



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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NOTICE OF PUBLIC HEARING

Notice is hereby given pursuant to M.G.L. c. 30A, §2, that the Department of Public Health will hold a public hearing on the emergency promulgation of 105 CMR 801.000, *Severe Lung Disease Associated with Vaping Products*.

This regulation is adopted to address the Governor's Declaration of Emergency Detrimental to the Public Health made pursuant to M.G.L. c. 17, §2A, and M.G.L. c. 111, §§ 1-3, 5, & 6, due to severe lung disease associated with the use of e-cigarettes and vaping products in the Commonwealth. On September 24, 2019, the Commissioner of Public Health, with approval of the Governor and the Public Health Council, issued Orders to effectuate the Declaration. This regulation prohibits the sale of vaping products in the Commonwealth and authorizes a standing order for nicotine replacement therapy.

Since the Declaration, reports of suspected vaping-related disease in Massachusetts residents have increased to 204 and the number of confirmed cases rose to 20. There have been two fatalities from vaping-related disease occurring in the Commonwealth. To date, no specific vaping product has been linked to all cases.

This regulation was promulgated as an emergency regulation because observance of the requirements of notice and a public hearing would be contrary to the public interest. Although all reported cases of severe lung disease associated with vaping products demonstrate a history of vaping and a history of vaping products containing tetrahydrocannabinol, nicotine, or a combination of both, the cause of the disease remains unknown. To date, no specific vaping product, including the related devices and liquids, or other substance, has been identified as linked to all cases. Delayed implementation of the regulations in order to comply with the requirements of notice and to hold a public hearing would result in additional individuals becoming sick, hospitalized and potentially even dying from vaping related pulmonary illness. The Department found that immediate adoption was necessary to preserve public health, safety, or general welfare, due to the increasing instances of severe lung disease associated with the use of e-cigarettes and vaping products in the Commonwealth. As required by M.G.L. c. 30A, §2, the Department now intends to hold a public hearing regarding this regulation.

The public hearing will be held on Friday, November 22, 2019, at 10:30 AM in the Public Health Council Room, Second Floor, Department of Public Health, 250 Washington Street, Boston, MA, 20108.

Speakers are requested to provide a copy of their oral testimony. The Department encourages all interested parties to submit testimony electronically to the following address:

Reg.Testimony@state.ma.us. Please submit electronic testimony as an attached Word document or as text within the body of an email and type "Vaping products regulation" in the subject line. All submissions must include the sender's full name and address. The Department will post all electronic testimony that complies with these instructions on its website. Parties who are unable to submit electronic testimony should mail submissions to William Anderson, Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, MA 02108. All written or oral comments submitted to the Department may be posted on the Department's website and released in response to a request for public records. All testimony must be submitted by 5:00 p.m. on Friday, November 29, 2019.

A copy of the proposed amendments may be viewed on the Department's website or obtained from the Office of the General Counsel at 617-624-5220.

Small Business Impact Statement
(As required by M.G.L. c. 30A §§ 2, 3 & 5)

CMR No: 105 CMR 801

Estimate of the Number of Small Businesses Impacted by the Regulation:

This regulation is adopted to address the Governor's Declaration of Emergency Detrimental to the Public Health due to severe lung disease associated with the use of e-cigarettes and vaping products in the Commonwealth and is made pursuant to M.G.L. c. 17, §2A, and M.G.L. c. 111, §§ 1-3, 5, & 6. On September 24, 2019, the Commissioner of Public Health, with approval of the Governor and the Public Health Council, issued Orders to effectuate the Declaration. This regulation prohibits the sale of vaping products in the Commonwealth and authorizes a standing order for nicotine replacement therapy.

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This regulation was promulgated as an emergency regulation because observance of the requirements of notice and a public hearing would be contrary to the public interest. Although all reported cases of severe lung disease associated with vaping products demonstrate a history of vaping and a history of vaping products containing tetrahydrocannabinol, nicotine, or a combination of both, the cause of the disease remains unknown. To date, no specific vaping product, including the related devices and liquids, or other substance, has been identified as linked to all cases. Delayed implementation of the regulations in order to comply with the requirements of notice and to hold a public hearing would result in additional individuals becoming sick, hospitalized and potentially even dying from vaping related pulmonary illness. The Department found that immediate adoption was necessary to preserve public health, safety, or general welfare, due to the increasing instances of severe lung disease associated with the use of e-cigarettes and vaping products in the Commonwealth. As required by M.G.L. c. 30A, §2, the Department now intends to hold a public hearing regarding this regulation.

105 CMR 801 directly impacts any business that sells or displays vaping products in Massachusetts, including vaping product retailers, convenience stores, gas stations, and medical and retail marijuana dispensaries. The emergency regulation may indirectly impact those businesses that produce or manufacture vaping products and/or the components thereof, including cultivators, producers, manufacturers and distributors. Not all of the impacted businesses meet the definition of small business, nor are they necessarily subject to the emergency regulation, found at G.L. c. 30A, § 1(5A) and 13 C.F.R. § 121.201.

In order to ascertain the number of small businesses potentially subject to the emergency regulation, the Department consulted the U.S. Small Business Administration's online searchable database of self-certified small businesses and searched by the following North American Industry Classification Systems codes:

453991 Tobacco Stores (zero results in Massachusetts)
445120 Convenience Stores (zero results in Massachusetts)
453998 All Other Miscellaneous Retail Stores (except Tobacco Stores) (31 results in Massachusetts) (note: the index of NAICS lists this code with reference to Electronic Cigarette Stores)
447110 Gasoline Stations with Convenience Stores (five results in Massachusetts)

Searching the index of NAICS codes (2017) for the words vapor, nicotine, cannabis, and hemp did not identify any relevant codes.

