September 16, 2020

RE: Further Guidance for Labeling / FAQ's

All Licensees,

On June 23, 2020 the New Mexico Department of Health amended rules governing the medical cannabis program. Amended items include new labeling requirements and testing requirements for all usable cannabis products. To clarify, all usable cannabis products are required to utilize a version of the standardized label for displaying all the required information in order to be in compliance. Attached is an example of the standardized label that will be required to be on usable cannabis products (See appendix A).

Any usable cannabis products manufactured, produced, or processed **BEFORE** October 1, 2020 will need to be labeled according to the new requirements. Any usable cannabis products manufactured, produced, or processed on or **AFTER** October 1, 2020 will need to be labeled, imprinted and embossed according to the new requirements. As a reminder, **ALL** other regulations that were amended on June 23, 2020 have been in effect since that date and are to be followed or a notice of contemplated action will result. The department also understands that testing requirements that are set for implementation in April 2021 are part of labeling, and as a result further guidance for testing expectations will be provided at a later date.

Imprinting:

As directly copied from regulation 7.34.4.15 C.:

C. Imprinting of certain usable cannabis products with universal THC symbol**:** A manufacturer and a licensed non-profit producer shall ensure that the universal New Mexico THC warning symbol, or a comparable symbol denoting THC content, is embossed or otherwise imprinted directly upon the following usable cannabis products that contain THC, prior to sale or distribution of any such product to a qualified patient or primary caregiver:

(1) chocolate;
(2) soft confections;
(3) hard confections or lozenges; and
(4) pressed pills and capsules

This regulation specifies that imprinting should use the universal New Mexico THC warning symbol or a comparable symbol. This comparable symbol must still signify that THC is present within the product. One example of a comparable symbol would be "THC!" or a cannabis leaf and exclamation mark. Comparable symbols must be approved by the MCP to ensure compliance.

A few other questions relate to the definition of confections and what products fall under this category. In general, confections are defined as a fancy dish, sweetmeat or sweet food usually made with sugar, syrup, or honey. A **few** specific examples of confections that apply include: cookies, brownies, chocolate, chocolate bars, fudge, caramel, toffee, lollipops, and gummies.

Drug information sheets (DIS)

On October 1, 2020, Drug information sheet's (DIS) will be required for all usable cannabis products that are dispensed to patients. DIS need to be available upon request either printed or electronically. Patients reserve the right to receive DIS's via a printed hard copy if it requested upon purchase. DIS shall follow the example provided as per the amended regulation NMAC 7.34.16.C (See Appendix B) Acceptable electronic versions include, QR codes, a link to a google drive document, RFID, etc. Other electronic versions may be considered at the departments discretion and approval.

Below is a list of frequently asked questions (FAQS) related to current concerns:

1. Does the font need to be Times New Roman as is used in Table 8?

   The regulations do not specify font, the only requirement is the font size. The label printed in the regulations is sample label of the required information. However, the idea behind a standardized label is to standardize the format, text, size, and content of all labels for all usable cannabis products in the program. The other thing to consider is that the label needs to be presented in legible form, not italicized, and a minimum font size.

   Again, this is to accomplish a few things: 1). Ensure all products are presented to patients for purchase in an easy to understand, legible, and correct manner. 2) Ensure all products are labeled the same throughout the program for compliance purposes. 3). In the end it will be easier on LNPP's to produce a standardized label that will ensure all of the required information is on the package, aside from marketing and graphics.

2. Do the boxes all need to be outlined as is done in Table 8?

   The label provided in the regulations is a sample. However, the idea behind this is a standardized label to make it easier for patients to find information.

3. Is there a requirement for the amount of white space compared to text for the boxes?

   Refer to the aforementioned responses. See question 2.

4. Do the words represented in Table 8 have to remain exactly as presented, or can they be abbreviated?

   No. The label needs to be clear and concise in the information provided for patients.

5. At the top of the table “Table 8. Sample Label for Usable Cannabis Products” is in the text, can we safely assume that this does not have to be on our labels?

   Yes.

6. In the case a product has a blend of strains used in production - sometimes 10 to 20 strains may be blended - how do we list the strain?

   In that instance the dominant strain type would be used (Sativa, Indica or hybrid).

7. It appears that Table 8 is only wanting the total amounts of active ingredients PER CONTAINER. We always list the total amount per container, but also by individual serving size. Are we allowed to add this and where would we add this to Table 8?

   The issue is without end product testing of all products, the amount per serving is only an estimate based on the calculations of the manufacturer or LNPP. The value is not a true value in a sense that it is 100% accurate.

8. Table 8 is in black and white, are we allowed to use color?

   Refer to the response to question 1. Using color could cause some issues for meeting the legible criteria / compliance.

9. Would it be okay if we prepared an example of our "table labels” for pre-approval by the MCP?

   The department is always willing to review items proactively prior to implementation for pre-approval.

