

2019 OCT -4 AM 11: 59

This is an emergency amendment to 7.34.4 NMAC, Section, 14, effective 10/4/2019.

7.34.4.14 LABELING OF USABLE CANNABIS: A non-profit producer shall not sell or otherwise distribute a usable cannabis product that has not been packaged and labeled in accordance with this rule.

A. The label shall identify:

- ~~[A.]~~ **(1)** the name of the entity that produced the cannabis, and the name of the manufacturer of the cannabis-derived product (as applicable);
- ~~[B.]~~ **(2)** a batch number or code;
- ~~[C.]~~ **(3)** a production date or expiration date, including a “use by” or “freeze by” date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;
- ~~[D.]~~ **(4)** the number of units of usable cannabis or concentrated cannabis-derived product contained within the product, as identified in department rules for the enrollment of qualified patients;
- ~~[E.]~~ **(5)** for dried, usable cannabis: the quantity of THC and CBD, which shall be expressed by weight;
- ~~[F.]~~ **(6)** for concentrated cannabis derived product: the quantity of THC and CBD, which shall be expressed by weight and by percentage of total weight;
- ~~[G.]~~ **(7)** pesticide(s) used in the production of the cannabis or cannabis-derived product;
- ~~[H.]~~ **(8)** instructions for use;
- ~~[I.]~~ **(9)** warnings for use;
- ~~[J.]~~ **(10)** instructions for appropriate storage;
- ~~[K.]~~ **(11)** approved laboratory analysis, including the results of strength and composition within ten percent (10%) of numbers shown on the package;
- ~~[L.]~~ **(12)** the name of the strain, product facts, or a nutrition fact panel, and a statement that the product is for medical use by qualified patients, to be kept away from children, and not for resale;
- ~~[M.]~~ **(13)** whether the batch from which the product was derived was sampled and tested by an approved laboratory; and
- ~~[N.]~~ **(14)** the name of the department approved testing facility used for active ingredient analysis, and quantity of THC and CBD (as applicable).

B. Vaporization products label: All cannabis-derived products that are intended to be consumed by vaporization must additionally include a plainly legible health warning on the label that states in bolded text, **“WARNING: Vaping cannabis-derived products containing tetrahydrocannabinol (THC) has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death.”**

[7.34.4.14 NMAC - N, 2/27/2015; A, 2/29/2016; A/E, 10/4/2019]

NMAC Transmittal Form

NEW MEXICO  2019 OCT -4 AM 11: 59
Commission of Public Records
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Volume: Issue: Publication date: Number of pages: (ALD Use Only) Sequence No.

Issuing agency name and address: Agency DFA code:

Contact person's name: Phone number: E-mail address:

Type of rule action: (ALD Use Only)
New Amendment Repeal Emergency Renumber Most recent filing date:

Title number: Title name:

Chapter number: Chapter name:

Part number: Part name:

Amendment description (If filing an amendment):

Amendment's NMAC citation (If filing an amendment):

Are there any materials incorporated by reference? Yes No Please list attachments or Internet sites if applicable.

If materials are attached, has copyright permission been received? Yes No Public domain

Specific statutory or other authority authorizing rulemaking:

This emergency rulemaking by the Secretary of the Department of Health is made in accordance with the following authorities: Sections 9-7-6, 26-2B-2, 26-2B-7, 24-1-3, and 14-4-5.6 NMSA 1978.

Notice date(s): Hearing date(s): Rule adoption date: Rule effective date:

2019 OCT -4 AM 11: 59

Concise Explanatory Statement For Rulemaking Adoption:

Findings required for rulemaking adoption:

Findings MUST include:

- Reasons for adopting rule, including any findings otherwise required by law of the agency, and a summary of any independent analysis done by the agency;
- Reasons for any change between the published proposed rule and the final rule; and
- Reasons for not accepting substantive arguments made through public comment.

The findings in support of this emergency amendment are as stated in the attached letter from Cabinet Secretary Kathyleen M. Kunkel dated October 4, 2019, as well as the attached Advisory statement and Public Health Order, both dated October 3, 2019, which are hereby incorporated by reference.