Alternatively, the Department conducts a pricing survey of all tobacco retailers in the Commonwealth. Of those tobacco retailers, approximately 4,000 report selling nicotine vapor products. The survey does not collect information about the number of employees, and therefore the Department is not able to determine whether or not these retailers

meet the definition of a small business.

There are also approximately 70 entities in the Commonwealth with adult use licenses from the Cannabis Control Commission, and approximately 50 entities with medical use licenses. Those numbers are not exclusive, and includes licenses for cultivation and manufacture as well as sale, so those numbers include some entities not directly affected by the emergency regulation. The Department does not have information about the number of employees and therefore is not able to determine whether or not these businesses meet the definition of a small business.

Select Yes or No and Briefly Explain

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to create, file, or issue additional reports? The emergency regulation does not include a reporting requirement.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures? The emergency regulation does not include a recordkeeping requirement.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to provide additional administrative oversight? The emergency regulation does not include a requirement that small businesses will have to provide administrative oversight provision.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to hire additional employees in order to comply with the proposed regulation? The Department does not anticipate that additional employees will need to be hired. Pursuant to the requirements G.L. c. 30A ss. 2, 3, and 5, and 950 CMR 20.04(2), the Department will file an amended regulation and an amended Small Business Impact Statement addressing this question following receipt of comments, the public hearing scheduled for November 22, 2019, and the subsequent Public Health Council meeting.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)? The Department does not anticipate that small businesses will require professional services to comply with the emergency regulation. Pursuant to the requirements G.L. c. 30A ss. 2, 3, and 5, and 950 CMR 20.04(2), the Department will file an amended regulation and an amended Small Business Impact Statement addressing this question following receipt of comments, the public hearing scheduled for November 22, 2019, and the subsequent Public Health Council meeting.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation? The emergency regulation does not require that small businesses purchase any product or make any capital investments in order to comply with the emergency regulation. Pursuant to the requirements G.L. c. 30A ss. 2, 3, and 5, and 950 CMR 20.04(2), the Department will file an amended regulation and

		an amended Small Business Impact Statement addressing this question following receipt of comments, the public hearing scheduled for November 22, 2019, and the subsequent Public Health Council meeting.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Are performance standards more appropriate than design/operational standards to accomplish the regulatory objective?</p> <p>(Performance standards express requirements in terms of outcomes, giving the regulated party flexibility to achieve regulatory objectives and design/operational standards specify exactly what actions regulated parties must take.)</p> <p>This question is not applicable as this emergency regulation does not require design/operational standards.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Do any other regulations duplicate or conflict with the proposed regulation?</p> <p>A prior regulation of the Cannabis Control Commission (CCC), 935 CMR 501.100(1)(c), stated that registered marijuana dispensaries "must make vaporizers available for sale to registered qualifying patients." However, this provision has been removed from regulation filed by the CCC with the Secretary on October 18, 2019, which will become effective on November 1, 2019. See 935 CMR 501.100 (version filed Oct. 18, 2019).</p> <p>Other CCC regulations filed with the Secretary on October 18, 2019, permit in certain circumstances, but do not require, the sale of vaporizers at medical marijuana treatment centers (MTCs), and the teaching of the use of vaporizers at MTCs. 935 CMR 501.105(19)(g), (h).</p> <p>Accordingly, there is no conflict between the CCC regulation and the emergency regulation.</p>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<p>Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities?</p> <p>Small businesses subject to this emergency regulation must cooperate with municipal board of health or Department of Public Health inspections.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?</p> <p>There is no requirement in the emergency regulation for educational services.</p>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<p>Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?</p> <p>This emergency regulation may deter the formation of small businesses that intend to limit their business exclusively or primarily to the sale or display for the purpose of selling vaping products while the emergency regulation is in effect. Pursuant to the requirements G.L. c. 30A ss. 2, 3, and 5, and 950 CMR 20.04(2), the Department will file an amended regulation and an amended Small Business Impact Statement addressing this question following receipt of comments, the public hearing scheduled for November 22, 2019, and the subsequent Public Health Council meeting.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?</p> <p>The Department does not anticipate that the emergency regulation will encourage the formation of</p>

		small businesses in Massachusetts. Pursuant to the requirements G.L. c. 30A ss. 2, 3, and 5, and 950 CMR 20.04(2), the Department will file an amended regulation and an amended Small Business Impact Statement addressing this question following receipt of comments, the public hearing scheduled for November 22, 2019, and the subsequent Public Health Council meeting.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation provide for less stringent compliance or reporting requirements for small businesses? The emergency regulation imposes a temporary ban on the sale and display of all vaping products; the regulation imposes the same compliance requirements on all businesses regardless of size. It is not possible to protect the public health in any manner that is less stringent.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses? The emergency regulations impose a temporary ban on the sale and display of all vaping products; the regulations impose the same compliance requirements on all businesses regardless of size. It is not possible to protect the public health in any manner that is less stringent.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? The emergency regulations impose a temporary ban on the sale and display of all vaping products; the regulations impose the same compliance requirements on all businesses regardless of size. It is not possible to protect the public health in any manner that is less stringent.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective? This question is not applicable as this emergency regulation does not establish design or operational standards.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses? The emergency regulations impose a temporary ban on the sale and display of all vaping products; the regulations impose the same compliance requirements on all businesses regardless of size. It is not possible to protect the public health in any manner that is less stringent.