

Virginia Department of Health
Office of Licensure and Certification

October 25, 2012

Guidance Document: Granting of a Temporary Variance to Regulations for the Licensure of Abortion Facilities

PURPOSE: To provide guidance to licensed abortion facilities and applicants for licensure as abortion facilities regarding the process for requesting, evaluating, and granting/denying temporary variances to the Regulations for Licensure of Abortion Facilities, 12 VAC 5-412.

Effective Date: October 25, 2012

Introduction

The Regulations for the Licensure of Abortion Facilities, adopted by the Board of Health as emergency regulations pursuant to Virginia Code § 32.1-127(B)(1) and 2011 Va. Acts ch. 670, permit the State Health Commissioner to grant temporary variances to specific regulations governing the licensure of abortion facilities as follows:

12VAC5-412-90. Allowable variances.

Upon finding that the enforcement of a specific regulation would be an impractical hardship unique to the abortion facility, the Commissioner may grant a variance temporarily waiving the enforcement of the specific regulation, provided patient safety, patient care, and services are not adversely affected.

General Guidance

- I. Requesting a Temporary Variance
 - A. A temporary variance may be requested by:
 1. Any licensed abortion facility
 2. Any provider who has applied for licensure as an abortion facility
 - B. To request a temporary variance, the management of a licensed abortion facility or applicant for licensure must submit a letter, signed by the facility administrator, to the State Health Commissioner at the Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, Virginia, 23233.
 1. The letter requesting a temporary variance shall:
 - a. Clearly identify the facility for which a temporary variance is being requested;
 - b. Identify the specific regulation requirement to which a temporary variance is being sought;
 - c. Explain in detail why enforcement of the specific regulation creates an impractical hardship unique to the facility;
 - d. Explain in detail how patient safety, patient care, and the services offered will not be adversely affected if the variance was to be granted;
 - e. Provide a detailed explanation of the proposed alternatives to meet the purpose of the specific regulation to which the temporary variance is sought that will ensure the protection and well-being of patients; and
 - f. Provide a detailed plan for the long term compliance with the specific regulation to which a temporary variance is sought to ensure compliance when the variance expires.

2. Process for Review of a Request for a Temporary Variance
 - a. The Office of Licensure and Certification will evaluate each request for a temporary variance to a specific regulation based on the information provided by the facility.
 - b. Additional clarifying or supporting information may be requested by the Office of Licensure and Certification.
 - c. The Office of Licensure and Certification will make a recommendation to the State Health Commissioner to either approve or deny the requested temporary variance based on its consideration of the following factors:
 - i. Whether the waiving of enforcement of the specific regulation at the requesting facility will adversely affect or create the potential for an adverse affect to patient safety, patient care, or the services offered;
 - ii. Whether adequate safeguards are in place to meet the purpose of the specific regulation to which the temporary variance is requested; and
 - iii. Whether the facility has an acceptable plan in place that addresses the long term compliance with the specific regulation to which a temporary variance is sought.
3. The State Health Commissioner will review the recommendation of the Office of Licensure and Certification and based on the recommendation, and his own expertise and discretion, grant or deny the temporary variance.
4. Inspectors from the Office of Licensure and Certification may conduct an unannounced, on-site inspection of an abortion facility to, among other reasons, assess compliance with the terms of any temporary variance issued by the State Health Commissioner.

II. Term of the Temporary Variance

1. Unless otherwise stated, a temporary variance for an abortion facility expires when the license expires, April 30th of each year.
2. Requests to re-issue a temporary variance shall be received by the Office of Licensure and Certification at least 60 days prior to the expiration of the current variance. Such requests shall comply with Section I.B.1 above.
3. A temporary variance for waiver of enforcement of a specific regulation can be rescinded or modified by the State Health Commissioner if:
 - a. The temporary variance adversely affects, or creates the potential to adversely affect, patient safety, patient care, or services;
 - b. It would no longer be an impractical hardship unique to the abortion facility to comply with the specific regulation to which a temporary variance was granted; or
 - c. The abortion facility fails to meet any condition attached to the temporary variance;
4. At no time shall a variance granted to one facility be extended to general applicability to other facilities.