Issuing authority (If delegated, authority letter must be on file with ALD):

Name:

Abinash Achrekar

Check if authority has been delegated

Title:

Deputy Cabinet Secretary

Signature: (BLACK ink only)

Date signed:



10-4-19

October 4, 2019

State Records and Archives
Attn: Pamela Lujan y Vigil
Rules Management Analyst
Administrative Law Division
Commission of Public Records
1205 Camino Carlos Rey
Santa Fe, NM 87505

Regarding Emergency Rule Amendment to 7.34.4.14 NMAC, "Labeling of Usable Cannabis"

Dear Ms. Lujan y Vigil:

The New Mexico Department of Health (Department) is filing an emergency rule amendment to 7.34.4.14 NMAC, "Labeling of Usable Cannabis". This emergency amendment is ensure the protection of patients enrolled in the New Mexico Medical Cannabis Program.

On October 3, 2019, the Department released a Public Health Advisory statement (see attached), which is hereby incorporated by reference. The Public Health Advisory statement concerns the recent outbreak of lung injuries associated with vaporizing ("vaping") of nicotine, tetrahydrocannabinol (THC), cannabidiol (CBD) and other substances, and warns of imminent public health risks posed by vaping and by the use of electronic cigarettes, which have recently been linked to severe breathing problems, lung damage, and even death. The Advisory statement urges members of the public to refrain from vaping, no matter the substance or source, until current investigations are complete.

Also on October 3, 2019, the Department issued a Public Health Order (see attached), in accordance with the Public Health Act, NMSA 1978, § 24-1-1 *et seq.* and the Lynn and Erin Compassionate Use Act, NMSA 1978, § 26-2B-1 *et seq.*, which is also hereby incorporated by reference. The Public Health Order directs the Medical Cannabis Program of the Department to require that medical cannabis producers affix a label to all cannabis-derived vaping products containing THC that includes the statement in bolded text: **"WARNING: Vaping cannabis-derived products containing tetrahydrocannabinol (THC) has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death."**

Consistent with the Public Health Order, and in accordance with the State Rules Act at NMSA 1978, § 14-4-5.6, the Department now amends rule 7.34.4.14 NMAC via emergency rulemaking. For the reasons stated, the Department finds that the time required to complete the procedures of the State Rules Act would cause an imminent peril to the public health, safety, and welfare. This emergency amendment is temporary, and will expire in 180 days pursuant to NMSA 1978, § 14-4-5.6(E), unless a permanent rule is adopted under the normal rulemaking process in that period.


OFFICE OF THE SECRETARY

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Sincerely,

Kathleen M. Kunkel
Cabinet Secretary



for Sec.

**New Mexico Department of Health
Public Health Advisory – October 2, 2019**

**Vaping Related Lung Injury: A Summary of the
Public Health Risks and Recommendations for the Public**

The New Mexico Department of Health (“NMDOH”) seeks to inform the public about the imminent public health risks posed by the use of electronic cigarettes (e-cigarettes), or vaping, which has recently been linked to severe breathing problems, lung damage, and even death. *NMDOH urges everyone to refrain from vaping, no matter the substance or source, until current investigations are complete.*

Background

Vaping is inhaling aerosol from an e-cigarette or other vaping device that heats a liquid that can contain nicotine, tetrahydrocannabinol (THC), cannabidiol (CBD) or other substances. The shapes and sizes of these devices vary and include colorful vape pens, modified tank systems, and new pod-based devices that can look like USB flash drives, cell phones, credit card holders, and highlighters. These devices are frequently referred to as e-cigarettes, e-cigs, vapes, vape pens, electronic vaporizers, pod mods, or pod systems.

Since June 2019, NMDOH has received reports that 14 individuals in New Mexico have developed severe lung injury requiring hospitalization after vaping, with certain individuals requiring intensive care. Across the U.S., the Centers for Disease Control and Prevention (CDC) has reported over 805 cases of lung damage associated with vaping across 46 states and 1 U.S. territory. Twelve deaths due to severe lung injury associated with vaping have been reported by CDC.

NMDOH, along with other states, the CDC, the U.S. Food and Drug Administration (FDA), local health departments, and healthcare providers are working hard to determine what is in the vape products that is making people sick. The FDA and the CDC have initiated investigations, including testing of a wide range of vapor products, and investigations into supply chains of vapor products. The CDC and FDA have not yet determined the specific cause of this outbreak and have recently advised consumers to consider refraining from vaping pending the outcome of their investigations.

