports the idea that universal labeling be implemented by using an exit bag that would include the universal language on the bag. [cite] He suggests that the actual product name, medication name, prescription number, retailer information, product strength and directions of use along with food all be placed on the product. *See* Exhibit 14. All other noted information in the rule could be placed on an insert in the bag.

Written Comments of NMCCC – November 22, 2019

NMCCC states that it supports giving patients pertinent product information with clear labels indicating THC content. *See Exhibit 14, written comments of NMCCC at 3.* However, it argues that the proposed labeling requirements are not realistic in terms of available space on many products. As an example, it states that the information required in Table 8 of the proposed rule is not possible to include on smaller containers at 8-point type or larger. It supports using the drug information sheets as proposed in Table 9.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department in this subsection revised the previous 8-point type standard to 1/16th of an inch. The font size has been effectively reduced, in response to public comment. It has also been converted to a specific measurement in recognition of the fact that point sizes are not necessarily fixed sizes. *See Exhibit 25.*

Recommendation: The Recommendation for this proposed subsection of the rule is made in conjunction with the Recommendation for proposed Section 16(C) below. Thus, please see the discussion below in the section on Subsection 16(C).

7.34.4.16(C) NMAC (Table 9 – Sample Drug Information Sheet) – Drug information sheets

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule would also require that drug information sheets be provided to qualified patients and primary caregivers at the time a cannabis product is sold or distributed to them. *See Exhibit 9.* The drug information sheet would contain all the information contained in the package label, as well as certain additional information, such as information regarding any pesticides used in the product's production or manufacture.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department removed and modified various labeling requirements in Subsections 16(B) and (C) in response to public comments. In particular, the Departments revised these subsections in response to public comments that the previously proposed contents of the label were too numerous to fit onto a label. The Department also proposed to require less information on the product labels, and to have the removed information included in the drug information sheets as set forth in the revised Subsection 16(C). *See Exhibit 25.*

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that the propose rules found in 7.34.4.16(B) & (C) NMAC are in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt these proposed rules.

7.34.4.16(D) NMAC – Expiration and best by dates

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This new proposed rule would prohibit removing or obscuring an expiration date and would require that products whose expiration dates have passed be wasted in accordance with the terms of the rule. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.16(E) NMAC – Vaporization products label

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This new proposed rule contains a requirement that cannabis derived products that contain THC and that are intended to be consumed by vaporization (vaping) have a warning affixed which states in bolded text, “WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and event death.” *See Exhibit 9.* This requirement was first instituted by a public health order of the Department and an emergency rule that took effect on October 4, 2019. The warning was required in consideration of the recent outbreak of severe lung injuries stemming from vaping of TCH and nicotine products, described above in regard to 7.34.4.14(C) NMAC.

Written Comments of Safe Access New Mexico – November 22, 2019

Jason Barker submitted written comments on behalf of Safe Access New Mexico that focused on the proposed vaping labeling requirements found in 7.34.4.16(E) NMAC, in particular, the following language: “WARNING: Vaping THC has been associated with cases of sever lung injury, leading to difficulty breathing, hospitalization, and event death.” *See Exhibit 14,* written comments of Jason Barker on behalf of Safe Access New Mexico at 1-2.

Mr. Barker argues that the foregoing warning is “completely false and even worse it misleads the general public and program participants about the scientific facts about THC and it’s many medical benefits.” *Id.* He also suggests that the following language should be added to the labeling requirement: “It is important to note that this illness is not caused by anything intrinsic to cannabis.” *Id.* at 2.

Mr. Barker asserts that on November 8, 2019, the Center for Disease Control and Prevention (CDC) confirmed that out of 29 samples of lung fluid from affected patients all samples tested positive for Vitamin E acetate. He further asserts that this led the CDC to consider Vitamin E acetate to be a “chemical of concern,” not solely THC. *Id.* Mr. Barker also notes that the CDC issued vaping guidance noting that products containing THC, especially those obtained off the

street are linked to most of the cases and play a major role in the outbreak. He further notes that the CDC recommended that people refrain from using e-cigarettes or vaping products that contain nicotine. *Id.*

Mr. Barker argues that New Mexico has unfairly singled out medical cannabis vaping products with this warning label requirement. He notes that the DOH did not require warning labels on nicotine vaping products, or on HEMP CBD vaping products. *Id.* He also argues that the DOH has ignored the true problems causing the outbreak of lung injuries associated with e-cigarettes and vaping. *Id.* He also asserts that the DOH has failed to mention other problems that the CDC has found, such as adulterants, contaminants, heavy metals, residual solvents, chemical residues, and other health concerns, such as mold and dangerous bacteria. *Id.* at 2-3. He further asserts that it is important to note that illness is not caused by anything intrinsic to cannabis. *Id.* at 3.

