

**STATE OF NEW MEXICO  
BEFORE THE SECRETARY OF HEALTH**

**IN THE MATTER OF THE PROPOSED  
REPEAL AND REPLACEMENT OF  
7.34.4 NMAC, AND PROPOSED  
AMENDMENTS TO 7.34.2.7 AND  
7.34.3.7 NMAC**

**STATEMENT OF REASONS  
FOR ADOPTION OF RULES**

The Cabinet Secretary for the New Mexico Department of Health (“Department”), Kathyleen M. Kunkel, hereby adopts the repeal and replacement of Medical Cannabis Program rule 7.34.4 NMAC, and the amendments of 7.34.2.7 NMAC and 7.34.3.7 NMAC. This decision is based on the entire record in this matter, which includes Exhibits 1 through 31, the audio recording of the hearing, and the Report and Recommendation of the Hearing Officer, Craig Erickson, Esq., dated January 30, 2020 and received by the Cabinet Secretary on January 31, 2020 via Federal Express. The rules shall become effective on March 24, 2020, upon publication in the New Mexico Register.

In further support of this action, the Cabinet Secretary finds the following:

1. The Department of Health is authorized to promulgate rules as may be necessary to carry out the duties of the Department and its divisions. NMSA 1978, § 9-7-6(E).
2. The Department is also authorized to promulgate rules to implement the purpose of the Lynn and Erin Compassionate Use Act. NMSA 1978, § 26-2B-7.
3. By a letter dated October 7, 2019, the Cabinet Secretary designated Mr. Erickson to serve as Hearing Officer for the purpose of conducting the hearing, receiving and reviewing public comment, and submitting a recommendation regarding the proposed rule amendments.

4. Notice of the November 22, 2019 hearing for the proposed rule changes was provided to the public in accordance with NMSA 1978, Section 9-7-6(E) and NMSA 1978, § 14-4-5.2, which included publication in the Albuquerque Journal newspaper on October 15, 2019, and publication in the New Mexico Register on October 15, 2019.

5. Notice of the January 16, 2020 hearing for the proposed rule changes was provided to the public in accordance with NMSA 1978, Section 9-7-6(E) and NMSA 1978, § 14-4-5.2, which included publication in the Albuquerque Journal newspaper on December 17, 2019, and publication in the New Mexico Register on December 17, 2019.

6. Public rule hearings were held at the Harold Runnels Building Auditorium at 1190 Saint Francis Drive in Santa Fe, New Mexico, on November 22, 2019 and January 16, 2020 in accordance with NMSA 1978, Section 9-7-6(E).

7. Members of the public were afforded the opportunity to submit data, views, and arguments on the proposed rules orally and in writing, and those comments were received by the Hearing Officer until the close of each respective hearing.

8. The purpose of the proposed repeal and replacement of 7.34.4 NMAC and proposed amendment to 7.34.2.7 NMAC and 7.34.3.7 NMAC is to adopt various revisions to those rules, as more fully described in the rulemaking record, which revisions include but are not limited to the following:

- a. Identical revisions and additions to definitions at 7.34.2.7, 7.34.3.7, and 7.34.4.7 NMAC;
- b. Revisions and additions to licensed nonprofit producer (LNPP) licensing requirements at 7.34.4.8 NMAC;

- c. Revisions and additions to standards for the production of medical cannabis at 7.34.4.9 NMAC;
- d. Revisions and additions to the standards for testing of dried usable cannabis and cannabis-derived products at 7.34.4.10 NMAC;
- e. Addition of new “wastage” standards for destruction of medical cannabis at 7.34.4.11 NMAC;
- f. Added provisions for quality assurance testing standards at 7.34.4.12 NMAC;
- g. Revisions and additions to manufacturer licensing requirements at 7.34.4.14 NMAC;
- h. Revisions and additions to manufacturing requirements at 7.34.4.15 NMAC;
- i. Revisions and additions to packaging and labeling standards at 7.34.4.16 NMAC;
- j. Additions and revisions to laboratory licensing requirements at 7.34.4.17 NMAC;
- k. Additions and revisions to laboratory operational requirements at 7.34.4.18 NMAC;
- l. Addition of a new section that addresses instrumentation requirements for laboratories at 7.34.4.19 NMAC;
- m. Revisions and additions to courier licensing requirements at 7.34.4.20 NMAC;
- n. Addition of a new section concerning application and operational requirements for cannabis consumption areas at 7.34.4.26 NMAC;
- o. Addition of a new section concerning provisions for enforcement of the NM Parental Responsibility Act, NMSA 1978, 40-5A-1 *et seq.* as to persons who work for licensed nonprofit producers and approved entities; and

