COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting

November 21, 2019

9AM

TOPIC	**PAGES**

Call to Order: Kris Ratliff, Committee Chairman

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment

Agenda Items

• Update on Regulatory/Policy Actions	1
• Recommend Adoption of Guidance for Sample Size for Pharmaceutical Processors	2-4
• Discussion on Prohibiting CBD and THC-A Oil Vaping Formulations	5-29
• Discussion of Topics Not Included in Periodic Regulatory Review	30-32
• Recommend Adoption of Regulations for Use of Medication Carousels and RFID Technology Currently used in Innovative Pilot Programs	33-36
• Consider Requirements for Maintenance of Records regarding Immunizations	37-52
• Develop and Recommend Adoption of Guidance for What Constitutes a "New" Prescription Requiring an Offer to Counsel	53-56
• Recommend Adoption of Guidance to Clarify if Collaborative Practice Agreement is Required for Each Patient	57-60
• Recommend Amending Guidance Document 110-15 Delegation of Authority for Disciplinary Matters	61-63
• Recommend Readoption of Guidance Documents 110-18 and 110-23	64-75
• Recommend Readoption of Guidance Documents 110-27 and 110-34	Handouts

Adjourn

The Board will have a working lunch at approximately 12pm.

Board of Pharmacy
Chart of Regulatory Actions as of November 12, 2019

Board of Pharmacy

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *Register Date: 11/11/19* *Comment period: 11/11/19 to 1/10/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] Proposed - *DPB Review in progress* [Stage 8779]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 538 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 15 and 21 [Action 4538] Final - *Register Date: 11/11/19* *Effective: 12/11/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals [Action 5396] Final - *Register Date: 11/11/19* *Effective: 12/11/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Final - *At Secretary's Office for 20 days*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *Register Date: 10/14/19* *Comment period: 10/14/19 to 12/13/19* *Emergency regulation in effect until 6/12/20*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Emergency/NOIRA - *AT Attorney General's Office* [Stage 8778]

Agenda Topic: Recommend Adoption of Guidance for Sample Size for Pharmaceutical Processors

Background:

Regulation 18VAC110-60-300 states the sample size shall be a statistically valid sample as determined by the board. Therefore, the board needs to identify what constitutes a statistically valid sample.

Included in Agenda Packet:

- Draft guidance document for consideration
- Sampling Requirements found in USP Chapter <561>

Possible Action:

- Motion to recommend full board to adopt draft guidance document for sample size for pharmaceutical processors as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Statistically Valid Sample Size for Pharmaceutical Processors

A sample size consistent with the sampling requirements found in United States Pharmacopeia Chapter <561> *Articles of Botanical Origin* shall be deemed to satisfy the requirement in Regulation 18VAC110-60-300 for a "statistically valid sample".

18VAC110-60-300

B. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

⟨561⟩ ARTICLES OF BOTANICAL ORIGIN

SAMPLING

In order to reduce the effect of sampling bias in qualitative and quantitative results, it is necessary to ensure that the composition of the sample used be representative of the batch of drugs being examined. The following sampling procedures are the minimum considered applicable to vegetable drugs. Some articles, or some tests, may require more rigorous procedures involving more containers being sampled or more samples per container.

Gross Sample

Where external examination of containers, markings, and labels indicates that the batch can be considered to be homogeneous, take individual samples from the number of randomly selected containers indicated below. Where the batch cannot be considered to be homogeneous, divide it into sub-batches that are as homogeneous as possible, then sample each one as a homogeneous batch. It is recommended to include samples from the first, middle, and last containers where the *No. of Containers in Batch* (*N*) is 11 or more and each container in the batch is numbered or lettered in order.

No. of Containers in Batch (*N*)	**No. of Containers to Be Sampled (*n*)**
1–10	All
11–19	11
>19	$n = 10 + (N/10)$

(Round calculated "*n*" to next highest whole number.)

Samples are taken from the upper, middle, and lower sections of each container. If the crude material consists of component parts that are 1 cm or less in any dimension, and in the case of all powdered or ground materials, withdraw the sample by means of a sampling device that removes a core from the top to the bottom of the container, not less than two cores being taken from different angles. For materials with component parts over 1 cm in any dimension, withdraw samples by hand. In the case of large bales or packs, samples should be taken from a depth of 10 cm because the moisture content of the surface layer may be different from that of the inner layers.

Prepare the gross sample by combining and mixing the individual samples taken from each opened container, taking care not to increase the degree of fragmentation or significantly affect the moisture content.

For articles in containers holding less than 1 kg, mix the contents, and withdraw a quantity sufficient for the tests. For articles in containers holding between 1 and 5 kg, withdraw equal portions from the upper, middle, and lower parts of the container, each of the samples being sufficient to carry out the tests. Thoroughly mix the samples, and withdraw an amount sufficient to carry out the tests. For containers holding more than 5 kg, withdraw three samples, each weighing not less than 250 g, from the upper, middle, and lower parts of the container. Thoroughly mix the samples, and withdraw a portion sufficient to carry out the tests.

Laboratory Sample

Prepare the laboratory sample by repeated quartering of the gross sample.

NOTE—Quartering consists of placing the sample, adequately mixed, as an even and square-shaped heap and dividing it diagonally into four equal parts. The two opposite parts are then taken and carefully mixed. The process is repeated as necessary until the required quantity is obtained.

The laboratory sample should be of a size sufficient for performing all the necessary tests.

Test Sample

Unless otherwise directed in the individual monograph or test procedure below, prepare the test sample as follows.

Decrease the size of the laboratory sample by quartering, taking care that each withdrawn portion remains representative. In the case of unground or unpowdered drugs, grind the withdrawn sample so that it will pass through a No. 20 standard-mesh sieve, and mix the resulting powder well. If the material cannot be ground, reduce it to as fine a state as possible, mix by rolling it on paper or sampling cloth, spread it out in a thin layer, and withdraw the portion for analysis.

Official text. Reprinted from *First Supplement* to *USP38-NF33*.

Agenda Topic: Discussion on Prohibiting CBD and THC-A Oil Vaping Formulations

Included in Agenda Packet:

- Excerpt of September 25, 2019 board meeting draft minutes
- FDA Statement issued October 4, 2019
- CDC Statement updated November 14, 2019
- Quarantine Order issued by Massachusetts Cannabis Control Commission
- Articles regarding recent state bans

Action:

- Discuss a possible recommendation to the full board regarding what action, if any, should be taken to address concerns with CBD or THC-A formulations intended to be vaped.

Adoption of emergency regulations for Pharmaceutical Processors

The board reviewed SB1719 passed during the 2019 General Assembly session and draft amendments relating to registered agents and wholesale distribution of CBD and THC-A oil. It was noted that SB1719 required the adoption of emergency regulations regarding the registration of registered agents for patients certified to receive cannabidiol or THC-A oil and for the wholesale distribution of oils between processors. During discussion, it was noted by the board that a Power of Attorney could obtain registration as a registered agent, but not as a parent/guardian.

MOTION:

The board voted unanimously to adopt the emergency regulations and Notice of Intended Regulatory Action to replace the emergency regulations for Pharmaceutical Processors as presented. (motion by Logan, seconded by Boone)

Adoption of exempt regulations for Pharmaceutical Processors

The board reviewed SB1719 and draft amendments to 18VAC110-60-130 and 18VAC110-60-170. SB1719 allows a processor to employ individuals with less than two years of experience to perform certain tasks under supervision and allows a processor to begin cultivation as soon as a permit is issued. These statutory amendments require an exempt regulatory action to conform the requirements in regulation to the new statutory allowances.

MOTION:

The board voted unanimously to adopt the exempt regulations for Pharmaceutical Processors as presented. (motion by Ratliff, seconded Nelson)

During discussion, several board members expressed concern for vaped products based on recent warnings from the CDC and FDA involving patient harm.

ACTION ITEM:

The board requested staff to research with counsel whether it had legal discretion in registering CBD and THC-A oil products that are intended to be vaped or it could prohibit pharmaceutical processors from producing vaped products.

Adoption of Proposed Regulations for Labeling Dispensed Prescriptions

At the June 5, 2019 board meeting, the board requested that staff send a letter regarding the proposed regulations for Labeling Dispensed Prescriptions to consumer groups such as Senior Connections and AARP to obtain feedback on this topic. The board was provided copies of the letters sent to Senior Connections, Virginia Citizen Consumer Council, Virginia Association of Area Agencies on Aging, Virginia Navigators, and Virginia AARP. The board did not receive any feedback from these organizations. The board reviewed the proposed amendments to 18VAC110-20-275 as recommended by the Regulation Committee and included in the agenda packet.

MOTION:

The board voted 7:3 to adopt the proposed amendments as recommended by the Regulation Committee. (motion by Nelson, seconded Boone; opposed by Warriner, Ratliff, and Jenkins)

FDA STATEMENT

Statement on consumer warning to stop using THC vaping products amid ongoing investigation into lung illnesses

For Immediate Release:

October 04, 2019

Statement From:

Norman E. "Ned" Sharpless MD

Español (/news-events/press-announcements/declaracion-del-comisionado-interino-de-la-fda-ned-sharpless-md-advirtiendo-los-consumidores-que)

Over the past several weeks, the U.S. Food and Drug Administration has been working tirelessly along with the U.S. Centers for Disease Control and Prevention (CDC) and other federal, state and local partners to investigate the distressing incidents of severe lung injuries and deaths associated with the use of vaping products. The latest number of reported cases and deaths (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know), released by the CDC yesterday, continues to underscore the need for us to gather critical information and provide consumers with actionable information to help best protect themselves and their loved ones.

This is why today, we're strengthening our message to the public in an updated consumer alert (/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping) stating that they should not use vaping products containing tetrahydrocannabinol (THC), the primary psychoactive component of the cannabis plant. Additionally, consumers who choose to use any vaping products should not modify or add any substances such as THC or other oils to products purchased in stores and should not purchase any vaping products, including those containing THC, off the street or from other illicit channels.

This is a complex, ongoing and evolving investigation. In addition to our own analyses, we are also diligently reviewing published literature of third-party analyses of samples and data, which are beneficial to our ongoing investigation. At this time, the FDA does not have enough data to identify the cause, or causes, of the lung injuries in these cases. Additionally, while no one compound or ingredient has emerged as a singular culprit, we do know that THC is present in most of the samples being tested. Because of this, the agency believes it is prudent to stop using vaping products that contain THC or that have had any substances added to them, including those purchased from retail establishments. Simply put, inhaling harmful contaminants in the lungs could put a patient's health at risk and should be avoided.

For those who choose to continue the use of vaping products, particularly those containing THC, we urge you to monitor for symptoms and promptly seek medical attention if you have concerns about your health. We are also continuing to encourage the public to submit detailed reports of any unexpected tobacco- or vaping-related health or product issues to the FDA via the online Safety Reporting Portal (/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products). And, importantly, no youth or women who are pregnant should be using any vaping product, regardless of the substance.

This alert builds on initial recommendations the FDA issued several weeks ago and is based on new information we're continuing to learn from both patients and the samples that have been tested so far. For example, additional testing revealed that a majority of the hundreds of samples of vaping products tested by the states or by the FDA so far have been identified as containing THC. Additionally, according to recent findings (https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e1.htm?s_cid=mm6839e1_w), most of the patients impacted by these illnesses reported using THC-containing products, suggesting THC products are playing a role in the these illnesses. That said, some patients have reported using both THC products and nicotine products, as well as a smaller number reporting using only nicotine products. Similarly, testing on the samples collected or received by the FDA shows a variety of products, or product components, with different ingredients or delivery systems making this investigation especially challenging.