Mr. Barker reports that Americans for Safe Access (ASA) points out that CDC investigators have not been able to pin down one factor or set of factors that is likely to cause illness, and that Vitamin E acetate has been implicated as a potential cause of illness in many cases involving illicit cannabis cartridges, but was not present in all samples. *Id.* at 4.

Mr. Barker states that ASA recommends that patients stop using cannabis-containing cartridges entirely, at least to the extent possible, until their cause of the illnesses and deaths has become clear. *Id.* ASA does not support an outright ban because they believe that would drive patients to go to the black market. Instead, ASA supports bans on the inclusion of any additives not derived from cannabis. *Id.* ASA also recommends that patients only purchase products that have undergone testing by independent, third-party laboratories. *Id.* It also recommends that patients use vape pens instead of other delivery mechanisms. *Id.* at 4-5.

Mr. Barker appears to support the recommendations of ASA.

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

A public comment was made that the warning that is required on labels for vaping products should specify that the recent outbreak of vaping-related injuries was not caused by anything intrinsic to cannabis. *See* Exhibit 25. The Department responds by stating that the investigation of vaping-related injuries is ongoing, and the Department is unable to render any such conclusion at this time.

Recommendation: The Department has provided a reasonable basis for the proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department also included reference to potential recall in subsection regarding failure to comply with packaging or labelling requirements. The recall section is found in Section 24. See Exhibit 9.

7.34.4.16(E)⁶ NMAC – Failure to comply with packaging or labeling requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This new proposed rule identifies that a non-profit producer that does not comply with the packaging or labeling requirements of the rule can see their sales and distribution of non-compliant products suspended and may be subject to discipline against their licensure. See Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.17 NMAC – Department-Approved Testing Laboratories; General Provisions

7.34.4.17(C) NMAC – Application materials

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

Additional proposed subsections have been added to this rule to include laboratory application materials requirements, which include documented proof of initial demonstrations of capability (in accordance with rule); proof that buildings are not located within 300 feet of a school, church, or daycare center, and an attestation of the same. See Exhibit 9.

7.34.4.17(C)(17) NMAC – Application materials

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

In response to public comment, the Department included reference here to “continuing demonstration of capability”. This expression has been included within Section 19, to distinguish from initial demonstrations of capability. See Exhibit 25.

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that the proposed rule found in 7.34.4.17(C) NMAC is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

⁶ Designated as Section 16(F) in the *DOH Summary of Medical Cannabis Rule Amendments*, Exhibit 9.

7.34.4.17(C)(18) NMAC – Application materials

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

This subsection was revised to include the grandfathering provision regarding application of the 300-foot rule to laboratory locations. *See Exhibit 25.*

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department’s statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.17(E) NMAC – Proficiency testing and inspection

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

In response to public comment, the Department replaced references to “program manager” with “program director or designee”, here and in other passages of the rule that referenced a “program manager.” *See Exhibit 25.*

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that the proposed rule found in 7.34.4.17(E) NMAC is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.17(G) NMAC –Identification cards

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This rule is proposed to be amended by adding a requirement that laboratory employees carry their Department-issued employee I.D. card at all times during their work and present the card to law enforcement upon request. *See Exhibit 9.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added a provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a laboratory’s licensed premises. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.17(H) NMAC – Reporting theft to department

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This new proposed rule would add a theft and break-in reporting requirement for Department-approved testing laboratories. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.17(I) NMAC – Term of approval

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This rule is proposed to be amended by adding requirements that a laboratory that intends to change locations, that intends to make a physical modification or addition to its facilities (new testing equipment, etc., or that intends to make a substantial change to its standard operating procedures or types of tests to be conducted, first seek amendment to their licensure. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.17(J)(1) NMAC – Amended Licenses

Written Comments of Jason Marks – November 22, 2019

Jason Marks submitted written comments on this rule in conjunction with his comments on 7.34.4.8(R)(2) NMAC. *See Exhibit 14.* Those comments are discussed above.