p. Revisions and additions to section concerning disciplinary actions against licensed producers and approved entities.

9. An emergency rule amendment to 7.34.4.14 NMAC was previously adopted by the Cabinet Secretary on October 4, 2019 and published in the NM Register, Vol. XXX, Issue 20 on October 29, 2019. Text regarding the inclusion of a vaporization products label, which was initially adopted via emergency rule amendment at 7.34.4.14(B) NMAC, is now integrated into section 7.34.4.16(B)(12) NMAC.

10. The Department previously adopted an amendment to 7.34.4 NMAC, to add a section regarding reciprocity for individuals who hold proof of authorization to participate in the medical cannabis program of another state of the United States, the District of Columbia, a territory or commonwealth of the United States or a New Mexico Indian nation, tribe or pueblo. That section was originally contained at 7.34.4.30 NMAC, and is designated within the replacement of 7.34.4 NMAC as 7.34.4.28 NMAC.

11. The Cabinet Secretary concurs with the rationales and positions stated in the summaries of rulemaking at Exhibits 9 and 25, and in the Department's correspondence with the Hearing Officer dated 2/18/20 at Exhibit 31, which contain responses to public comments and reasons for not adopting recommendations that were made in public comment; and the Cabinet Secretary by this reference incorporates the summaries and responses contained in those exhibits.

12. The reasons for changes between the original proposed rules and the final rules are principally as stated in the summaries of rulemaking at Exhibits 9 and 25. The majority of those changes were made in response to public comments received during the rulemaking.

13. Additional revisions to the original proposed rules have been made to the labeling requirements at 7.34.4.16 NMAC, and to the associated sample labels at Tables 8 and 9, to

remove the proposed “per serving” cannabinoid content labeling requirements. The “per serving” cannabinoid content requirements have been removed in consideration of the fact that no proposed serving size has been identified.

14. An additional revision was also made to the original proposed rules, to modify the THC and CBD quantification standard in drug information sheets at 7.34.4.16(C) NMAC from “weight in milligrams” to “percentage of weight”. This edit was made to correct a drafting error, and to mirror the labeling requirements at 7.34.4.16(B) NMAC, which specify “percentage of weight”.

15. The bulk of public comments received in this rulemaking concerned revised testing standards at 7.34.4.10 NMAC. The Cabinet Secretary responds to those comments as follows.

16. With respect to pesticide testing, the Cabinet Secretary finds that such testing is vital to ensuring the health and safety of the public.

17. As shown recently during the outbreak of injuries related to the vaporization (“vaping”) of cannabis and tobacco products, the burning of pesticide residues in cannabis poses serious health risks to the public. Those risks are amplified with respect to qualified patients in the Medical Cannabis Program, many of whom have compromised immune systems as a result of their medical condition.

18. Several states currently require testing for pesticides in cannabis in recognition of the public health threat posed, including (but not limited to) Colorado, Arizona, Oklahoma, California, Washington, Michigan, Illinois, Minnesota, North Dakota, Alaska, Hawai’i, Arkansas, and Connecticut, as well as the District of Columbia. Some states altogether prohibit the application of pesticides to cannabis, including Delaware, Massachusetts, and Maine.

19. The pesticides identified in the rule at 7.34.4.10(C)(6) NMAC were taken from Colorado regulations regarding the testing of cannabis, in anticipation that those pesticides will be included in common testing panels.