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Federal, state and local agencies will continue to work as quickly as possible to get to the bottom of what's causing people to become ill by following up with patients and doctors to collect important details about the products or substances involved, where they were purchased and how they were being used. In particular, the FDA's work to investigate the illnesses includes sample collections in coordination with states, sample analysis, criminal and civil investigations, and coordination with state and federal partners.

Although these cases present similarly in patients, it is not clear if they have a common cause, or if they have differing pathogenesis with similar presentation. The investigation has not identified any specific substance or product that is linked to all cases. The FDA is using state-of-the-art methods to assess the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids along with opioids, cutting agents/diluents and other additives, pesticides, poisons and toxins. To date, the agency has collected or received more than 440 samples from 18 states – and that number continues to grow. The FDA is working quickly and thoroughly in testing the samples, prioritizing those associated directly with patient illnesses. More than half of the vaping liquid products have undergone some form of evaluation, with additional testing on these and other samples continuing daily.

We are leaving no stone unturned in following all potential leads regarding any particular product, constituent or compound that may be at issue. In that spirit, the FDA's Office of Criminal Investigations (OCI) began parallel investigative efforts shortly after the emergence of the associated illnesses.

Our OCI agents are focused on identifying the products that are making people ill and following the supply chain to the source. We are not pursuing any enforcement actions associated with personal use of any vaping products; our interest is in the suppliers. And as I previously said, if we determine that someone is manufacturing or distributing illicit, adulterated vaping products that caused illness and death for personal profit, we would consider that to be a criminal act. We are prepared to use our authorities to the fullest extent possible, and will work with other federal, state and local authorities to take appropriate action as the facts emerge in order to protect the public health.

What we've learned so far is that this ongoing investigation is complex and evolving. Every day we're gathering more information, and every day we seek to use that information to better understand the relationship between any specific products or substances and the reported illnesses.

We're committed to working to answer these and other critical questions as quickly as possible, but we also recognize that it will likely take some time. Importantly, the demographic diversity of the patients, as well as the products or substances they've reported using and the samples being tested may mean there are multiple causes of these illnesses—some of which may escape us or may never be fully understood.

As this complex investigation continues, we urge consumers to take heed of our warning and stop using THC vaping products, and to not use vaping products of any kind that are purchased off the street or from unknown sources. And we remain steadfast in our commitment to work with our federal, state and local partners to identify the cause or causes of these illnesses.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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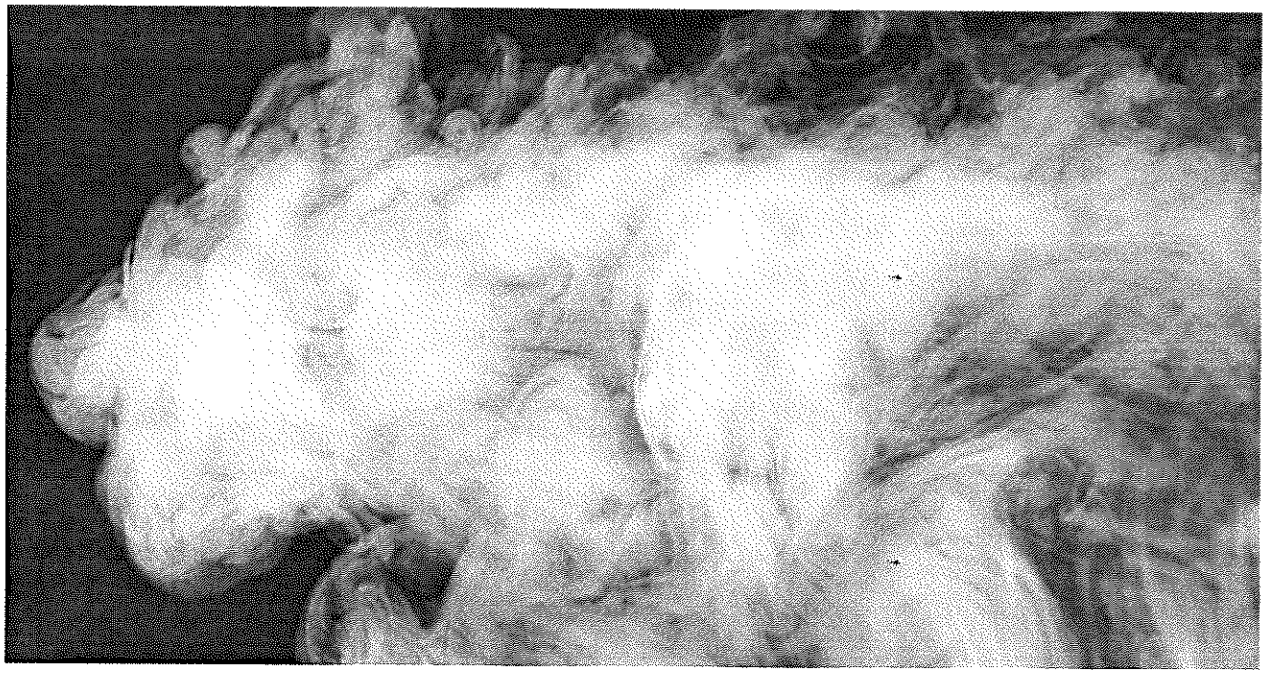
Related Information

- Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street (/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping)
- Lung Illnesses Associated with Use of Vaping Products (/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products)
- Safety Reporting Portal for Tobacco Products (/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products)

More Press Announcements (/news-events/newsroom/press-announcements)

Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street

FDA strengthens warning to public to stop using THC-containing vaping products and any vaping products obtained off the street.



Español (/consumers/articulos-en-espanol/actualizacion-de-enfermedades-vinculadas-al-uso-de-cigarrillos-electronicos-la-administracion-de)

Audience:

- Consumers and family members of consumers who use vaping products containing tetrahydrocannabinol (or THC), a psychoactive component of the marijuana plant.
- Consumers who have used vaping products of any kind obtained off the street or from unknown sources.
- Consumers experiencing symptoms such as cough, shortness of breath or chest pain after using vaping products.
- Health care professionals treating patients who use vaping products.

Purpose:

In its continued efforts to protect the public, the U.S. Food and Drug Administration (FDA) is strengthening its warning to consumers to stop using vaping products containing THC amid more than 1,000 reports of lung injuries (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)—including some resulting in deaths—following the use of vaping products. The FDA is working closely with the U.S. Centers for Disease Control and Prevention (CDC), as well as state and local public health partners to investigate these illnesses as quickly as possible.

While the work by federal and state health officials to identify more information about the products used, where they were obtained, and what substances they contain is ongoing, the FDA is providing members of the public with additional information to help protect themselves.

Problem and Scope:

A majority of the samples tested by the states or by the FDA related to this investigation have been identified as vaping products containing THC. Through this investigation, we have also found most of the patients impacted by these illnesses reported using THC-containing products, suggesting THC vaping products play a role in the outbreak.

Recommendations for the Public:

- Do not use vaping products that contain THC.
- Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources.
- Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments.
- No vaping product has been approved by the FDA for therapeutic uses or authorized for marketing by the FDA. The agency recommends contacting your health care provider for more information about the use of THC to treat medical conditions.
- No youth or pregnant women should be using any vaping product, regardless of the substance. Adults who do not currently use tobacco products should not start using these products. If you are an adult who uses e-cigarettes instead of cigarette smoking, do not return to smoking cigarettes.
- If you choose to use these products, monitor yourself for symptoms (e.g., cough, shortness of breath, chest pain) and promptly seek medical attention if you have concerns about your health. If you are concerned about your health after using a vaping product, contact your health care provider, or you can also call your local poison control center at 1-800-222-1222. Health care providers also can contact their local poison control center.

FDA Actions:

More information is needed to better understand whether there is a relationship between any specific products or substances and the reported illnesses. To help gather and analyze as much information as possible, the FDA is working closely with federal and state partners to identify the products or substances that may be causing the illnesses.

The FDA's Forensic Chemistry Center is using state-of-the-art technology to analyze hundreds of samples submitted by a number of states for the presence of a broad range of chemicals, including nicotine, THC, other cannabinoids, and opioids along with cutting agents/diluents and other additives, pesticides, poisons, heavy metals and toxins.

No one substance has been identified in all of the samples tested. Importantly, identifying any compounds that are present in the samples will be one piece of the puzzle but will not necessarily answer questions about what is causing these illnesses.

Federal and state partners are following any potential leads. The FDA is committed to taking appropriate actions as the facts emerge and keeping the public informed as we have more information to share.

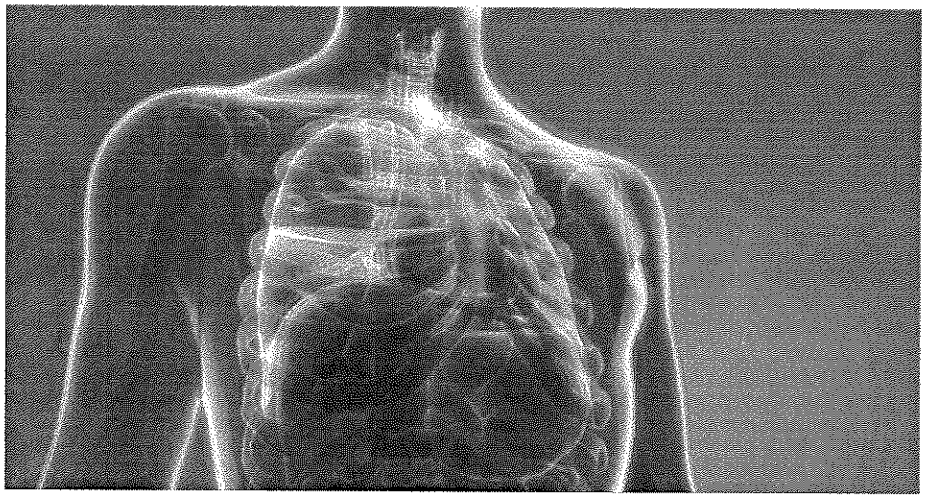
How to Report a Problem:

CDC and the FDA encourage the public to provide detailed information related to any unexpected tobacco- or e-cigarette-related health or product issues to the FDA via the online Safety Reporting Portal (https://www.safetyreporting.hhs.gov).

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Smoking & Tobacco Use

Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products



CDC, the U.S. Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners are investigating a multistate outbreak of e-cigarette, or vaping, product use associated lung injury (EVALI).

Updated November 14, 2019, at 1:00 PM EST

What is New

CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). Recent CDC laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in **all** of the samples. Vitamin E acetate might be used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.

CDC recommends that people should not use e-cigarette, or vaping, products that contain THC, particularly from informal sources like friends, or family, or in-person or online dealers. Until the relationship of vitamin E acetate and lung health is better understood, vitamin E acetate should not be added to e-cigarette, or vaping, products. In addition, people should not add any substance to e-cigarette or vaping products that are not intended by the manufacturer, including products purchased through retail establishments. CDC will continue to update guidance, as appropriate, as new data become available from this outbreak investigation.

What We Know

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New Laboratory Findings:

- Analyses of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) of patients with e-cigarette, or vaping, product use associated lung injury identified vitamin E acetate, an additive in some THC-containing products.
- Recent CDC laboratory test results of BAL fluid samples from 29 patients submitted to CDC from 10 states found vitamin E acetate in **all** of the samples.
  - THC was identified in 82% of the samples and nicotine was identified in 62% of the samples.
  - CDC tested for a range of other chemicals that might be found in e-cigarette, or vaping, products, including plant oils, petroleum distillates like mineral oil, MCT oil, and terpenes (which are compounds found in or added to THC products). None of these chemicals of concern were detected in the BAL fluid samples tested.
- This is the first time that we have detected a chemical of concern in biologic samples from patients with these lung injuries. These findings provide direct evidence of vitamin E acetate at the primary site of injury within the lungs.
- These findings complement the ongoing work of FDA and some state public health laboratories to characterize e-liquid exposures and inform the ongoing multistate outbreak.