Recommendation: The Department has provided an adequate justification and reasonable basis for this proposed rule. The Hearing Officer recommends that the Secretary find that the proposed rule is in harmony with, springs from, and is reasonably consistent with the statutory purposes of the Department pursuant to the authority to establish rules given to it in LECUA. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.17(J)(2) NMAC – Amended Licenses

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department added text in this subsection to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete laboratory application for amended licensure, and that the laboratory will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18 NMAC – Department-Approved Testing Laboratories; General Operational Requirements

7.34.4.18(A) NMAC – Receipt of test samples

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to add a requirement to this rule that laboratories apply the testing standards contained elsewhere in this subsection of the rule to determine whether a sample of usable cannabis passes a given test. *See Exhibit 9.*

Recommendation: The proposed revisions of the rule are reasonably consistent with the Department’s statutory authority to promulgate rules and the purposes of the statute. The Hearing Officer recommends that the Secretary adopt the rules.

7.34.4.18(C) NMAC – Recording of samples received

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to clarify this rule by stating that a laboratory that receives a usable cannabis sample for testing must record the batch number or code that is recorded by an LNPP or manufacturer in an electronic tracking system specified by the Department. This is intended to more clearly associate test samples with the batches from which they are derived. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18(D)(3)(b) and 18 (O) NMAC – Sample handling, storage and disposal

Written Comment of Vicente Sederberg, LLP – November 22, 2019

Vicente suggest removing the section in this rule which references the optional transport of cannabis waster from an approved laboratory to a state or local law enforcement office. Vicente argues that disposal is already governed by 7.34.1.11 NMAC and 7.34.4.18(D) NMAC and adding the additional optional language in this rule could confuse laboratory operators and potentially result in non-compliance. *See* Exhibit 14, Vicente comment at 6.

DOH Summary of Medical Cannabis Program Rule Amendments – January 16, 2020

The Department replaced previous destruction text at Subsection 18(D)(3)(b) with reference to wastage requirements of the rule. *See* Exhibit 25. A similar edit was made at Subsection 18(O), which had referenced destruction of excess cannabis, but which is deleted in deference to the wastage requirements found in Section 11. These revisions were made in response to public comment.

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18(E) NMAC – State and local law

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to revise this rule by requiring laboratories to comply with all state and federal laws, including but not limited to zoning, occupancy, licensing, and building codes. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18(K)(2) NMAC – Recording of analytical data

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to revise this rule by including certain requirements regarding the recording of analytical data, including requirements for making changes to recorded data. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable

consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18(P) NMAC⁷ – Drugs and alcohol

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to add this subsection to require that laboratory employees and contractors not be under the influence of drugs or alcohol in the workplace. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.18(Q) NMAC⁸ – Failures to meet testing requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

Department proposes to add this subsection to include a requirement that repeated failures to comply with testing requirements may result in disciplinary action against a laboratory. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.19 NMAC – Department-Approved Testing Laboratories Instrumentation; Initial Demonstrations of Capability

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes this new section of the rule that identifies instrumentation requirements for the various tests to be conducted under Department rule. *See Exhibit 9.* These instrumentation requirements are proposed to ensure that the testing instrumentation that is utilized for the various tests can accurately measure for the concentrations of contaminants that are specified.

The Department states that the permitted instrumentation for testing does not include enzyme-linked immunosorbent assay (ELISA) instrumentation. The Department further states, upon information and belief, and based upon a review scientific literature, that ELISA is only accurate in testing for one type of mycotoxin tested under the rule (that is, aflatoxin B1). The Department further asserts that ELISA tends to undermeasure for the other three mycotoxins, and

⁷ Listed in the *DOH Summary of Medical Cannabis Rule Amendments – November 22, 2019* as Subsection “Q”.

⁸ Listed in the *DOH Summary of Medical Cannabis Rule Amendments – November 22, 2019* as Subsection “R”.

over-measures for ochratoxin B and ochratoxin C, which can then be reported as a false positive for ochratoxin A. *Id.*

The Department also reports that ELISA is “notorious for reporting false negatives and false positives.” In addition, it states that the preferred method for mycotoxin testing is LCMS. The Department notes that when using LCMS, the mycotoxin and pesticide tests can typically be combined into one analysis, such that costs of testing can be reduced. The Department states that, in contrast, ELISA testing typically costs in the range of \$400.00 per plate. *Id.*