20. The action levels for the listed pesticides were modeled on rules from Oregon. Oregon's action levels are somewhat less stringent than those of Colorado; and the Department expects that requiring testing for these specific pesticides will enable laboratories to use existing instrument platforms (HPLC) with relatively small and affordable modifications, without having to obtain costly new testing instruments. Utilizing Colorado's action levels would likely result in much higher costs and lower feasibility at the present time.

21. The chief concern raised in public comment regarding the addition of pesticide testing and heavy metals testing was the anticipated added costs that qualified patients would incur, due to the cost of additional instrumentation that laboratories would acquire. The Cabinet Secretary finds that the costs of each of the tests specified in the rule are significantly outweighed by their benefit to public health and safety. Moreover, the Department expects that the actual added costs to qualified patients resulting from additional testing will be substantially less than the costs suggested in some of the public comments.

22. As one example: a laboratory representative commented that the laboratory would need to charge \$250 per sample as a result of pesticide testing. (No information was submitted in support of this assertion, but it is assumed to be true for purposes of this example.) Pursuant to Department rule, each batch of dried cannabis can be no greater than five pounds; whereas there is no limit on the maximum size of a batch of concentrated cannabis product. There are 2,240 grams in a five-pound batch of dried cannabis. Dividing \$250 by 2,240 grams would result in an \$0.11 increase in the cost per gram resulting from pesticide testing. This would be

only a nominal increase over the current average price of \$10.26 per gram of dried usable cannabis (based on 2019 fourth quarter producer reports).

23. Similarly, assuming *arguendo* that heavy metals testing will add \$150 to the cost of testing a sample (as was stated in the same laboratory representative's written comment), this would represent an increase of less than seven cents per gram of dried cannabis (\$150 divided by 2,240 grams per five pound batch) resulting from heavy metals testing. Here also, this would represent only a nominal increase over the average price per gram of dried cannabis.

24. Some commenters stated that the risk of heavy metals contamination in cannabis is low, considering the growing methods utilized by NM producers. However, many producers in New Mexico grow cannabis in native soil, both indoors and outdoors, which can contain heavy metals; and heavy metals contamination can also come from water sources. Cannabis is also known to be a bio-accumulator, which can concentrate heavy metals to toxic levels. Heavy metals present a genuine threat to public health and safety.

25. The heavy metals testing requirements are based in part on testing standards of California, Washington, Nevada, and Oregon; and those states, along with Colorado, Arizona, California, Nevada, Alaska, Minnesota, Hawai'i, Connecticut, Maryland, Maine, and the District of Columbia, all require heavy metals testing of cannabis, in recognition of the significant public health threat posed. The Cabinet Secretary finds that heavy metals pose a significant public health threat to qualified patients, and that heavy metals testing is necessary to ensure public health and safety.

26. In consideration of the anticipated financial impacts to laboratories, and in order to better enable the implementation of heavy metals testing, the Department will stagger implementation of the heavy metals testing portion of the rule, consistent with 7.34.4.10(A)

NMAC (as amended via this repeal and replacement), by requiring that heavy metals testing begin on July 1, 2021. This delay in implementation will afford laboratories sufficient time to obtain necessary testing instruments to conduct heavy metals testing and to train staff in the instruments' operation.

27. The instrumentation requirements identified at Table 7 will require that specific instruments be utilized for each of the tests. One commenter stated that these requirements should be revised to permit ELISA (enzyme-linked immunosorbent assay) testing for mycotoxins. The instrumentation requirements identified for mycotoxin testing are significantly more robust than the ELISA method, and the Department maintains that ELISA is not a sufficiently reliable method for testing for mycotoxins, particularly with respect to aflatoxin B2, G1, and G2.

28. The Department received one public comment from a representative of an approved laboratory, stating that mycotoxin testing should be removed from the rule, based on the allegation that cannabis does not support the growth of mycotoxins. This comment was made by a representative of a laboratory that has historically used the ELISA method to test for mycotoxins. Again, the Cabinet Secretary finds that ELISA is not a reliable method for testing for mycotoxins.