About the Outbreak:

- As of **November 13, 2019**, 2,172* cases of e-cigarette, or vaping, product use associated lung injury (EVALI) have been reported to CDC from 49 states (all except Alaska), the District of Columbia, and 2 U.S. territories (Puerto Rico and U.S. Virgin Islands).
  - Forty-two deaths have been confirmed in 24 states and the District of Columbia **(as of November 13, 2019)**.
  - Latest outbreak information is updated every Thursday.
  - CDC continues to work closely with FDA, states, public health partners, and clinicians on this investigation.

About Patient Exposure:

- All EVALI patients have reported a history of using e-cigarette, or vaping, products.
  - Vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI).
  - THC is present in most of the samples tested by FDA to date, and most patients report a history of using THC-containing e-cigarette, or vaping, products.
  - The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak.

What We Don't Know

- While it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak.

What CDC Recommends

- CDC recommends that you do not use THC-containing e-cigarette, or vaping, products.
- CDC also recommends that people should **not**:

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- Buy any type of e-cigarette, or vaping, products, particularly those containing THC from informal sources like friends, or family, or in-person or online dealers.
- Modify or add any substances such as vitamin E acetate to e-cigarette, or vaping, products that are not intended by the manufacturer, including products purchased through retail establishments.

- Since the specific cause or causes of lung injury are not yet known, the only way to assure that you are not at risk while the investigation continues is to consider refraining from use of all e-cigarette, or vaping, products.
- Adults using e-cigarettes to quit smoking should not go back to smoking; they should weigh all risks and benefits and consider utilizing FDA-approved nicotine replacement therapies .
- Adults who continue to use an e-cigarette, or vaping, product, should carefully monitor themselves for symptoms and see a healthcare provider immediately if they develop symptoms like those reported in this outbreak.
- Irrespective of the ongoing investigation:
  - E-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant.
  - Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. There is no safe tobacco product. All tobacco products, including e-cigarettes, carry a risk.
  - THC use has been associated with a wide range of health effects, particularly with prolonged frequent use. The best way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products. Persons with marijuana use disorder should seek evidence-based treatment by a health care provider.

Key Facts about Use of E-Cigarette, or Vaping, Products

- Electronic cigarettes — or e-cigarettes — are also called vapes, e-hookahs, vape pens, tank systems, mods, and electronic nicotine delivery systems (ENDS).
- Using an e-cigarette product is commonly called vaping.
- E-cigarettes work by heating a liquid to produce an aerosol that users inhale into their lungs.
- The liquid can contain: nicotine, tetrahydrocannabinol (THC) and cannabinoid (CBD) oils, and other substances and additives. THC is the psychoactive mind-altering compound of marijuana that produces the "high".

Key Facts about Vitamin E Acetate

- Vitamin E acetate might be used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.
- Vitamin E is a vitamin found in many foods, including vegetable oils, cereals, meat, fruits, and vegetables. It is also available as a dietary supplement and in many cosmetic products, like skin creams.
- Vitamin E acetate usually does not cause harm when ingested as a vitamin supplement or applied to the skin. However, previous research suggests when vitamin E acetate is inhaled, it may interfere with normal lung functioning.

If you have questions about CDC's investigation into the lung injuries associated with use of e-cigarette, or vaping, products, contact CDC-INFO or call 1-800-232-4636.

Latest Outbreak Information

Updated every Thursday

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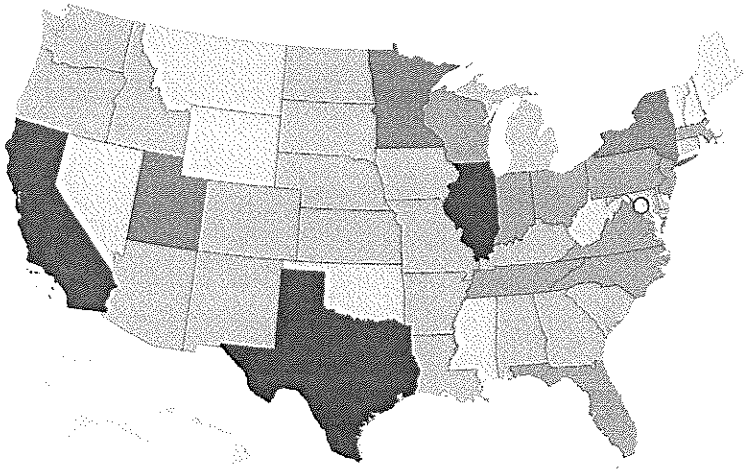
- This complex investigation spans almost all states, involves over 2,000 patients, and a wide variety of brands and substances and e-cigarette, or vaping, products.
- As of **November 13, 2019**, 2,172* cases of e-cigarette, or vaping, product use associated lung injury (EVALI) have been reported to CDC from 49 states (all except Alaska), the District of Columbia, and 2 U.S. territories (Puerto Rico and U.S. Virgin Islands).
  - Forty-two deaths have been confirmed in 24 states and the District of Columbia **(as of November 13, 2019)**.
    - The median age of deceased patients was 52 years and ranged from 17 to 75 years **(as of November 13, 2019)**.
  - More deaths are under investigation.
- Among 1,378 patients with data on sex **(as of October 15, 2019)**:
  - 70% of patients are male.
- Among 1,364 patients with data on age **(as of October 15, 2019)**:
  - The median age of patients is 24 years and ages range from 13 to 75 years.
  - 79% of patients are under 35 years old.
  - By age group category:
    - 14% of patients are under 18 years old;
    - 40% of patients are 18 to 24 years old;
    - 25% of patients are 25 to 34 years old; and
    - 21% of patients are 35 years or older.
- Among 867 patients with information on substances used in e-cigarette, or vaping, products in the 3 months prior to symptom onset** **(as of October 15, 2019)**:
  - About 86% reported using THC-containing products; 34% reported exclusive use of THC-containing products.
  - About 64% reported using nicotine-containing products; 11% reported exclusive use of nicotine-containing products.

Number of Lung Injury Cases Reported to CDC as of November 13, 2019

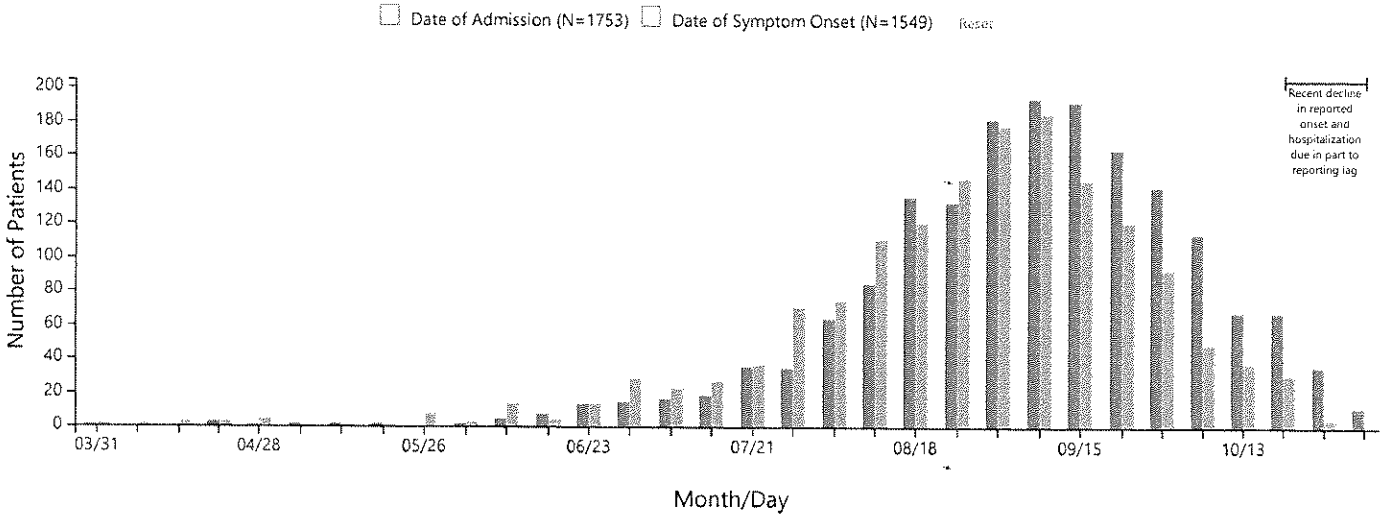


Territories AS GU MH FM PW PR VI

Data Table

15

Dates of symptom onset and hospital admission for patients with lung injury associated with e-cigarette use, or vaping — United States, March 31–November 9, 2019



Data Table

	03/31/2019	04/07/2019	04/14/2019	04/21/2019	04/28/2019	05/05/2019	05/12/2019	05/19/20
Date of Admission (N=1753)	1	0	0	3	1	2	2	
Date of Symptom Onset (N=1549)	2	2	3	3	5	1	1	

Scroll for additional info

Region Name	Start Date	End Date
Recent decline in reported onset and hospitalization due in part to reporting lag	10/20/2019	11/03/2019

What CDC is Doing

Public Health Response:

- CDC's Lung Injury response efforts are committed to:
  - Identify and define the risk factors and the source for lung disease associated with e-cigarette product use, or vaping.
  - Detect and track confirmed and probable cases in the US.
  - Communicate actionable recommendations to state, local, and clinical audiences.
  - Establish lab procedures that can assist with the public heath investigation and patient care.

Partnerships:

- CDC is working 24/7 to identify the cause or causes of this outbreak.
- CDC continues to work closely with FDA, states, public health partners, and clinicians on this investigation by providing consultation and technical assistance to states on communication, health alerts, public outreach, and surveillance.

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- CDC has activated the Emergency Operations Center (EOC) to coordinate activities and provide assistance to states, public health partners and clinicians around the nation.
- CDC worked with states to create primary and out-of-hospital case definitions to classify confirmed and probable cases in a consistent way. States are in the process of classifying patients.
  - CDC will report numbers of confirmed and probable lung injury cases once states have finalized their classification of cases.
- By invitation, CDC has deployed Epidemic Intelligence Service (EIS) officers and other CDC staff to support states.

Media and Communication:

- CDC is maintaining an outbreak webpage with key messages and weekly updates on case counts, deaths, and resources.
- CDC is holding congressional briefings, media telebriefings, and regular calls with health departments, clinicians to provide timely updates.

Laboratory Testing:

- CDC is currently testing bronchoalveolar lavage (BAL) fluid samples and other samples.
- CDC is testing pathologic specimens, including lung biopsy or autopsy specimens, associated with patients.
- CDC is offering aerosol emission testing of case-associated product samples from e-cigarette, or vaping, products and e-liquids. Analysis of aerosol emissions will augment FDA's ongoing work to characterize e-liquid and will improve our understanding of exposure among case-patients associated with the Lung Injury outbreak. CDC is coordinating e-cigarette, or vaping, product analysis with FDA.
- Results may provide insight into the nature of the chemical exposure(s) contributing to this outbreak.
- CDC developed guidance documents to assist public health laboratories, healthcare providers, pathologists, and others with specimen collection, storage, and submission to CDC for testing.
- For more information and resources visit For the Public, For Healthcare Providers and For State and Local Health Departments as well as our Publications and Resources page.

* The increase in lung injury cases from last week represents both new patients and recent reporting of previously-identified patients to CDC.