In addition, the Department states that Section 19(F) of this proposed rule provides that laboratories and laboratory applicants submit to the Department an initial demonstration of capability (IDC) for each type of test that the laboratory intends to conduct. The IDCs include demonstrations of method calibration, method accuracy, method detection, low system background, and analyte detection. The purpose of the IDC requirements is to ensure that a laboratory or laboratory applicant is capable of conducting the tests that they intend to conduct, and that the method that is utilized returns accurate results. *Id.*

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department received a comment stating that the ownership disclosures for laboratories should only apply to ownership above a certain percentage. *See* Exhibit 25. The commenter suggests that requiring detailed disclosures regarding laboratory ownership may have a negative impact on access to funding streams. *Id.* The Department responds by saying first that it does not understand why that would be the case, and, second, stating that it is important to know who has an ownership interest in a licensed laboratory. *Id.*

Recommendation: The Department has provided a reasonable basis for this proposed rule. The Hearing Officer recommends that the Secretary adopt the proposed rule.

7.34.4.19(F) NMAC – Initial and continuing demonstrations of capability required

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department revised this subsection to include reference to the new phrase “continuing demonstration of capability.” *See* Exhibit 25. The Department states that an initial demonstration of capability is required before a laboratory begins to conduct a given test, after there has been a change in method or instrumentation, when a new instrument is installed, and whenever the method has not been performed in a 12-month period. The Department further states that, in contrast, a continuing demonstration of capability is required as part of the renewal licensure process. The creation and use of references to a “continuing demonstration of capability” were made in response to public comment regarding the use of the expression “initial demonstration of capability.” *See* Exhibit 25.

The Department responds to a commenter who suggested that requiring IDCs as part of the licensing renewal process is unnecessary. *See* Exhibit 25. As discussed above, the Department now proposes to rename the IDC to be submitted at the time of renewal as a “Continuing Demonstration of Capability” (CDC). The Department further asserts that it is important that a laboratory demonstrated proficiency in testing at each licensing cycle. Further, the Department is concerned that a laboratory may change testing processes without informing the Department of the change. Thus, the Department asserts that requiring a CDC at the time of renewal provides assurance to the Department that a laboratory’s testing methods remain accurate, and that the laboratory continues to adhere to Department rules.

In response to public comment, the Department also notes that it is necessary that IDCs occur whenever equipment is moved. *Id.* It notes that laboratory testing equipment is extremely sensitive and removing an instrument from one location to another can impact the calibration of the equipment.

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.19(G) NMAC – Use of internal standards

The Department added text in this subsection requiring that a laboratory utilize internal standards to ensure proper measurement of analyte quantification. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.19(H) NMAC – Reporting results

The Department here clarified that the action levels for each and every analysis must be followed in accordance with the testing requirements of the rule. *See* Exhibit 25.

Recommendation: As revised, the Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20 NMAC – Department-Approved Couriers; General Provisions

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed rule amends and replaces the previously designated 7.34.4.16 NMAC.

7.34.4.20(B)(15) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes to amend this rule by correcting the faulty reference to “non-profit producer” in the courier section, to refer instead to “applicant.” *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The rule, as revised, is consistent with the agency’s statutory purposes, and the Hearing Officer recommends that the Secretary adopt the rule.

7.34.4.20(B)(20) NMAC Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments for Public Hearing – January 16, 2020

The Department here included the grandfathering provision in the passage regarding application of the 300-foot rule to courier locations. *See* Exhibit 25.

Recommendation: The Department has provided a reasonable basis for this proposed rule, consistent with its statutory authority. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(B)(24) NMAC – Application requirements

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

The Department proposes in this subsection to add a requirement to require that requires attestation that a courier will not transport cannabis across state lines, stating that transportation of cannabis across state lines would violate state and federal law. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(C) NMAC – Application fee

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed subsection to the rule would establish a \$1,500.00 application fee for courier applicants. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(D)(12) NMAC – General requirements

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This proposed new subsection to the rule would add a requirement that couriers, when transporting cannabis, not utilize vehicles that indicate that the vehicle is used for the transportation of cannabis. *See Exhibit 9.* The Department states that this could, for example, include a courier name or logo, if the courier is exclusively or primarily engaged in the transport of cannabis. This is intended as a safety precaution for patients and for courier employees.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(E) NMAC – Identification cards

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The Department here added a provision to clarify that an employee who cannot produce a Department-issued identification card on request shall not remain on a courier's licensed premises. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(G) NMAC – Amended license

