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Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-412
Regulation title(s)	Regulations for Licensure of Abortion Facilities
Action title	Amend Regulation to Suspend Portions of 2017 Rulemaking
Final agency action date	March 19, 2019
Date this document prepared	March 13, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Henrico County Circuit Court issued an Order in *Melendez v. Virginia State Board of Health* (Case No. CL17-1164) that suspended the amendments made to 13 sections of 12VAC5-412 in 2017. This rulemaking amends those 13 sections to return them to the standards that were in effect prior to the 2017 amendments. The amendments will reinstate (i) the prior standard by which the State Health Commissioner evaluates variance requests and the requirements for variance requests; (ii) the requirement that the person responsible for granting access to patient records be on premises within one hour of a surveyor's arrival and that patient lists be produced upon a surveyor's request within two hours; (iii) the requirement that a physician remain on the premises until the last patient is discharged; (iv) the requirement that the physician give a discharge order; and (v) the requirement to have drugs capable of treating several enumerated conditions.

The amendments also reintroduce requirements that protocols related to patients' rights must be consistent with the Joint Commission Standards of Ambulatory Care, and that infection prevention plans must be consistent with the "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. The amendments will reinstate requirements related to safety and security policies and procedures, maintenance, firefighting equipment and systems, and building design and construction standards.

The amendments eliminate the prohibition against removing copies of personnel records from the premises unless redacted and the qualification that clinical records or charts include certain information only if medically indicated. The amendments also reinstate the requirement to report incidents reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, board decision, etc.). "Mandate" is defined as "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

On February 21, 2019, the Circuit Court of Henrico County entered an Order in *Melendez v. Virginia State Board of Health* (Case No. CL17-1164), suspending sections 80, 100, 180, 190, 200, 220, 280, 300, 320, 330, 350, 360, and 370 of 12VAC5-412, as amended effective March 22, 2017.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The State Health Commissioner approved this Final Action regarding the Regulations for Licensure of Abortion Facilities, on behalf of the State Board of Health while the board was not in session on March 19, 2019.