** Based on complete reports received.

Page last reviewed: November 14, 2019
Content source: Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion

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Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

November 12, 2019

Licensed Marijuana Establishments
Licensed Medical Marijuana Treatment Centers

Case No. 2019AM-0065-00

QUARANTINE ORDER
APPLYING TO VAPORIZER PRODUCTS
M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi),
935 CMR 500.340: Quarantine Order, and
935 CMR 501.340: Quarantine Order

Relying on M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi) and associated regulatory authority, the Commonwealth of Massachusetts Cannabis Control Commission (Commission), acting through its Executive Director, orders all licensed Marijuana Establishments and Medical Marijuana Treatment Centers (each, the "Respondent" and collectively, the "Respondents") to quarantine vaporizer products based on his determination that these products pose an immediate or serious threat to the public health, safety, or welfare and the quarantine is necessary to protect the public health, safety or welfare. Marijuana Establishments remain subject to compliance with the existing order issued by the Commissioner of the Department of Public Health (DPH) and emergency regulations issued by DPH banning adult-use vaporization products.

This order shall be effective upon all Respondents issued a final license on or before November 12, 2019, at 12:01 P.M. ("effective date"). Respondents issued a final license after the effective date shall be subject to the order on receipt of notice of the order.

Findings

In making its determination, the Commission finds as follows:

(1) In the course of an ongoing investigation into the nation-wide outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI), the Centers for Disease Control (CDC), Food and Drug Administration (FDA), state and local health departments, and public health partners collected data from EVALI patients during from August 2019 to October 2019. In response to this outbreak, the DPH Commissioner banned vaporization products and DPH subsequently issued emergency regulations.

(2) The Commission remains in contact with CDC, FDA, and DPH to receive updates on reported cases of illness associated with vaporizer products and devices.

(617) 701-8400 | MassCannabisControl.Com | CannabisCommission@State.MA.US

(3) During its investigative process, the CDC received Bronchoscopy and bronchoalveolar lavage (BAL) fluid specimens from 29 EVALI patients in 10 states.[1]

(4) The CDC's investigative update of November 2019 found "direct evidence of vitamin E acetate at the primary site of injury within the lungs."[2]

(a) On November 8, 2019, the CDC issued an investigative update finding that vitamin E acetate was detected in all 29 BAL samples, and that THC or its metabolites were detected in 23 of 28 EVALI patient BAL samples. The CDC's investigative update further found that as of October 15, 2019, 86% of 867 EVALI patients reported using THC-containing products in the three months preceding symptom onset.[3]

(b) In its investigation, the CDC tested for a wide range of substances found in e-cigarette, or vaping, products, including plant oils, petroleum distillates like mineral oil, medium-chain triglyceride oil (MCT oil), and terpenes, which are compounds botanically found in or artificially added to THC products. Among the tested substances, only Vitamin E acetate was detected in the CDC's testing analysis.[4]

(c) The BAL fluid specimens represent the first identification of a "potential toxicant of concern" within EVALI patients. The findings yielded by the EVALI-patient biologic specimens now provide direct evidence of vitamin E acetate at the primary site of patient injury; however, further study is needed before a causal link can be established between vitamin E acetate exposure and EVALI.[5]

(d) The CDC findings do not rule out the possibility that more than one compound or ingredient may cause lung injury, or that other toxicants may also contribute to EVALI.[6]

(e) The CDC findings do not identify whether the THC products implicated in the EVALI patient study were sourced from legal or illicit markets. However, a recent coordinated epidemiologic investigation by the Illinois Department of Public Health and Wisconsin Department of Public Health involved detailed interviews with 86 patients reporting lung injury symptoms and finding that "the

[1] Blount BC, Karwowski MP, Morel-Espinosa M, et al., Evaluation of Bronchoalveolar Lavage Fluid from Patients in an Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — 10 States, August–October 2019. MMWR Morb Mortal Wkly Rep. ePub: 8 November 2019, available at http://dx.doi.org/10.15585/mmwr.mm6845e2.
[2] Id.
[3] Id.
[4] Id.
[5] Id.
[6] Id.

vast majority reported using illicit THC-containing products sold as prefilled cartridges and obtained from informal sources."[7]

(5) The Commission's regulations require all marijuana products sold or marketed for sale undergo contaminant testing, including testing for heavy metals, by Independent Testing Laboratories accredited to the International Organization for Standardization 17025 (ISO/IEC 17025: 2017) and performed in accordance with the Commission's Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products. 935 CMR 500.160; 935 CMR 501.160.

(6) The Commission's existing testing regulations and protocols do not require testing for vitamin E acetate.

(7) Current manufacturing processes and information available to the Commission do not definitively preclude the possibility that licensed vaporizer products contain vitamin E acetate or other potential ingredients of concern.

(8) Current manufacturing processes and information available to the Commission do not definitively preclude the possibility that licensed vaporizer products contain devices or component parts that pose adverse health effects when used to vaporize cannabis oil.

(9) The Commission has broad authority to investigate the risk to public safety, health, and welfare posed by vaporizer products and their component parts through product testing and any other means pursuant to its statutory and regulatory authority and to quarantine products that pose an immediate or serious threat to the public health, safety or welfare. M.G.L. c. 94I, M.G.L. c. 94G, § 4(a)(xix) and (a½)(xxxi), 935 CMR 500.340, 935 CMR 501.340.

(10) The Commission will coordinate with DPH to monitor and evaluate the causes and findings related to EVALI cases. M.G.L. c. 94I, M.G.L. c. 94G, § 4(k). To this end, at its November 7, 2019 public meeting, the Commission formally requested that DPH provide the Commission with all information collected regarding cases of pulmonary illness reported from September 24, 2019 to November 7, 2019.

(11) On October 24, 2019, Suffolk Superior Court Judge Douglas H. Wilkins, issued a decision in the matter of Vapor Technology Association & others v. Charlie Baker and another, Suffolk Superior Court Civil No. 2019-3102-D, and found

[7] Ghinai I, Pray IW, Navon L, et al. E-cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury — Illinois and Wisconsin, April–September 2019. MMWR Morb Mortal Wkly Rep 2019;68:865–869, available at http://dx.doi.org/10.15585/mmwr.mm6839e2 ("Among 112 THC-containing products for which the source was reported, 100 (89%) were acquired from informal sources (e.g., friends, family, school, dealers, or off the street). The remaining 12 were bought at an out-of-state cannabis dispensary (six), online (five), or from a vape or tobacco shop (one).").

that "[t]he parties have not presented any evidence specifically linking the vaping of crushed cannabis flower to the outbreak" of vaping-related illnesses. Based on this finding, he ordered that the display and sale of medical-use products for the vaping of crushed marijuana flower sold lawfully in the Commonwealth be permitted.

Order

Based on his authority and these findings, the Executive Director has determined that additional testing of certain products for vitamin E acetate and other substances of concern and the development of additional regulatory and policy safeguards is necessary to protect the public health, safety and welfare.

The Commission, acting through its Executive Director, hereby **ORDERS** as follows:

(1) Respondent shall quarantine and cease the sale and distribution of the following marijuana products and devices:

   (a) All vaporizer products defined as any product intended for human consumption by THC inhalation whether for one-time use or reusable, that relies on vaporization or aerosolization, including but not limited to vape pens, vape cartridges, aerosol products, and inhalers ("vaporizer products" or "quarantine products"); and

(2) Nothing herein shall prevent the display, sale or distribution of devices designed to exclusively vaporize marijuana flower for medical-use patients.

(3) Respondent shall place quarantined products on administrative hold in the Commission's seed-to-sale tracking system of record. Respondent shall similarly designate quarantined products in any secondary seed-to-sale tracking system utilized by the Respondent;

(4) Respondent may transfer, transport or otherwise distribute vaporizer products to other Marijuana Establishments, Medical Marijuana Treatment Centers and Independent Testing Laboratories subject to compliance with the Commission's laws, regulations, and policies, but may not sell the vaporizer products subject to this order to patients, caregivers or consumers, unless otherwise authorized by the Commission;

(5) In accordance with the Commission vote at the public meeting on November 7, 2019, and as otherwise allowed by law, the Commission may promulgate regulations and policies pertaining to new and existing vaporizer products to ensure public safety, including additional testing for vaporizer products and devices.

(6) Respondent may request an amendment or modification of this order to authorize the sale of specific vaporizer products that have been tested and deemed compliant with the Commission's regulations and policies;

(7) Nothing herein prohibits or otherwise prevents a certifying health care provider and qualifying patient from discussing the respective risks and benefits of marijuana products, including vaporizer products, within the context of a bona fide healthcare provider-patient relationship;

(8) Respondent shall post notice of this order in a conspicuous location at the Marijuana Establishment or Medical Marijuana Treatment Center;

(9) Respondent shall immediately comply with the requirements of this order upon its receipt.

(10) Respondent shall comply with all provisions of 935 CMR 500.340 and 935 CMR 501.340; and

(11) Respondent shall comply with all provisions of 935 CMR 500.000, *et seq.* 935 CMR 501.000, *et seq.*, and 935 CMR 502.000, *et seq.*.

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that his order shall take effect on Tuesday, November 12, 2019, at 12:01 P.M. The Commission may amend the effective date of this order based on developing public health findings, legal proceedings, or other matters not known to the Commission at the time the order was issued. Failure to comply with the above conditions may result in action against Respondent up to and including suspension and/or revocation of licensure.

Nothing herein should be construed as precluding or limiting the Commission's authority to take additional administrative action to protect the public health, safety, and welfare. The Commission may investigate whether certain marijuana products and/or marijuana accessories or their component parts pose a substantial risk to public health and take appropriate action.

The order shall remain in effect until the Commission rescinds or amends the order or until such other time specified in 935 CMR 500.500 and 935 CMR 501.500. The Commission may amend or modify this order as applicable to one particular licensee, a group of licensees or as applicable to all Commission licensees. The Commission may adjust the scope of quarantined products in accordance with this order and 935 CMR 500.321: *Administrative Hold* and 935 CMR 501.321: *Administrative Hold.*

Respondent may request a hearing within twenty-one (21) calendar days after the effective date stated below by making such request in writing to the Commission at 101 Federal Street, 13th Floor, Boston, MA 02210. The Commission may consolidate multiple hearing requests into a single group hearing based on common issues of fact and law.

Questions about the order may be directed in writing to the above address, by phone (617-701-8400) on Monday – Friday from 9:00 A.M. – 5:00 P.M. or email at CannabisCommission@ma.state.us.

Effective this 12th day of November 2019:

Commonwealth of Massachusetts Cannabis Control Commission

Shawn Collins, Executive Director

Commission's Order Supports Ban on Marijuana Vaping Products

The state's 4-month ban on marijuana oil vaping products will remain in place after the state's Cannabis Control Commission issued a quarantine order.

By **Associated Press**, Wire Service Content Nov. 12, 2019, at 7:08 p.m.

THE ASSOCIATED PRESS

BY STEVE LEBLANC, Associated Press

BOSTON (AP) — The state's four-month ban on marijuana oil vaping products will remain in place after the state's Cannabis Control Commission issued a quarantine order Tuesday.

The order targets vape pens, vape cartridges, aerosol products, and inhalers that use oil-based vaping materials. It doesn't apply to medical marijuana vaping devices designed for marijuana flower, which don't use oil-based materials.

The commission is also asking testing labs if they can check for vitamin E acetate. The Centers for Disease Control and Prevention has identified vitamin E as a culprit in vaping-associated lung injuries. The labs currently test for contaminants like heavy metals.

Suffolk Superior Court Judge Douglas Wilkins had ruled last week that marijuana cultivated for medical use, including oil-based vaping materials, must be exempted from Republican Gov. Charlie Baker's four-month ban on vaping materials starting Tuesday — unless the cannabis commission took action since the commission is the single state entity authorized to regulate marijuana.

Tuesday's action by the commission continues the ban for oil-based vaping materials for medical use.

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The vaping industry is also challenging the broader ban in court.