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This proposed new subsection of the rule proposes an additional requirement that a courier that intends to change locations, board directors, courier facilities, etc. or that intends to make a substantial change to the courier's methods of storage, transport or delivery, submit an application for amended licensure. *See Exhibit 9.*

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The Department also added text to Subsection 20(G)(2) to specify that the Medical Cannabis Program will identify materials that remain to be submitted for completion of an incomplete courier application for amended licensure, and that the courier will have 30 days to either submit the required materials or otherwise contact the Department regarding the application before the application is closed as incomplete. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(H) NMAC – Reporting of theft to department

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This proposed new subsection of the rule proposes to add a theft and break-in reporting requirement to the courier rules. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(I) NMAC – Drugs and alcohol

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This proposed new subsection of the rule proposes to add a prohibition against courier employees being under the influence of drugs or alcohol in the workplace. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.20(J) NMAC – Inventory of sales equipment

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This proposed new subsection of the rule proposes to add a provision that the Department an require a courier to use certain equipment, software, and services to track distribution, inventory, and other information, and for the purpose of reporting information to the Department. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.21 NMAC – Qualified Personal Production Application and Licensure

This rule replaces the former 7.34.4.18 NMAC. It has not been revised in this rulemaking process, and there were no public comments on it.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22 NMAC – Non-Profit Producer Application and License Requirements

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This rule replaces and amends the former 7.34.4.19 NMAC. *See Exhibit 9.*

7.34.4.22(B)(5) NMAC – Production and distribution information and materials

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The Department proposes to add an exception to this rule, which would provide that an applicant must submit to the Department an attestation that qualified patients shall not be permitted to consume cannabis or cannabis-derived products on the entity’s property “unless the consumption occurs in a department approved cannabis consumption area.” *See Exhibit 9.* This amended is proposed in recognition of the recent additions to the statute regarding cannabis consumption areas, which are addressed in Section 26 of the rule (see below).

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22(C)(1) NMAC – Facility information

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The Department to add language to the rule related to the required facility information for an application to the description of the facilities and equipment that shall be used in the production and distribution of cannabis to include the facilities and equipment to be used for the manufacture of cannabis-derived products. *See* Exhibit 9. The Department notes that LNPPs are permitted within their licensure to manufacture cannabis-derived products in accordance with the applicable Department rule.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22(C)(2) NMAC – Facility information

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The Department included the grandfathering provision in this subsection regarding the application of the 300-foot rule to LNPP locations. *See* Exhibit 25.

Recommendation: The Department has provided a reasonable basis for this proposed rule, consistent with its statutory authority. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22(H)(3)(f) NMAC – Personnel records

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The Department added a requirement in this subsection that applicants for LNPP licensure must undergo training that addresses robbery awareness and conflict de-escalation for all employees. This provision is intended to ensure greater education and awareness among LNPPs of robbery threats, and to promote the adoption of de-escalation methods in addressing theft, thereby reducing potential threats to employees and customers. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22(H)(3)(g) NMAC –Personnel records

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In this subsection, the Department added a requirement that LNPP employees must undergo general food safety training. This is a requirement for manufacturers, but is equally important for LNPPs, which commonly sell cannabis-infused products. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.22(L) NMAC – State and local laws

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The Department proposed to amend this subsection to change the existing reference to “local ordinances” to clarify that LNPPs must comply with both state and local laws regarding construction, occupancy, and operation of a facility or building, including zoning requirements, etc. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.23 NMAC – Security Requirements for Licensed Producers

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This rule replaces the former 7.34.4.20 NMAC. *See Exhibit 9.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.24 NMAC – Recalls of Usable Cannabis

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The Department here added a new section to address product recalls. This section requires LNPPs and manufacturers to create and implement written procedures for recalling cannabis and

cannabis products that are sold or otherwise distributed to qualified patients, primary caregivers, or other cannabis establishments. The licensee must notify the Department within 24 hours of initiating a product recall, and the Department may order the immediate recall of a product if it deems it necessary to protect public health and safety. *See Exhibit 25.*

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.25 NMAC – Denial of an Initial Producer License

This rule replaces the former 7.34.4.21 NMAC. It has been revised in this rulemaking process only to change references to the medical cannabis “manager” to “director,” and there were no public comments on it.