10. We will put barcodes on to the product as required by regulation which will contain the 16-digit product and batch codes. However, we have no plan to use barcodes within our system or to utilize the barcodes at all. Is this a problem?

    Eventually the department will require the barcodes to be fully functional for transparency and compliance. It will be required for all LNPP’s to utilize the barcode system in the future.

11. Will products manufactured before October 1, 2020, that are not imprinted or embossed need to be destroyed?

    No. All products manufactured, produced, or processed BEFORE October 1, 2020 will not be required to be imprinted, embossed or destroyed. However, all usable cannabis products manufactured, produced, or processed will need to be labeled prior to distribution on or after October 1, 2020 according to the new regulations in order to be in compliance.

12. Can DOH alert manufacturers when their items are pulled from shelves (in addition to the dispensaries)?

    No. It is the responsibility of the LNPP to dispense regulation compliant products and to work with the manufacturer to ensure all products are in compliance prior to distribution.

13. CBD is regulated, has COAs, and should be treated like any other ingredient that could be input into a manufacturing process. If patients are requesting more diversity of product, why is the incorporation of CBD *not* allowed in the MCP?

    Hemp derived CBD has been prohibited from being included in products produced in the medical cannabis program. Hemp is under the jurisdiction of other state agencies (NMED, NMDA) and is not tested or regulated in the same manner in which cannabis produced under MCP is. Further guidance regarding hemp and manufacturing within the medical cannabis program can be found in the regulations governing the medical cannabis program.

    7.34.4.15 NMAC states the following:

    (38) that hemp, hemp extract, and hemp derived products (other than hemp paper) are not combined in any manner with usable cannabis that is intended to be sold or otherwise distributed in the medical cannabis program; and

    (39) that cannabis and cannabis derived products that are kept in manufacturing areas at all times be clearly segregated from hemp and hemp derived products.

14. Can a manufacture expand their facilities (ex. Multiple locations)?

    The department is working on further clarification on this question.

Thank you for time and effort as a partner of the medical cannabis program.

Have a great day,

Martinik Gonzales

Martinik Gonzales
License and Compliance Manager
NM Dept. of Health

Appendix A:

Sample Label:

<table>
<tr><th colspan="3">Sample Label for Usable Cannabis Products</th></tr>
<tr><td colspan="2">Producer:</td><td>Manufacturer:</td></tr>
<tr><td colspan="2">Name of strain:</td><td>Total units:</td></tr>
<tr><td>Net weight: mg</td><td>Manufacture/Production date: / /</td><td>Expiration date: / /</td></tr>
<tr><td colspan="3">Laboratory Analysis</td></tr>
<tr><td colspan="2">PER SERVING:</td><td>PER CONTAINER:</td></tr>
<tr><td colspan="2">THC: mg / % THC: %</td><td>THC: mg / % THC: %</td></tr>
<tr><td colspan="2">CBD: mg / % CBD: %</td><td>CBD: mg / % CBD: %</td></tr>
<tr><td colspan="3">Testing laboratory:</td></tr>
<tr><td colspan="3">Instructions for use:</td></tr>
<tr><td colspan="3">WARNING: This product contains medical cannabis. Do not drive a vehicle or operate heavy machinery while under the influence of this product. Consumption of THC when pregnant, or by a mother who is breastfeeding, may adversely impact an infant’s development.
WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.
KEEP OUT OF REACH OF CHILDREN.</td></tr>
<tr><td colspan="3">! THC NM
BARCODE 1 2 3 4 5
! THC NM</td></tr>
</table>

Appendix B:

Drug Information Sheet (DIS)

Sample Drug Information Sheet for Usable Cannabis Products	
Cannabis Facts	
Product name:	
Product strain:	
Producer of cannabis:	
Manufacturer of cannabis product:	
Net product weight:	
Total units:	
Manufacture date:	
Product expiration date:	
Batch number or code for manufactured product:	
Batch number or code for cannabis:	
Instructions for use:	
Instructions for storage:	
Nutrition facts:	
Product ingredients:	
Allergy warnings:	
Laboratory Analysis	
PER SERVING:	**PER CONTAINER:**
THC: mg / % THC: %	**THC: mg / % THC: %**
THCA: mg / % THCA %	**THCA: mg / % THCA %**
CBD: mg / % CBD: %	**CBD: mg / % CBD: %**
CBDA: mg / % CBDA %	**CBDA: mg / % CBDA %**
Testing laboratory:	
WARNING: This product contains medical cannabis. This product is for medical use by qualified patients only. This product is not for resale. Do not drive a vehicle or operate heavy machinery while under the influence of this product. Consumption of THC when pregnant, or by a mother who is breastfeeding, may adversely impact an infant's development. **WARNING: Vaping THC has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.** **KEEP OUT OF REACH OF CHILDREN.**