Shops caught selling vaping materials during the ban face fines of up to $1,000 per offense. There is no prohibition against individuals owning or using vaping products.

The industry has argued the ban will destroy the state's $331 million nicotine vapor products industry and irreparably harm local businesses.

Baker issued the emergency ban in September in response to lung illnesses attributed to use of e-cigarette products.

State health officials last week announced that a third state resident died from a vaping-related lung illness.

The state Department of Public Health announced Wednesday that a man in his 50s from Worcester County died, after telling officials he vaped both nicotine and the marijuana compound THC.

Officials say more than 200 suspected cases of vaping-associated lung injury have been reported to the health department since September.

The action by the cannabis commission comes as state lawmakers prepare to debate a bill that would ban flavored vaping and tobacco products, including menthol and mint flavors. Lawmakers argue that the flavored products are meant to entice young teens into smoking.

Anti-smoking activists praised the Massachusetts House for taking up the measure.

"Ending the sale of all flavored tobacco products, including mint and menthol, is smart public health policy and will prevent thousands of kids in Massachusetts from becoming enticed into a lifetime of addiction," said Kevin O'Flaherty from the Campaign for Tobacco-Free Kids.

Some convenience store owners oppose the ban on menthol cigarettes and have pressed lawmakers to eliminate that portion of the bill.

House lawmakers plan to debate the measure on Wednesday.

Tags: Massachusetts, Rhode Island

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RECOMMENDED

TIME

As the Number of Vaping-Related Deaths Climbs, These States Have Implemented E-Cigarette Bans

Getty Images

BY JAMIE DUCHARME
UPDATED: OCTOBER 15, 2019 4:28 PM ET | ORIGINALLY PUBLISHED: SEPTEMBER 25, 2019

Amid growing concern over a mysterious outbreak of vaping-related lung illnesses and deaths, as well as a persistent epidemic of youth use, states are stepping in to limit access to e-cigarette products—but many are facing challenges from vaping retailers and industry groups in court.

State vaping bans are filling what many see as a regulatory void caused by federal inaction. E-cigarettes work by vaporizing a liquid mixture of nicotine, flavorings and other chemicals, and many proponents argue that they are a healthier alternative to cigarettes. The Food and Drug Administration (FDA) did not gain regulatory power over e-cigarettes until 2016, so many popular brands that launched before that date, including market leader Juul, are currently available for sale despite lacking explicit FDA authorization. The agency has given manufacturers until May 2020 to retroactively apply for authorization; if at that point they cannot prove their products are "appropriate for the protection of public health," they could be removed from the market.

The Trump Administration in September announced a plan to pull youth-friendly flavored e-cigs from the market, at least until FDA applications are complete.

As states wait for a federal policy to be finalized, some are acting on their own, and a number of others—including Illinois, New Jersey and Delaware—are considering similar legislation. These are the states that have enacted vaping bans so far, and those that have been blocked in court.

Michigan

In early September, Michigan became the first state to announce its intent to limit the sale of vaping products, when Gov. Gretchen Whitmer said she would issue an emergency ban on the online and retail sale of nicotine vaping products in any flavor except tobacco. Whitmer also said she would restrict the marketing of vaping products by forbidding the use of terms like "clean," "safe" and "healthy." (While e-cigarettes contain fewer known toxic chemicals than traditional cigarettes, research on their health effects is inconclusive.)

The emergency ban was made official on Sept. 18, and was set to last 180 days. Retailers were given two weeks to comply with the policy—but on Oct. 15, a Michigan Court of Claims judge sided with retailers who claimed in a lawsuit that Whitmer overstepped her authority by enacting the ban, the Detroit *Metro Times* reports. The judge's injunction, which lasts six months, means shops can once again sell flavored vaping products, the *Metro Times* reports.

Before the injunction, Michigan lawmakers were working on implementing a permanent policy, according to the state's Department of Health and Human Services.

New York

New York on Sept. 17 became the first state to actually implement a statewide ban on most flavored nicotine vaping products, just days after Gov. Andrew Cuomo called for emergency action. Cuomo's policy drew some derision from public health advocates, however, because it does not restrict the sale of menthol-flavored products. (The state's health commissioner is evaluating an additional ban on menthol products, according to Cuomo's office.) Though they have been more heavily regulated than tobacco-flavored products, mint and menthol e-liquids have not been subject to as many sale restrictions as sweet and fruity flavors, because some public health officials fear that banning them would push users back toward menthol-flavored tobacco products still for sale. Still, federal data show mint and menthol vaping products are today almost as popular among teenagers as fruit flavors.

Just before the ban was set to take effect Oct. 4, an appellate court placed a hold on the ban, allowing retailers to continue selling their products. Jurisdiction passed to the state Supreme Court, which will decide whether to grant the Vapor Technology Association, an industry group, a preliminary injunction on the ban.

Massachusetts

On Sept. 24, Gov. Charlie Baker declared a public health emergency in the face of more than 500 vaping-related lung illnesses and at least seven deaths reported to the U.S. Centers for Disease Control and Prevention (CDC), including five illnesses in Massachusetts. Baker also announced the country's strictest vaping prohibition yet: a four-month, statewide ban on online and retail sales of all marijuana and tobacco vaping products, flavored or otherwise. A release from Baker's office suggests that Massachusetts lawmakers chose to ban both marijuana and nicotine products due to continuing uncertainty over what is causing the lung illnesses reported across the country. The CDC has said that many of the people who have reported vaping-related illnesses used products containing THC, a compound in marijuana, but some reported using only nicotine.

Massachusetts' policy went into effect immediately, and lasts through January 25, 2020.

Rhode Island

The day after Massachusetts' ban was announced, Rhode Island Gov. Gina Raimondo signed an executive order directing the state's Department of Public Health to ban the sale of flavored e-cigarettes in the state. Raimondo did not specify at the signing whether the order also applies to menthol flavors, but noted that the ban will not extend to unflavored tobacco products.

At a briefing on Sept. 25, officials said the ban could go into effect as early as the following week. NBC 10 News reports it will be in place for 120 days afterwards. The state can then extend it for another 60 days.

At the signing of the order, Raimondo called vaping a "public-health crisis" for children, and said she is convening a group of medical experts to advise her on the best ways to contain the problem.

Montana

Gov. Steve Bullock on Oct. 8 directed Montana's Department of Public Health and Human Services to draft emergency administrative rules that would ban the sale of all flavored e-cigarettes, including those containing THC and CBD, for 120 days. The rules were set to take effect on Oct. 22, but a Montana judge on Oct. 19 signed a temporary restraining order that blocked the policy, after vape shop owners filed a lawsuit claiming the action was overly restrictive and could put stores out of business.

Washington

In Washington state, health officials on Oct. 9 passed an emergency rule banning the sale of flavored vaping products. The 120-day rule went into effect following an executive order from Gov. Jay Inslee, who called on the state's Board of Health to ban all flavored vaping products, including those containing THC. The decision was met with fierce opposition from e-cigarette users who said they had used the products to quit smoking, as well as vape shop owners. Some chanted "shame" at the Board of Health's voting session, the Seattle *Times* reports.

Oregon

Following in its neighbor's footsteps, Oregon health officials on Oct. 11 filed rules that would forbid the sale of flavored nicotine and cannabis vaping products for six months, and subject repeat-offending retailers to fines of up to $500 per violation, per day. As in other states, however, Oregon's policy was partially blocked by an appeals judge, who halted the ban on nicotine products. The ban on cannabis products was not affected.

California

Though California has not enacted a statewide ban on vaping products, Gov. Gavin Newsom on Sept. 16 issued an executive order focused on curtailing the state's youth vaping epidemic. Among other actions, the order allocates at least $20 million for a "vaping awareness campaign," and calls on state agencies to develop recommendations for limiting the sales of vaping products to anyone younger than 21, and the sales of illegal and counterfeit vaping products broadly. The order also requests that the California Department of Public Health develop standards requiring e-cigarette retailers to post warning signs about the health risks of vaping. Newsom has also said he would like to ban flavored e-cigarettes outright, but cannot do so through executive action alone.

Over the summer, San Francisco—where Juul is based—became the first major U.S. city to ban the sale of all nicotine e-cigarette products. A Juul-backed coalition opposes the ban, and it will go before a public vote in November. The Los Angeles County Board of Supervisors is moving toward a similar ban on flavored products.

WRITE TO JAMIE DUCHARME AT JAMIE.DUCHARME@TIME.COM.

TIME

Issues for Discussion

Comments on Proposed Regulations

Periodic Review

Board of Pharmacy

Final amendments to regulations pursuant to the Board's periodic review were published in the Virginia Register of Regulations on November 11, 2019 and become final on December 11, 2019. There were comments on proposed regulations that addressed issues that were either: 1) not included in the proposed regulations or the Notice of Intended Regulatory Action; 2) not on sections being amended; or 3) would require a change in the Code of Virginia.

The Regulation Committee should review those comments and decide which, if any, it wishes to discuss further and/or address in regulatory or statutory changes.

The following written comment was received from the National Association of Chain Drug Stores (NACDS):

> *Delete definition of "personal supervision" to allow audio-visual technology supervision of compounding in retail pharmacies.
>
> *In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians.
>
> **In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.
>
> **In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

The following written comment was received from CVSHealth (it was also posted electronically on the Townhall):

> *In section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician.

*In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist.

**In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.

*In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency.

*In section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

*In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

*In section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date.

*In section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device.

***In section 240, allow for chart orders in correctional facilities. (Current language identical to 54.1-3408.01)

**In section 420, change the provision of a seven-day supply of a drug in a unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply.

* = Issue was not addressed in the Notice of Intended Regulatory Action or proposed regulations

** = Section was not amended in the proposed regulatory action

*** = Requires a change in the Code of Virginia

Agenda Item: Consideration of amendments to incorporate changes currently in approved as pilots

Included in your agenda package is:

DRAFT amendments to 18VAC110-20-425 and 18VAC110-20-460

Staff note:

Amendments would incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock.

Committee action:

Motion to recommend amendments to sections 425 and 460 by a fast-track action.

18VAC110-20-425

C. Medication carousels that are a component of a robotic pharmacy system in a hospital, may be utilized to store drugs; however, a pharmacist shall verify all drugs manually picked from the carousel.

Pharmacist verification of all manual picks is not required provided:

1. the order for the patient specific drug, verified by a pharmacist for accuracy, is electronically transmitted to the medication carousel from the computer operating the system; and bar code technology is utilized to verify the accuracy of the manually picked drug by both the pharmacy technician who must scan each drug unit removed from the medication carousel prior to dispensing and by the nurse, or other person authorized to administer the drug, prior to administration of the drug to the patient.
2. the drug is removed from the medication carousel to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia, and bar code technology is utilized to verify the accuracy of the manually picked drug by the pharmacy technician who must scan each drug unit removed from the medication carousel prior to removal.

A pharmacist shall verify all manual picks from a medication carousel that is not utilized as a component of a robotic pharmacy system.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

<u>E. A hospital pharmacy may utilize Radio-frequency Identification (RFID) to identify and track drugs to be used as floor stock. Pharmacies utilizing RFID tagging of drugs shall be exempt from the requirements of subsection C of 18 VAC 110-20-490, subsection A of 18 VAC 110-20-460 and subsection A of 18 VAC 110-20-355 provided they comply with the following requirements:</u>

<u>1. A pharmacist shall verify of the accuracy of the radio-frequency identification tagging process including:</u>

<u>a. The addition, modification, or deletion of all drugs in the RFID database;</u>

b. The RFID tagging of all drugs; and
c. The tagging and editing of the contents of the kit of drugs for floor stock.

2. A record of the RFID process shall be maintained manually or in a computerized record from which information can be readily retrieved, including the date and initials of the pharmacist verifying the accuracy of the process.