Recommendation: The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.26 NMAC – Prohibitions, Restrictions, and Limitations on the Production and Distribution of Medical Cannabis and Criminal Penalties

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This rule replaces the former 7.34.4.22 NMAC. *See Exhibit 9.*

Recommendation: The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.27 NMAC – Cannabis Consumption Areas

DOH Summary of Medical Cannabis Program Rule Amendments – November 22, 2019

This proposed new subsection of the rule identifies the application and operational requirements for cannabis consumption areas. *See Exhibit 9.* The Department states that SB406 (2019) amended the statute to create cannabis consumption areas that are occupied on licensed premises in accordance with DOH rules. The Department proposes to allow cannabis consumption areas to be operated at licensed non-profit producers’ approved dispensary locations. Pursuant to NMSA 1978, § 26-2B-7, access to cannabis consumption areas must be restricted to qualified patients and their primary caregivers; cannabis consumption cannot be visible from any public place or from outside the cannabis consumption area; and qualified patients who consume cannabis on the premises must have a designated driver or other means of transportation consistent with applicable law (a patient cannot drive a motor vehicle from a cannabis consumption area while under the influence of cannabis).

Written Comment of Jason Marks – November 22, 2019

Jason Marks is an attorney who states that he represents more than one-quarter of all the entities holding medical cannabis production licenses. *See* Exhibit 14, written comments of Jason Marks at 1. He argues that the Department may not reserve the power to promulgate ad hoc rules and may only promulgate rules through a formal rulemaking process with notice and comment, and publishing such rules in the Register and the Administrative Code. He argues that 7.34.4.26(B)(12) NMAC violate these principles without going through notice and comment, or publication. 7.34.4.26(B)(12) NMAC is a subsection of the new rule which addressed cannabis consumption areas and appear in a list of items that are required when an LNPP applies for approval for such an area. The subsection in question follows a list of 11 specific items required as part of the application and provides that the Department may seek “such additional information or materials as the department may require.”

Mr. Marks argues that the forgoing rule would violate NMSA 1978, § 9-7-6(C) by allowing the Department to enact rules without a public hearing on the proposed action before the Secretary or a designated hearing officer. He urges the Hearing Officer to strike this proposed subsection of 7.34.4.26(B).

Recommendation: The proposed rule is in harmony with and reasonably consistent with the Department’s statutory authority. The Hearing Officer recommends that the Secretary adopt the rule.

7.34.4.28 NMAC – Reciprocity

This proposed rule was addressed by the Hearing Officer in his January 30, 2020 Report to the Secretary.

7.34.4.29 NMAC – Enforcement of Parental Responsibility Act

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The Department states that this section includes provisions for enforcement of the New Mexico Parental Responsibility Act, NMSA 1978, § 40-5A-1, *et seq.*, which applies to persons who apply for or hold a license, certificate, registration or permit that is issued by a licensing board or other authority that issues licenses, certificates, registrations, or permits to engage in a profession or occupation regulated in New Mexico. *See* Exhibit 9.

The Department further states that the DOH Medical Cannabis Program fits within that description, insofar as it permits persons to work for licensed non-profit producers and approved entities. Such person may be prohibited from working for the LNPP or approved entity if they are not in compliance with a judgment and order for child support that was issued by a district court or tribal court, or if they are not in compliance with a subpoena or warrant relating to paternity or child support proceedings.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.30 NMAC – Monitoring and Corrective Actions

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This rule replaces the former 7.34.4.23 NMAC. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.30(B)(3)(r) NMAC – Financial records; quarterly reports

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The Department proposes to remove this subsection, which stated an existing requirement that LNPPs include a detailed description of thefts, robberies, and break-ins in their quarterly reports. The Department proposes to replace that subsection with the proposed theft and break-in provision that has been proposed to be added at 7.34.4.8(Y) NMAC. *See* Exhibit 9.

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The Department states that Subsection B requires that manufacturers maintain sales records, in addition to LNPPs. Also, it removed reference to the word “confidential” in reference to sales records, stating that sales records may be deemed confidential in accordance with applicable laws, such as HIPAA or the Lynn and Erin Compassionate Use Act at NMSA 1978, § 26-2B 7(H), depending on facts and circumstances. The Department also states that the passage as previously written could give the impression that all sales records are always confidential which is incorrect. The Department notes as an example that a manufacturer’s sales to an LNPP would not necessarily be deemed confidential. *See* Exhibit 25.