Although NMDOH regulates in-state manufacturers of medical cannabis vaping products to ensure they are as safe as possible for those who choose to vape, NMDOH warns that individuals put themselves at risk any time they inhale a foreign substance into their lungs. The risk of vaping now includes death. CDC continues to warn that any tobacco product use, including e-cigarettes, is unsafe, especially for youth, pregnant, and breastfeeding women.

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Sudden and acute lung injury from vaping is a new health problem.

We are learning from this investigation that lung injury can happen very suddenly to people who vape, including people who have not been vaping for a long time, and young, healthy people who do not have lung disease or other health problems. This is different from most other health issues caused by vaping and smoking, which happen over a long time and can be worse in people who have other medical conditions. Additionally, most patients do not have a recent history of smoking regular cigarettes, suggesting these lung issues are exclusively related to vaping. Many types of vape products may be causing the lung damage from vaping.

Almost all people with lung damage from vaping say that they vaped or “dabbed” the cannabis products THC and CBD in cartridges, waxes, oils, and other forms. Some people report vaping only nicotine. Many people report vaping a combination of both nicotine and cannabis products. The investigation is still in process, but the one thing that people with the lung illness have in common is a history of vaping.

The CDC, FDA and state health departments are contacting the people who had lung injury from vaping to find out which products they used, where they purchased the products, and to collect their vape products to test for harmful ingredients.

Signs of severe lung injury include breathing problems and other symptoms.

People with lung injury from vaping typically have symptoms that start a few days to a few weeks before they go see a doctor. All people hospitalized developed some type of breathing problems, but many people also have other symptoms. The symptoms reported by those who have gotten sick are:

- Breathing symptoms: trouble catching their breath, coughing, chest pain
- Gastrointestinal symptoms: nausea, vomiting, diarrhea, abdominal pain
- Non-specific symptoms: feeling tired, fever, weight loss

There is no test that a doctor can do to know that breathing problems are from vaping right away. Laboratory blood tests and an x-ray or CT scan of the lungs may be necessary. People with vaping-related lung disease are usually admitted to the hospital because of their breathing problems.

Be aware that your child's respiratory issues could be related to vaping.

Parents should be aware that numerous cases involve children under age 18. E-cigarettes and vaping devices are available in more than 15,000 flavors that may be attractive to children. Preliminary results from the 2019 National Youth Tobacco Survey reported more than one in four high-school students use vapor products with an overwhelming majority reporting use of fruit, menthol, or mint flavors. The appeal of flavored nicotine vapor products, as well as advertising and promotional activities targeted at youth, are contributing to the dramatic increase in youth vaping. Be aware of the symptoms in case your middle or high school child develops symptoms and seek medical attention.

No definitive cause for severe lung injury related to vaping.

There are many different possible ingredients added to cannabis and nicotine to make the cartridges, waxes, and oils used for vaping. Multiple people who were diagnosed with lung damage from vaping say that they received the cannabis products from unlicensed smoke shops or individuals. Vape products sold by unlicensed retailers are not tested and can contain harmful ingredients. State and federal investigators do not know if all of the people in the country with this illness use the same vape products, or if the products were contaminated with the same substance. The long-term effects of vaping are still unknown, but these short-term effects are alarming.

Recommendations for the public.

1. NMDOH urges everyone to quit vaping altogether, but particularly THC products. For those who continue, you are urged to avoid buying any vaping products on the street and never modify a store-bought vape product.
2. If you, or your child, have vaped at all in the past few months and are having new problems with breathing or other symptoms, you should seek medical care immediately and tell your healthcare provider about your history of vaping.
3. If you decide to stop vaping, do not replace vaping with smoking combustible cigarettes. Ask your doctor for FDA-approved quitting treatments.

Resources:

For additional information, please contact NMDOH or review the [CDC's recommendations](#) about the vaping-related lung injuries.