3. A pharmacist shall perform a daily random check for verification of the accuracy of 5% of all kits prepared that day utilizing the RFID technology. A record of the random check shall be maintained manually or in a computerized record from which information can be readily retrieved, including:

a. The date of verification;

b. Description of all discrepancies identified; and

c. Initials of the pharmacist verifying the accuracy of the process.

4. All records required by this subsection shall be maintained for a period of two years from the date of verification by the pharmacist.

Agenda Item: Discussion of immunization records:

Included in your agenda package is:

Copy of minutes of 3/29/18 – referral to Regulation Committee

Copy of petition for rulemaking regarding maintenance of records

Information about the Virginia Immunization Information System

Staff note:

Committee needs to discuss issue of maintenance of immunization records or reporting to VIIS

- **3,4-methylenedioxy-N-tert-butylcathinone**
- **4-fluoro-N-ethylamphetamine**
- **beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)**

Classified as powerful synthetic opioids:

- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl)**
- **2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)**
- **N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)**

(motion by Saenz, second by S. Elliott)

PETITION FOR RULEMAKING:

- Amend 18VAC110-20-240, *Manner of maintaining records, prescriptions, inventory records*

The Board reviewed a petition for rulemaking submitted by Judy Dietrick to amend Regulation 18VAC110-20-240 to extend the requirement for retention of records beyond two years, to include records of vaccine administration. The Board reviewed the comments regarding this petition and several questions arose. One was regarding the reporting to the VIIS system for immunizations. Ms. Allyson-Bryant informed the Board that reporting to the VIIS system is only required for EMS, although several physicians voluntarily register with VIIS for reporting even though it is not required. The request to maintain records of immunizations longer than the required 2 years was discussed and it was stated this may be overly burdensome based on volume of records. Ms. Allen noted that since there was already a system in place to report to the VIIS, possibly the Board should discuss requiring pharmacies to register and report to the system for immunizations. Ms. Yeatts stated this would be a legislative change to require such registration.

MOTION:

The Board voted unanimously to deny the petition for rulemaking and to refer the subject to the Regulation Committee for exploration of further options for immunization reporting and improvements to records retention. (motion by Allen, second by M. Elliott)

ADOPTION OF PROPOSED REGULATIONS FOR:

- Requirement for E-profile number on applications

Ms. Yeatts provided a handout of the suggested regulatory language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an e-profile ID number upon application and renewal.

MOTION:

The Board voted unanimously to adopt proposed language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an E-profile ID number upon application and renewal. (motion by Cathcart, second by Boone)

- Fee increase for all

Staff provided several handouts to the Board indicating the Board will

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle Initial, Suffix,)		
Judy Lifland Dietrick		
Street Address	**Area Code and Telephone Number**	
9611 Podium Dr	703 938 4384	
City	**State**	**Zip Code**
Vienna	VA	22182
Email Address (optional)	**Fax (optional)**	
LIFLANDJ @ yahoo.com		

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18 VA 110-20-240 Manner of maintaining records, prescriptions, inventory records

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Doctors are required to keep records for 10 years. I tried to get info on pneumonia vaccines given to me at Safeway and Walgreens and I was told they do not keep records after 2 years.
I think law should be changed so records are kept 10 years as they would be in a doctor's office.
Vaccines are part of a patient's medical records and should be available longer than 2 years.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference. 54.1-2400

Signature: Judy Lifland Dietrick Date: 2/1/2018

FAQ

What is the purpose of VIIS?

The purpose of VIIS is to create one definitive and accurate immunization record for all residing in Virginia. This can increase immunization rates and decrease rates of over-immunization

How much does it cost to use the Virginia Immunization Information System (VIIS)?

There is no cost associated with maintaining a record in VIIS or with the use of the registry system. Access to authorized users, training, and customer support is free.

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Who is an authorized user?

An authorized user are:

- Health care provider or health plans
- Schools head start programs, and day care centers.
- Individuals or organizations as required by law or in the management of a public health crisis
- Other immunization registries

What is the Virginia Law concerning sharing of immunization data through VIIS?

Authority to Share Immunizations in § 32.1-46

Are schools and child-care centers able to access vaccine records in VIIS?

Yes, as long as the school has a licensed health care professional who is gaining access to VIIS.

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Has the registry been pre-populated with any historical immunization information?

Yes, VIIS contains historical information. Immunization records can also be updated with historical data.

I already have an Electronic Health Record (EHR) system, how can I still participate in the registry system?

Data exchange from your office's EHR to VIIS is possible and will afford your office most benefits of VIIS without doing data entry into the EHR and VIIS.

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How can I obtain a copy of my immunization record from VIIS?

You can contact VIIS staff by phone at 804-864-8055 or by email at VIISInfo@vdh.virginia.gov

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How will VIIS affect the workload of my busy office staff?

Many offices have successfully integrated VIIS into the current business flow without disruption. Methods for integration can be discussed with your VIIS field consultant.

How can I get access to VIIS?

To gain access to VIIS, the site must complete the enrollment forms and training. Enroll Here.

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Is VIIS HIPPA compliant?

Yes, as VIIS is run by the Virginia Department of Health and accessed by authorized users it is HIPAA compliant

Thanks for reaching out about the Virginia Immunization Information System (VIIS). VIIS is a free statewide registry system which combines immunization histories for persons of all ages from both the public and the private sector. Immunization information is accessible to authorized users only. VIIS provides many benefits such as:

- Consolidates vaccination records from multiple providers into one record.
- Provides updated recommendations for immunization scheduling based on the CDC recommendations.
- Produces an official immunization record for patients that also serves as part of the school entry form (MCH-213 form).
- Generates reminder notices for patients who are due for vaccines.
- Serves as a great tool for vaccinating providers.

VIIS accepts vaccines for all ages and has data reported from most major chain pharmacies in Virginia as well as several smaller pharmacies. I'd be happy to talk to you about this in more detail if you'd like.

Thanks!
Christy
--
Christy Gray, MPH, CHES, CHTS-CP
Director, Division of Immunization
Virginia Department of Health
Richmond, VA 23219
Ph: 804-864-7928

On Fri, Nov 8, 2019 at 1:15 PM Forlano, Laurie <laurie.forlano@vdh.virginia.gov> wrote:
[Quoted text hidden]

Yeatts, Elaine <elaine.yeatts@dhp.virginia.gov> Fri, Nov 8, 2019 at 1:30 PM
To: "Gray, Christine" <christy.gray@vdh.virginia.gov>

Good to know. Participation is voluntary for all providers - is that correct?
[Quoted text hidden]

Gray, Christine <christy.gray@vdh.virginia.gov> Fri, Nov 8, 2019 at 1:32 PM
To: "Yeatts, Elaine" <elaine.yeatts@dhp.virginia.gov>

By law participation is voluntary for all providers with the exception of EMS providing vaccines.

Also, VDH policy is that if you are participating in our Virginia Vaccines for Children (VVFC) and Virginia Vaccines for Adults (VVFA) programs, all doses must be entered into VIIS.

Thanks!
Christy
--
Christy Gray, MPH, CHES, CHTS-CP
Director, Division of Immunization
Virginia Department of Health
Richmond, VA 23219
Ph: 804-864-7928

[Quoted text hidden]

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Code of Virginia
Title 32.1. Health
Chapter 2. Disease Prevention and Control

§ 32.1-46. Immunization of patients against certain diseases.

A. The parent, guardian or person standing in loco parentis of each child within this Commonwealth shall cause such child to be immunized in accordance with the Immunization Schedule developed and published by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The required immunizations for attendance at a public or private elementary, middle or secondary school, child care center, nursery school, family day care home or developmental center shall be those set forth in the State Board of Health Regulations for the Immunization of School Children. The Board's regulations shall at a minimum require:

1. A minimum of three properly spaced doses of hepatitis B vaccine (HepB).

2. A minimum of three or more properly spaced doses of diphtheria toxoid. One dose shall be administered on or after the fourth birthday.

3. A minimum of three or more properly spaced doses of tetanus toxoid. One dose shall be administered on or after the fourth birthday.

4. A minimum of three or more properly spaced doses of acellular pertussis vaccine. One dose shall be administered on or after the fourth birthday. A booster dose shall be administered prior to entry into the seventh grade.

5. Two or three primary doses of Haemophilus influenzae type b (Hib) vaccine, depending on the manufacturer, for children up to 60 months of age.

6. Two properly spaced doses of live attenuated measles (rubeola) vaccine. The first dose shall be administered at age 12 months or older.

7. One dose of live attenuated rubella vaccine shall be administered at age 12 months or older.

8. One dose of live attenuated mumps vaccine shall be administered at age 12 months or older.

9. All children born on and after January 1, 1997, shall be required to have one dose of varicella vaccine on or after 12 months.

10. Three or more properly spaced doses of oral polio vaccine (OPV) or inactivated polio vaccine (IPV). One dose shall be administered on or after the fourth birthday. A fourth dose shall be required if the three dose primary series consisted of a combination of OPV and IPV.

11. One to four doses, dependent on age at first dose, of properly spaced pneumococcal conjugate (PCV) vaccine for children up to 60 months of age.

12. Three doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade.

The parent, guardian or person standing in loco parentis may have such child immunized by a physician, physician assistant, nurse practitioner, registered nurse, or licensed practical nurse, or a pharmacist who administers pursuant to a valid prescription, or may present the child to the appropriate local health department, which shall administer the vaccines required by the State Board of Health Regulations for the Immunization of School Children without charge to the parent of or person standing in loco parentis to the child if (i) the child is eligible for the Vaccines for Children Program or (ii) the child is eligible for coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid), Title XXI of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP), or 10 U.S.C. § 1071 et seq. (CHAMPUS). In all cases in which a child is covered by a health carrier, Medicare, Medicaid, CHIP, or CHAMPUS, the Department shall seek reimbursement from the health carrier, Medicare, Medicaid, CHIP, or CHAMPUS for all allowable costs associated with the provision of the vaccine. For the purposes of this section, the Department shall be deemed a participating provider with a managed care health insurance plan as defined in § 32.1-137.1.

B. A physician, physician assistant, nurse practitioner, registered nurse, licensed practical nurse, pharmacist, or local health department administering a vaccine required by this section shall provide to the person who presents the child for immunizations a certificate that shall state the diseases for which the child has been immunized, the numbers of doses given, the dates when administered and any further immunizations indicated.

C. The vaccines required by this section shall meet the standards prescribed in, and be administered in accordance with, regulations of the Board.

D. The provisions of this section shall not apply if:

1. The parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices, unless an emergency or epidemic of disease has been declared by the Board;

2. The parent or guardian presents a statement from a physician licensed to practice medicine in Virginia, a licensed nurse practitioner, or a local health department that states that the physical condition of the child is such that the administration of one or more of the required immunizing agents would be detrimental to the health of the child; or

3. Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.

E. For the purpose of protecting the public health by ensuring that each child receives age-appropriate immunizations, any physician, physician assistant, nurse practitioner, licensed institutional health care provider, local or district health department, the Virginia Immuniza

Information System, and the Department of Health may share immunization and patient locator information without parental authorization, including, but not limited to, the month, day, and year of each administered immunization; the patient's name, address, telephone number, birth date, and social security number; and the parents' names. The immunization information; the patient's name, address, telephone number, birth date, and social security number; and the parents' names shall be confidential and shall only be shared for the purposes set out in this subsection.

F. The State Board of Health shall review this section annually and make recommendations for revision by September 1 to the Governor, the General Assembly, and the Joint Commission on Health Care.