The Department also clarified the rule to state that it shall have access to the financial records of producers, manufacturers, laboratories, and couriers. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.30(C) NMAC – Corrective action

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The Department proposes to amend this subsection by identifying that, with respect to violations that are cited on the basis of violations that are directly observed in the course of a monitoring visit, the LNPP will receive a written report of findings within 7 days, and will be afforded the opportunity to correct the violations within five days. The Department states that the purpose of this is to clarify that if, for example, the Department learns of a violation that is occurring off-site, the seven-day report provision and the five-day corrective action provisions will not apply. *See* Exhibit 9.

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The Department added manufacturers, laboratories, and couriers to the “monitoring visit” rule” that currently applies to LNPPs. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.30(D) NMAC –Suspension of license without prior hearing

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The Department substitute existing references to qualified patients and primary caregivers in this subsection with a reference to personal production license holders. The suspension of patients and primary caregivers is addressed separately within the patient rule at 7.34.3 NMAC, whereas this rule concerns producers (including PPL holders) and cannabis establishments. *See* Exhibit 25.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.31 NMAC – Disciplinary Actions and Appeal Process

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This rule replaces the former 7.34.4.24 NMAC. *See* Exhibit 9.

7.34.4.31(A) NMAC – Notice of disciplinary action

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The Department proposes to add this subsection to include a statement that a notice will be deemed to be served on the date of delivery that is shown on the return receipt of the certified U.S. postal mail, or on the last attempted delivery date. This is patterned after a similar standard that applies in the context of cases that fall within the Uniform Licensing Act, NMSA 1978, § 61-1-5. See Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.31(B) NMAC – Grounds for disciplinary action

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The Department propose to amend this subsection to provide that grounds for disciplinary action described in the rule are not exclusive of one another and can be imposed in any combination. See Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.31(B)(1)(b) NMAC – Grounds for disciplinary action

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The Department propose to amend this subsection to provide that grounds for disciplinary action described in the rule for major violations of public safety include “inversion,” or “attempted diversion or inversion” “Inversion” is a term, defined in the proposed rule, that refers to the unlawful acquisition of a cannabis plant, plant material, or cannabis-derived product; whereas “diversion” refers to the unlawful transfer of the same. See Exhibit 9.

Recommendation: The proposed rule is reasonably consistent with the Department’s statutory authority. The Hearing Officer recommends that the Secretary adopt the rule.

7.34.4.31(E) NMAC – Closure of applications period

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The Department proposes to add this subsection to state that a hearing cannot be requested solely on the basis that an applications period is closed. *See* Exhibit 9.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.31(F) NMAC – Timing and content of request for hearing

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The Department proposes to revise this subsection to provide that passage regarding timing and content of requests for hearing include clarifying text regarding the timeline for responding to a notice of contemplated action versus responding to a notice of immediate action. *See* Exhibit 9. This also includes a requirement that requests for hearing must be mailed via certified mail. This is intended to ensure that, in the event that a request for hearing becomes lost in the mail, the requestor has proof that the request was in fact sent on a given date within the specified periods.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.32 NMAC – Exemption from State Criminal and Civil Penalties

This rule replaces the former 7.34.4.25 NMAC. It was revised only by adding 7.34.4.32 NMAC, which provides that a reciprocal participant shall not be subject to criminal or civil prosecution.

Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.33 NMAC – Closure of a Non-Profit Producer or an Approved Entity

This rule replaces the former 7.34.4.26 NMAC. See Exhibit 9.


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The Department proposes this new section to establish closure requirements for LNPPs and approved entities. The text of the rule borrows from and adds to existing closure requirements in the rule. See Exhibit 9.


Recommendation: There were no comments on this proposed rule. The Hearing Officer recommends that the Secretary find that this proposed rule is in harmony with and reasonable consistent with the statutory purposes of the agency. The Hearing Officer recommends that the Secretary adopt this proposed rule.

7.34.4.34 NMAC replaces the former 7.34.4.26 NMAC. 7.34.4.35 replaces the former 7.34.4.27 NMAC. 7.34.4.36 NMAC replaces the former 7.34.4.28 NMAC. 7.34.4.37 NMAC replaces the former 7.34.4.29 NMAC. All are unchanged from the former rules and should be adopted by the Secretary.

Based upon the foregoing, the Hearing Officer recommends that the Secretary adopt the proposed amendments to 7.34.2.7 NMAC and 7.34.3.7 NMAC, and repeal and replace 7.34.4 NMAC.



Craig T. Erickson



Date