**PUBLIC HEALTH ORDER
OF THE CABINET SECRETARY OF
THE NEW MEXICO DEPARTMENT OF HEALTH
OCTOBER 3, 2019
Warning Labels for Cannabis-Derived Vaping Products
Containing Tetrahydrocannabinol (THC)**

WHEREAS, as of October 3, 2019, the Centers for Disease Control and Prevention (“CDC”) has reported 805 cases of lung injury associated with using electronic cigarettes (e-cigarettes), or vaping, across 46 states and 1 U.S. territory. 12 deaths have been reported to the CDC as a result of this outbreak¹;

WHEREAS, on September 27, 2019, the CDC reported that among the 86 patients from Illinois and Wisconsin who developed lung injury associated with electronic cigarette use in the last three months, the use of tetrahydrocannabinol (“THC”)-containing e-cigarette products was reported by 87% of patients. The CDC noted further that “the predominant use of prefilled THC-containing cartridges among patients with lung injury associated with e-cigarette use suggests that they play an important role.”²;

WHEREAS, as of October 3, 2019, the New Mexico Department of Health (“NMDOH”), reports that 14 individuals in New Mexico have developed severe lung disease requiring hospitalization after vaping, with certain individuals requiring intensive care and endotracheal intubation. Ten of the 11 patients interviewed by NMDOH have reported using THC-containing e-cigarette products.

WHEREAS, the specific cause of the disease has not yet been determined, and interventions targeting e-cigarette and vaping products are necessary to protect public health;

WHEREAS, in response to the outbreak of vaping-associated lung disease, the New Mexico Department of Health issued an advisory health warning concerning the dangers of vaping;

WHEREAS, the vaping of cannabis-derived products, including products containing THC, is popular among enrolled qualified patients of the New Mexico Medical Cannabis Program; and

WHEREAS, the New Mexico Department of Health administers the New Mexico Medical Cannabis Program and licenses producers of medical cannabis and manufacturers of medical cannabis-derived products, including cannabis-derived vaping products.

NOW, THEREFORE, I, Kathyleen M. Kunkel, Cabinet Secretary of the New Mexico Department of Health, in accordance with the authority vested in me by the laws of New Mexico,

¹ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

² E-cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury — Illinois and Wisconsin, April–September 2019 (https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e2.htm?s_cid=mm6839e2_w)

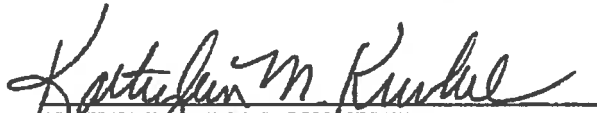
do hereby declare that the distribution and usage of cannabis-derived vaping products containing THC in New Mexico constitutes a condition of public health importance as defined in the New Mexico Public Health Act ("PHA"), § 24-1-2 (A), NMSA 1978, which presents a public health threat that is identifiable on an individual or community level, that can reasonably be expected to lead to adverse health effects in the community, and that poses an imminent threat of substantial harm to the population of New Mexico.

I DIRECT the Department of Health, Medical Cannabis Program to implement the full range of the powers and authority as set forth in the New Mexico Public Health Act, § 24-1-1, *et seq.*, NMSA (1978) and all regulations promulgated by the Secretary of Health pursuant thereto, and pursuant to the Lynn and Erin Compassionate Use Act, § 26-2B-1, *et seq.*, NMSA (1978) and all regulations promulgated pursuant thereto, to control conditions of public health importance by requiring that medical cannabis producers affix a label to all cannabis-derived vaping products containing THC that includes the statement in bolded text: **"WARNING: Vaping cannabis-derived products containing tetrahydrocannabinol (THC) has been associated with cases of severe lung injury, leading to difficulty breathing, hospitalization, and even death."** A licensee who fails to comply with this Order may be subject to disciplinary action pursuant to Department rule 7.34.4.24 NMAC, and any person who violates this Order may further be subject to criminal penalties pursuant to the Public Health Act at § 24-1-21.

THIS ORDER supersedes any other previous orders, proclamations, or directives to the extent they are in conflict. This Public Order shall take effect immediately and remain in effect until such time as it automatically expires 120 days from the date of issuance, or until such time as the NMDOH Cabinet Secretary rescinds it.

ATTEST:

THIS 3RD DAY OF OCTOBER, 2019


KATHYLEEN M. KUNKEL,
CABINET SECRETARY OF THE
STATE OF NEW MEXICO,
DEPARTMENT OF HEALTH