29. Mycotoxin testing has been required by the NM Department of Health since 2015, and several states, including (but not limited to) Colorado, Oklahoma, California, Nevada, Washington, Connecticut, Illinois, Michigan, and Minnesota, all currently require testing for mycotoxins in cannabis. As stated in the rulemaking summary at Exhibit 25, if the Department finds in the future that there are no positive test results for mycotoxins in cannabis, the



Department can revisit the mycotoxin testing requirement at that time. The Cabinet Secretary finds that the mycotoxin testing requirements remain reasonable and appropriate.

30. With respect to microbiological testing, the Department received comments criticizing the practice of testing for total yeast and mold, based on the assertion that only certain types of mold are hazardous to human health. One commenter stated that the Department should require testing for only certain specific types of *Aspergillus*. As expressed in the rulemaking summary at Exhibit 25, as well as the correspondence at Exhibit 31, the Department believes that testing for total yeast and mold can indicate problems with how cannabis is produced or processed, and the Department believes that existing approved laboratories may not be able to accurately speciate between different types of mold at the present time. The microbiological testing requirements are based on Section 2023 of the U.S. Pharmacopeia, as referenced in the prior version of the rule, and the Cabinet Secretary finds that these standards are reasonable and appropriate for the purpose of cannabis testing.

31. The rule includes minimum testing sample sizes at Table 7. The Department received various comments regarding these sample size provisions, including statements that laboratories can conduct the required tests using smaller samples. In response to public comments, the Department has modified the originally proposed sample sizes to significantly reduce the quantity of cannabis concentrate that must be sample for microbiological testing, from the originally proposed 10 grams to 1 gram. As expressed in the rulemaking record, the sample sizes have been increased overall in order to ensure that the samples are large enough to be representative of the batch. The sample sizes are based on the U.S. Pharmacopeia standards for testing dried botanicals and botanical extracts, and the Cabinet Secretary finds that these sample sizes are reasonable and appropriate for the purposes of the individual cannabis tests.

32. The Department received some critical public comments regarding the requirement that nonprofit producers and manufacturers conduct randomized, routine finished product testing. The Cabinet Secretary finds that this testing requirement is not overly burdensome on the licensees, and that such testing can reveal gaps in hygiene regarding the processing of cannabis and cannabis products. The Cabinet Secretary further finds that such testing is necessary for producers and manufacturers to determine whether the identified THC content of cannabis or a cannabis product is accurate, and whether the THC contained in a finished cannabis-derived product is homogenous in accordance with Department rule.

33. Several other states, including (but not limited to) Oregon, California, Washington, Nevada, and Massachusetts, all require finished product testing for cannabis. The Cabinet Secretary finds that the finished product testing requirements are reasonable and appropriate, and that this requirement is valuable for ensuring and promoting public health and safety.

34. The Department also received some critical public comments regarding quality assurance testing, described by some commenters as “secret shopper” testing. The Cabinet Secretary finds that quality assurance testing by NMDOH, like finished product testing by producers and manufacturers, will assist in identifying issues in production and manufacturing processes, as well as in verifying the THC content and homogeneity of THC of cannabis-derived products. The Cabinet Secretary finds that the quality assurance testing provisions are reasonable and appropriate, are consistent with the Department’s role in regulating the Medical Cannabis Program, and will aid in ensuring and promoting public health and safety.

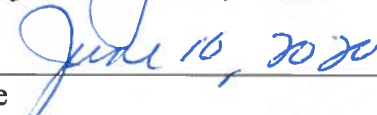
35. The Cabinet Secretary has familiarized herself with the rulemaking record, including the Report and Recommendation of the Hearing Officer, and finds that the Hearing

Officer has appropriately considered the proposed rule changes and the substantive comments made through public comment; and the Secretary adopts the Hearing Officer's recommendations concerning the proposed rule changes.

36. The Cabinet Secretary finds that the proposed rule changes are appropriate and consistent with authorizing laws, and accordingly, the proposed repeal and replacement of 7.34.4 NMAC, and the proposed amendments to 7.34.2.7 and 7.34.3.7 NMAC, are hereby adopted.

NEW MEXICO DEPARTMENT OF HEALTH

  
\_\_\_\_\_  
Kathyleen M. Kunkel, Cabinet Secretary

  
\_\_\_\_\_  
Date