Code 1950, § 32-57.1; 1968, c. 592; 1972, c. 558; 1979, c. 711; 1980, c. 410; 1989, c. 382; 1991, c. 133; 1992, cc. 127, 166; 1994, c. 62; 1995, cc. 729, 742; 1996, cc. 67, 533; 1999, cc. 632, 676, 738; 2000, c. 476; 2004, c. 855; 2005, cc. 643, 684; 2006, cc. 364, 396, 716; 2007, cc. 858, 922; 2011, c. 125; 2014, cc. 316, 344; 2016, c. 81; 2019, c. 222.

Virginia Administrative Code
Title 12. Health
Agency 5. Department of Health

Chapter 115. Virginia Immunization Information System

12VAC5-115-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Commissioner" means the State Health Commissioner or his designee.

"Data exchange" means electronically sending immunization information from an existing information system to VIIS and being able to retrieve information from VIIS.

"De-duplication" means the process in information systems that matches incoming data with existing client records and merges those identified as the same client.

"Health care entity" means any health care provider, health plan, or health care clearinghouse.

"Health care provider" means those entities listed in § 8.01-581.1 of the Code of Virginia, except that state-operated facilities shall also be considered health care providers for the purposes of this section. Health care provider shall also include all persons who are licensed, certified, registered, or permitted or who hold a multistate licensure privilege issued by any of the health regulatory boards within the Department of Health Professions, except persons regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Health plan" means an individual or group plan that provides or pays the cost of medical care and shall include any entity included in such definition as set out in 45 CFR 160.103.

"Participant" means a person or organization with a VIIS account.

"Patient" means the client who is receiving health services.

"Public health emergency" means any (i) public health event caused by an act of bio-terrorism or vaccine-preventable disease outbreak or (ii) other public health event resulting from natural or human cause.

"Security role" means the level of security assigned to a participant that determines what information the individual may access in the application and what system functions may be performed.

"VDH" or "Department of Health" means the Virginia Department of Health.

"Virginia Immunization Information System" or "VIIS" means the statewide immunization registry.

"VITA" means the Virginia Information Technologies Agency.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-20. Authorized participants.

A. Health care providers, including but not necessarily limited to any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist, or any entity listed in the definition of "health care provider" in § 8.01-581.1 of the Code of Virginia, are authorized to participate in VIIS.

B. Any health care entity may participate as long as it is licensed or certified in Virginia to deliver or support health care services or public health, requires immunization data to perform the health service function, and uses VIIS only for exchanging information on persons for whom it provides services.

C. Other state or regional immunization registries may exchange data with VIIS. They may share data and have access to data by contacting the VIIS program manager and complying with the registration procedure discussed in 12VAC5-115-30.

D. VDH shall give access to VIIS under the condition that having access to immunization information is required to perform the job function of the participant. The VIIS program manager or designee shall assign the security role of the participant based on his needs and job responsibilities.

E. Access to VIIS requires only Internet access and is free to participants.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-30. Registration procedures.

A. Participation in VIIS is voluntary.

B. Completed registration forms from authorized participants must be processed and approved by VDH before access to the system is allowed. Registration will require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS data are protected from unauthorized view and access. The participant shall update and submit the forms to VDH every year.

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C. Once the participant is approved, the participant shall sign a participant registration agreement with VDH. VDH will then provide training and activate the participant in the VIIS system.

D. Qualifying participant organizations shall designate an administrator for their organization. The administrator may then allow VIIS access by an employee in his organization and, in doing so, shall assume responsibility for registering that person, obtaining the most recent security forms that specify VITA or VDH security requirements, retaining all completed user forms, assigning the security role of the user, accepting legal responsibility for his proper use of VIIS, and terminating access to VIIS if the employee is noncompliant with VIIS requirements or no longer requires access.

E. An administrator may terminate his organization's participation at any time by notifying VDH in writing. All data entered by that organization shall remain in the system.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-40. Patient confidentiality.

A. Access to VIIS information is authorized only under the condition that access to individual immunization information is required to perform the participant's job function.

B. Participants shall not conduct any activity that jeopardizes the proper function or security of VIIS. They shall use patient data only as authorized by law and this chapter and must immediately notify the patient and VDH of any breach of personal privacy or confidentiality.

C. Patients shall have the opportunity to opt-out of VIIS by doing one of the following:

1. Contacting their health care provider to allow the viewing of their immunizations only by that provider who administered them; or

2. Contacting VDH in writing requesting to be taken out of VIIS and have their record no longer viewable.

D. Patient immunization records shall not be copied except for authorized use. These copies shall not be left where they are visible by unauthorized personnel and shall be shredded before disposal.

E. VIIS records shall be treated with the same confidentiality and privacy as any other health record. Any inappropriate use of VIIS records shall result in immediate suspension of participant privileges and an investigation conducted by VDH. Additional actions may be taken pursuant to § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges.

F. Nothing in this chapter alters the provision in 45 CFR Part 164 that permits covered health care entities to disclose protected health information to a public health authority without individual authorization.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-50. Security.

A. After VDH gives access to a VIIS participant, a secure connection is established between his browser and VIIS. The system is password protected.

B. Participants shall ensure that employees with authorized access do not disclose their user identification code or password to anyone, have physical security and password-enabled screen savers on computers accessing VIIS, make every effort to protect VIIS screens from unauthorized view, and log off the system whenever leaving the VIIS workstation.

C. The VIIS system, which is maintained on a secure website, shall automatically inactivate a user session after a predetermined period of inactivity. The inactivation period is determined by VITA security policy.

D. The VIIS system shall inactivate user accounts, denying access to the system when participants have not logged into the system after a predetermined period of time. This inactivation period is determined by VITA security policy. The administrator must reactivate the account.

E. There shall be a secure encrypted connection between VIIS and the participating organization sending or receiving data if data exchange is performed. The encryption process will be determined by VITA or VDH or both.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-60. Population of VIIS.

A. The VDH Divisions of Immunization and Vital Records have an agreement to populate demographic information in VIIS with birth certificate data. Death certificate data are used to make the VIIS record no longer viewable. Data exchange shall be performed on a periodic basis, but at least monthly.

B. Each participant shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for de-duplication of patients.

C. Data shall be reported in VIIS either by online data entry or by data exchange of files from other information systems. The participating provider or the health plan billed for the immunization shall report. Reporting shall occur within seven days of vaccine administration for online data entry participants. For data exchange participants, reporting shall occur within seven days of receipt of the information.

D. Both demographic and immunization data shall be reported by the participant.

1. Patient demographic information shall include, but is not limited to, patient's name, date of birth, gender, telephone number, home address, birth place, and mother's maiden name. The social security number, if provided, shall be encrypted by the application, appear as asterisks, and shall not print out on reports for that patient. The application shall allow only exact matches when the social security number is used for search purposes.

2. Patient immunization information shall include, but is not limited to, the type of immunization administered using industry standards such as vaccine groups, Health Level 7 codes, or Current Procedural Terminology codes; date the immunization was administered; identity of the health care provider who administered the vaccine; manufacturer; trade name; lot number; and, if present, any contraindications or religious or medical exemptions.

E. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy, and enough information to correctly merge with existing patients. Upon initial data delivery, and periodically thereafter, data shall be reviewed to determine data quality. Any rejected records shall be resolved by the participant in a timely way. VDH may suspend system privileges and take additional action in accordance with § 32.1-27 of the Code of Virginia for any organization that submits inaccurate data.

F. If insufficient information is reported to allow de-duplication of patients, incoming data will be placed in a pending file and must be manually merged, if appropriate. All participants shall identify a contact to work with VDH on pending files.

G. VDH shall incorporate immunization data pursuant to subsection E of § 32.1-46 of the Code of Virginia into VIIS by data exchange from other immunization systems, patient care management billing systems, or information systems to the extent possible.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-70. Release of VIIS data.

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A. Specific patient data shall not be disclosed except to the extent required or permitted by state and federal law or regulations, after contacting VDH. VDH will verify the source of the request.

B. Specific patient data may be disclosed to health care entities to the extent required or permitted by state and federal law or regulations. See subsection E of § 32.1-46 and § 32.1-127.1:03 of the Code of Virginia.

C. Patient data shall be erased when no longer needed, when the computer is being terminated, or in accordance with a data sharing agreement or a participant registration agreement with VDH.

D. Aggregate data from which personal identifying data has been removed or redacted may be released for the purposes of statistical analysis, research, or reporting only after approval by VDH.

E. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH. Additional actions may be taken in accordance with § 32.1-27 of the Code of Virginia. The VIIS program manager may reinstate privileges upon satisfactory completion of required remedial actions and guarantee of proper use of VIIS in the future.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

12VAC5-115-80. Data access in public health emergency.

A. The commissioner may access and release VIIS data in accordance with §§ 32.1-40 and 32.1-41 of the Code of Virginia.

B. The commissioner may designate additional persons to view VIIS information during a public health emergency. VDH shall contact designated authorized users, provide instruction for those who are not current participants, and activate an account.

C. The commissioner may include public health emergency announcements and notices or guidelines on the main screen that may be viewed immediately by the VIIS participants.

Statutory Authority

§ 32.1-46.01 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 22, eff. July 31, 2015.

Forms (12VAC5-115)

54.1-3408

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

Agenda Topic: Adopt Guidance for What Constitutes a "New" Prescription Requiring an Offer to Counsel

Included in Packet:

Copy of relevant statute, 54.1-3319

Excerpt from NABP Model Act

Background:

There are questions in the field about what constitutes a "new" prescription requiring an offer to counsel by a pharmacist. It is recommended that the board adopt guidance to clarify its position on this matter.

Possible action:

- Develop guidance to clarify what constitutes a "new" prescription; motion to recommend full board adopt developed guidance at December board meeting

From *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019

§ 54.1-3319. Counseling.

A. A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse. A pharmacist may conduct a prospective drug review before refilling a prescription to the extent the pharmacist deems appropriate in his professional judgment.

B. A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment, and may include any one or a combination of the following:

1. Face-to-face communication with the pharmacist or the pharmacist's designee;

2. A sign posted in such a manner that it can be seen by patients;

3. A notation affixed to or written on the bag in which the prescription is to be delivered;

4. A notation contained on the prescription container; or

5. By telephone.

For the purposes of medical assistance and other third-party reimbursement or payment programs, any of the above methods, or a combination thereof, shall constitute an acceptable offer to provide counseling, except to the extent this subsection is inconsistent with regulations promulgated by the federal Health Care Financing Administration governing 42 U.S.C. § 1396r-8 (g) (2) (A) (ii). A pharmacist may offer to counsel any person who receives a refill of a prescription to the extent deemed appropriate by the pharmacist in his professional judgment.

C. If the offer to counsel is accepted, the pharmacist shall counsel the person presenting the prescription to the extent the pharmacist deems appropriate in his professional judgment. Such counseling shall be performed by the pharmacist himself and may, but need not, include the following:

1. The name and description of the medication;

2. The dosage form, dosage, route of administration, and duration of drug therapy;

3. Special directions and precautions for preparation, administration, and use by the patient;

4. Common adverse or severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

5. Techniques for self-monitoring drug therapy;

6. Proper storage;

7. Prescription refill information; and

8. Action to be taken in the event of a missed dose.

Nothing in this section shall be construed as requiring a pharmacist to provide counseling when the person presenting the prescription fails to accept the pharmacist's offer to counsel. If the prescription is delivered to a person residing outside of the local telephone calling area of the pharmacy, the pharmacist shall either provide a toll-free telephone number or accept reasonable collect calls from such person.

D. Reasonable efforts shall be made to obtain, record, and maintain the following patient information generated at the individual pharmacy:

1. Name, address, telephone number, date of birth or age, and gender;

2. Individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

3. Any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

Such information may be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that such offer was accepted and that such counseling was provided.

