



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER  
Governor

KARYN E. POLITO  
Lieutenant Governor

MARYLOU SUDDERS  
Secretary

MONICA BHAREL, MD, MPH  
Commissioner

Tel: 617-624-6000  
[www.mass.gov/dph](http://www.mass.gov/dph)

**TO:** Commissioner Monica Bharel, MD, MPH and Members of the Public Health Council

**FROM:** Lindsey Tucker, Associate Commissioner  
Ruth Blodgett, Director for the Bureau of Community Health and Prevention

**DATE:** October 25, 2019

**RE:** Request of the Public Health Council to Approve Proposed Emergency Regulation 105 CMR 800.000, *Severe Lung Disease Associated with Vaping Products*

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### Introduction

On September 24, 2019, Governor Baker issued a Declaration of Emergency Detrimental to the Public Health made pursuant to M.G.L. c. 17, §2A (“Declaration”), due to severe lung disease associated with the use of e-cigarettes and vaping products in the Commonwealth. Pursuant to this Declaration, the Commissioner of the Massachusetts Department of Public Health (“Commissioner”) and Public Health Council (“Council”) approved two Orders of the Commissioner (“Orders”) that same day to address the public health emergency, as follows:

1. Prohibit the sale of all vaping products in retail establishments, online, and through any other means, including all non-flavored and flavored vaping products, including mint and menthol, including tetrahydrocannabinol (THC) and any other cannabinoid, in the Commonwealth
2. Order expanded access to nicotine replacement therapy through a statewide standing order

The Council additionally authorized the Commissioner, during the period of emergency, take such other actions, incur such liabilities, and establish such procedures which are consistent with, and of necessity are required by, the provisions of the Governor’s Declaration.

In continued response to the emergency vaping-related lung disease presents for the Commonwealth, the Department proposes an emergency regulation to formally adopt and clarify through regulation the Orders approved and issued on September 24, 2019 to effectuate the

Governor's Declaration. Such emergency regulation will ensure the continued and necessary prohibition on sales of vaping products in Massachusetts in order to protect the public health.

### **Basis for Ongoing Emergency**

As described in our September 24, 2019 memo to the Council, clinicians across the country began raising concerns in August 2019 related to possible cases of unexplained vaping-associated pulmonary illness. On August 30, 2019, the Centers for Disease Control and Prevention (CDC) released a clinical advisory providing background information on e-cigarette products, information on the multistate outbreak of severe pulmonary disease associated with e-cigarettes, and clinical features of patients with severe pulmonary disease, with a recommendation clinicians report all cases of severe pulmonary disease of unclear etiology and a history of e-cigarette product use within the past 90 days to state or local health departments. CDC recommendations have now been expanded to encompass other vaping products in addition to e-cigarettes.

In response to trends nationwide, CDC recommendations, and growing public health concerns in Massachusetts, on September 11, 2019, Commissioner Bharel declared all suspected cases of unexplained e-cigarette or vaping-associated pulmonary disease immediately reportable to the Department of Public Health for the next 12 months.<sup>1</sup> Since that declaration, the Department has received 184 reports from clinicians of suspected vaping-related disease in Massachusetts residents. Of these reports, the Department has reported to the CDC 16 cases which meet the CDC definition for confirmed case, and 30 cases which meet the CDC definition for probable case; the remainder still remain under Department investigation.<sup>2</sup> These reports of vaping-related illness represent a threefold increase in reports received and five times the number of confirmed cases reported to Council members a month ago. During that same timeframe, the Department reported one fatality as a result of vaping-related disease.

This trend is true nationwide as well: as of October 15, 2019, the CDC has confirmed 1,479, almost three times the number reported less than a month prior, across 49 states, the District of Columbia, and one U.S. territory – meaning 10 additional states have confirmed cases over that same timeframe. While cases still show a history of vaping and a history of using vaping products containing tetrahydrocannabinol (THC), nicotine, or a combination of both, the cause of the disease continues to remain unknown. To date, no specific vaping product, including the related devices and liquids, or other substance has been identified as linked to all cases.

Due to the continued, significant danger vaping products present during the ongoing investigation into the cause of vaping-related disease, the CDC issued guidance advising the only way people may assure they are not at risk while the investigation continues is to consider refraining from use of all e-cigarette and vaping products.<sup>3</sup>

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<sup>1</sup> <https://www.mass.gov/files/documents/2019/09/11/Vaping-Assoc-Lung-Disease-Declaration-9-11-19.pdf>

<sup>2</sup> [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease/health-departments/index.html#case-definitions](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/health-departments/index.html#case-definitions)

<sup>3</sup> [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)

Concurrent to the ongoing threat to public health for residents of the Commonwealth, the state judiciary outlined a process through which the Department may promulgate regulations in order to maintain the sales prohibition on vaping products currently established through an Order.

Accordingly, the Department finds that immediate adoption of this proposed regulation is necessary for the preservation of the public health, safety or general welfare, and that observance of the requirements of notice and a public hearing would be contrary to the public interest. Therefore, the Department seeks to promulgate this regulation as an emergency regulation.

**Proposed Emergency Regulation and Requested Action**

To preserve the existing prohibition on sales of vaping products for purposes of protecting public health, continuing our investigation into instances of this disease in Massachusetts residents, and continue to learn from the CDC's nationwide investigation, the proposed emergency regulation adopts all Orders issued pursuant to the Governor's Declaration. It is respectfully requested that the Public Health Council vote to approve the proposed regulation, 105 CMR 800.000, on an emergency basis, which allows the regulation to take effect upon filing with the Secretary of State's office while the regulatory process continues, as provided for in the state's administrative procedure laws outlined in M.G.L. c. 30A.