E. This section shall not apply to any drug dispensed to an inpatient of a hospital or nursing home, except to the extent required by regulations promulgated by the federal Health Care Financing Administration implementing 42 U.S.C. § 1396r-8 (g) (2) (A).

(1992, c. 689.)

From NABP Model Act, August 2019

Section 6. Pharmacist Care Services. [1]

(b) Patient Counseling[2]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:

(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(4) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

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[1] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

[2] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

Agenda Topic: Recommend Adoption of Guidance to Clarify if Collaborative Practice Agreement is Required for Each Patient

Included in Packet:

Draft guidance document

Background:

During a Joint Commission on Health Care study, it was reported to the researcher that confusion exists regarding whether a collaborative practice agreement is required for each patient to participate. The researcher inquired if the board would consider adopting guidance on this subject to clarify the board's position.

Action:

- Recommend to the full board that it adopt the guidance document as presented or as amended.

VIRGINIA BOARD OF PHARMACY

Guidance Regarding Collaborative Practice Agreements

To clarify if a collaborative practice agreement is required for each patient, the Board offers the following guidance.

1. A pharmacist and a practitioner or other authorized person as found in the definition of "collaborative agreement" in §54.1-3300 may enter into a collaborative practice agreement. Such agreement is not executed for each patient, but rather serves as a general agreement between the pharmacist and practitioner for how a pharmacist may implement, modify, continue, or discontinue drug therapy; order laboratory tests; or complete other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.
2. The agreement may only be implemented for an individual patient pursuant to an order from the practitioner for that patient.
3. Documented informed consent must then be obtained from the patient by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

§ 54.1-3300

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

1999, cc. 895, 1011; 2013, c. 192; 2018, c. 776.

18VAC110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a single physical location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.

2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.

3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

Agenda Topic: Recommend Amending Guidance Document 110-*15 Delegation of Authority for Disciplinary Matters*

Included in Packet:

Draft guidance document

Copy of §54.1-2400.2(G)

Background:

Staff has identified two actions that could be delegated to staff to expedite the handling of certain matters.

Action:

- Recommend to the full board that it adopt the guidance document as presented or as amended.

Virginia Board of Pharmacy

Delegation of Authority for Disciplinary Matters

The Board of Pharmacy delegates to the executive director the authority to offer a prehearing consent order (PHCO) in the following circumstances:

1. Action taken by another state board of pharmacy – PHCO would require compliance with other state's action.
2. Single dispensing error with no patient harm involving an individual who is a minor or medically compromised, or a drug with a narrow therapeutic index – PHCO would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.
3. Inspection report as part of an investigation which resulted in the citing of deficiencies, as identified in Guidance Document 110-9, for which the guidance document recommends a monetary penalty – PHCO would impose the recommended monetary penalty as indicated in Guidance Document 110-9.
4. Application for a change in pharmacist-in-charge (PIC) is submitted beyond the required timeframe for designating a new PIC – PHCO would impose recommended monetary penalty as indicated in Guidance Document 110-9 for either not having a PIC fully engaged in the practice at the pharmacy location or having a PIC in place, inventory taken, but application not filed with Board within the required timeframe.
5. Voluntary surrender of a license or registration for reasons not related to disciplinary action.

The Board of Pharmacy delegates to the executive director the authority to offer a confidential consent agreement (CCA) in the following circumstances:

1. Single dispensing error with no patient harm, except as noted in #2 above – CCA would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.

The Board of Pharmacy delegates to the executive director the authority to close cases that have insufficient evidence of a violation of law or regulation. The Board further delegates to the executive director the authority to issue an advisory letter to the person who was the subject of a complaint pursuant to §54.1-2400.2(G), when it is determined that a disciplinary proceeding will not be instituted.

§54.1-2400.2(G) (Effective until January 1, 2020)

G. Whenever a complaint or report has been filed about a person licensed, certified, or registered by a health regulatory board, the source and the subject of a complaint or report shall be provided information about the investigative and disciplinary procedures at the Department of Health Professions. Prior to interviewing a licensee who is the subject of a complaint or report, or at the time that the licensee is first notified in writing of the complaint or report, whichever shall occur first, the licensee shall be provided with a copy of the complaint or report and any records or supporting documentation, unless such provision would materially obstruct a criminal or regulatory investigation. If the relevant board concludes that a disciplinary proceeding will not be instituted, the board may send an advisory letter to the person who was the subject of the complaint or report. The relevant board may also inform the source of the complaint or report (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv), if appropriate, that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report. In providing such information, the board shall inform the source of the complaint or report that he is subject to the requirements of this section relating to confidentiality and discovery.

§54.1-2400.2(G) (Effective January 1, 2020)

G. Whenever a complaint or report has been filed about a person licensed, certified, or registered by a health regulatory board, the source and the subject of a complaint or report shall be provided information about the investigative and disciplinary procedures at the Department of Health Professions. Prior to interviewing a licensee who is the subject of a complaint or report, or at the time that the licensee is first notified in writing of the complaint or report, whichever shall occur first, the licensee shall be provided with a copy of the complaint or report and any records or supporting documentation, unless such provision would materially obstruct a criminal or regulatory investigation. If the relevant board concludes that a disciplinary proceeding will not be instituted, the board may send an advisory letter to the person who was the subject of the complaint or report. The relevant board may also inform the source of the complaint or report (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv), if appropriate, that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report. In providing such information, the board shall inform the source of the complaint or report that he is subject to the requirements of this section relating to confidentiality and discovery.

BOARD OF PHARMACY

Copies of the following documents may be viewed during regular work days from 8:15 a.m. until 5 p.m. at the offices of the Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233. Copies may also be downloaded from the board's webpage at http://www.dhp.virginia.gov/Pharmacy or the Regulatory Town Hall at http://www.townhall.virginia.gov or requested by email at pharmbd@dhp.virginia.gov. Questions regarding interpretation or implementation of these documents or requests for copies may be directed to Caroline D. Juran, Executive Director of the Board, at the address above or by telephone at (804) 367-4456. Copies are free of charge.

Guidance Documents:

http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm

110-1, List of categories of facility licenses and a brief description of each, revised November 28, 2019

110-2, Instructions for applicants for pharmacist licensure, revised March 28, 2018

110-3, Guidance on alternative delivery of prescriptions, pharmacy to physician or pharmacy to controlled substance registration type of delivery, re-adopted December 18, 2018

110-4, Continuing Education Guide for Pharmacists, revised December 11, 2017

110-5, Instructions and forms for reporting of thefts or losses of drugs, revised March 29, 2018

110-6, Pharmacies within opioid treatment programs, effective November 28, 2019

110-7, Practitioner/patient relationship and the prescribing of drugs for family or self, revised September 2019

110-8, Information on prescriptive authority in Virginia, revised January 15, 2016

110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide, revised June 22, 2018

110-10, Board guidance on dispensing of drugs from mobile vans, revised June 21, 2018

110-11, Board guidance on proof of identity for Schedule II drugs, revised June 21, 2018

110-12, Bylaws of the Board of Pharmacy, revised September 26, 2017

110-15, Delegation of authority in disciplinary matters, revised March 25, 2016

110-16, Board guidance on performing inventories, revised June 21, 2018

110-17, Instructions for graduates of foreign schools of pharmacy, revised October 12, 2016

110-18, Advance preparation of medications for administration, revised September 29, 2015

110-19, Transferring valid orders between medical equipment providers, revised June 21, 2018

110-20, Practice as a pharmacy technician trainee, revised March 21, 2017

110-21, Sanction Reference Points Manual, revised December 2018

110-22, Dispensing records; identification of pharmacist, revised June 21, 2018

110-23, Monetary penalties for inspection deficiencies for physicians selling controlled substances, adopted March 26, 2014

110-24, Competency examination required and passing score, revised June 21, 2018

110-25, Guidance for life of a prescription after a prescriber no longer in practice, revised June 21, 2018

110-27, Pharmacist-In-Charge responsibilities, revised December 1, 2015

110-28, Guidance for free clinic pharmacy permit applicants, re-adopted December 18, 2018

110-29, Guidance for physician dispensing, revised June 2016

110-30, Drugs within animal shelters and pounds, revised August 8, 2019

110-31, Approved capture drugs and drug administering equipment, Directive from the State Veterinarian, revised September 2016

110-32, Use of a drop-box for the collection of prescriptions, re-adopted December 18, 2018

110-33, Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, re-adopted December 18, 2018

110-34, Manufacturer and wholesale distributor licensure, revised September 29, 2015

110-35, Requirements for Prescriptions, revised September 26, 2017

110-36, Compliance with USP Standards for Compounding, revised November 28, 2019

110-37, Guidance for conducting informal fact-finding by an agency subordinate, re-adopted December 18, 2018

110-38, Requirement for Non-resident Pharmacies to Submit Current Inspection Report, revised December 12, 2016

110-39, Hours of continuous work and taking breaks by pharmacists, adopted March 21, 2017

110-40, Storage of Schedule II drugs in a pharmacy, December 18, 2018

110-41, Changes a pharmacist may make to a Schedule II prescription, re-adopted December 18, 2018

110-42, Continuing education audit and recommended sanctions, re-adopted December 18, 2018

110-43, Dispensing with an authorized generic, revised December 18, 2018

110-44, Protocol for prescribing or dispensing naloxone, revised November 28, 2019

110-46, Delivery of temperature-sensitive drugs, adopted December 11, 2017

110-47, Disposal of drugs, revised March 29, 2018

Guidance document: 110-18 Revised: September 29, 2015

Virginia Board of Pharmacy

Interpretation of "administer" to include preparation for administration

The Board of Pharmacy finds that the term "administer", as defined in § 54.1-3401, can be reasonably interpreted to include the advance preparation or "set up" of medications to be administered to patients provided such advance preparation is performed only by a person licensed to dispense or administer drugs (medical practitioner, pharmacist, registered nurse, licensed practical nurse, or physician assistant) and the advance preparation is reasonably concurrent with the actual administration and should not extend beyond the next scheduled dosage administration.

However, if the advance preparation is to assist a patient, living in a private residence, in the administration of drugs which would normally be self administered, including insulin, such advance preparation shall not exceed a fourteen (14) day supply.

If the advance preparation, as performed by a person licensed to dispense or administer drugs, is to assist in the administration of medications to students during a single-day field trip, such advance preparation shall not be made prior to the last working day before the day of the field trip and shall not exceed a one-day supply. Any packaging used in such advance preparation shall include the student's name and any other appropriate student identifier; physician's name; drug name and strength, and quantity; and appropriate directions for administration. For any field trip which is longer than one day in length, a student's prescription medication should be provided by the student's parent or guardian in a properly labeled prescription vial which has been dispensed from a pharmacy and, for oral medications, which contains only the quantity needed for the duration of the field trip.

Adopted: June 11, 1998
Revised: September 29, 2015

Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. Practitioner selling on an expired license.	18VAC110-30-30	Per individual	100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling location without application or Board approval.	18VAC110-30-80	must submit an application and fee	250
4. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks.	18VAC110-30-40	Per individual	250
6. Refrigerator/freezer temperature out of range greater than +/- 4 degrees.	18VAC110-30-110	determined using inspector'calibrated thermometer	100 Drugs may be embargoed
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
11. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 & 18VAC110-30-180	Minor 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500
16. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
22. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000
25. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		5000
29. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
30. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
31. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		500
32. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		5000
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
34. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
35. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

Minor Deficiencies

If five (5) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five.

Minor Deficiency	Law/Regulation Cite	Conditions
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
3. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	
10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock.	18VAC110-30-150	10% threshold

Minor Deficiency	Law/Regulation Cite	Conditions
12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
14. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
16. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	
20. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
23. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
24. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	
30. Equipment for non-sterile compounding does not comply with USP-NF standards.	54.1-3410.2	