

July 31, 2014

State Health Commissioner
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, VA 23233

RECEIVED
AUG 04 2014
VDH/OLC

Re: Falls Church Healthcare Center
Request for Variance

Dear Commissioner:

This letter serves a request by Falls Church Medical Center LLC, trading as (t/a) Falls Church Healthcare Center (where appropriate, the "Healthcare Provider"), the licensee of the Falls Church Healthcare Center (where appropriate, the "Facility") for a temporary variance (pursuant to 12VAC5-412.90) of the Regulations for Licensure of Abortion Facilities, 12 VAC 5-412, specifically Part VII related to design and construction titled "Local and State Codes and Standards." 12 VAC5-412.370.

The Healthcare Provider is committed to providing high quality care to Virginia's women and takes medically appropriate measures to protect the safety of patients and to ensure that a standard of high quality care is met. Consistent with the commitment to operate a Facility that ensures that Virginia women have access to high quality reproductive health care, the Healthcare Provider has sought and received a license renewal to continue operating through April 30, 2015.

In 2012 the Healthcare Provider submitted a license application and a detailed plan (the "Plan") to bring the facility into full compliance with Part VII within two years. The license application and the Plan included details about compliance steps and demonstrated that patient safety, patient care, and the services offered would not be affected adversely during operation of the Facility. Thus, the operation of the Facility reflected in the application and the Plan showed that patients would be protected upon the grant of a temporary variance. The operation reflected in the Plan, and indeed the current operation of the Facility, already ensures the protection and well-being of patients.

The Facility has taken steps to comply with 12 VAC5-412, including engaging an AIA Architect and retaining legal counsel. The Facility's architect developed detailed analyses of the regulations and a compliance checklist if all aspects of Part VII were required. This checklist was more than 30 pages long with single spacing, demonstrating the truly onerous nature of the regulations. Of the items on the checklist, most have virtually nothing to do with patient safety or quality of care. In fact, the Facility has never had a medical issue arise that would have been avoided if the new physical or administrative rules included in the VAC5-412 had been in place. The Healthcare Provider and the Facility have a record of safety and patient care second to none.

The Facility has also gathered information about the cost of complying with Part VII. In so doing, the Facility found it necessary to hire a new staff person to address compliance with the new regulations, increase the salary and responsibilities of a second staff person, and increase and reallocate time of the Facility's Director to address the regulations.

Although the Facility has not yet expended the hundreds of thousands of dollars (and likely more than a million dollars) that it would cost to engage in the reconstruction costs that would be necessitated by full compliance, the Facility has already expended tens of thousands of dollars in compliance costs in just the past year alone.

The Facility has also made upgrades to its facilities to improve quality of care and patient safety, some of which coincide with Part VII requirements and some of which do not. The Facility consistently watches for opportunities to improve its patient experience, based on feedback from patients and staff.

The cost of the bare essentials of reconstruction that would be required to achieve Part VII compliance would consume at least 40% of the Facility's revenues for the next four years. There can be no quality of care, patient safety or patient satisfaction justification for such expenditures. Certainly, one could not cover the costs through increases in fees charged to patients without substantially diminishing accessibility to the Facilities services. Therefore, were the Facility to have to actually devote that percentage of its revenues to Part VII compliance instead of the high-quality patient care that is currently being provided, the costs would effectively force closure of the Facility.

The compliance and attendant administrative expenditures would, moreover, consume many times over the reasonable maintenance and replacement allowances already used by the Facility to improve patient care and deprive the Facility of the capability of making those maintenance and replacement investments that have actual positive impacts on patient care.

The Healthcare Provider also requests a temporary variance because compliance with the architectural requirements in Part VII are virtually meaningless with respect to patient safety and would impose extraordinarily high costs and burdens. The high costs and burdens imposed by Part VII constitute -- in and of themselves -- impractical hardships in their application to the unique attributes of the Facility.

While the impact on the Facility is unique to the Facility, the Facility's position with respect to Part VII is not unique. Indeed, it is shared by the head of Virginia's executive branch.

On May 11, 2014, Governor McAuliffe announced that he was issuing an Executive Directive (ED-01) in which he acknowledged that Part VII "placed unprecedented construction requirements on [abortion] facilities" and expressed concern "that these new restrictions may negatively impact women's access to necessary health services."

In announcing the Executive Directive, Governor McAuliffe issued a news release in which he made the following statement: "I am concerned that the extreme and punitive regulations

RECEIVED

AUG 24 2014

VDH/OLC



adopted last year jeopardize the ability of most women's health centers to keep their doors open and place in jeopardy the health and reproductive rights of Virginia women,"

Accordingly, in ED-01, the Governor requested an accelerated review of Part VII, seeking advice on "whether new regulations should be promulgated, or whether any existing regulations should be amended or repealed."

In response, the Board of Health commenced on May 15, 2014, a periodic review and small business impact view of 12 VAC 5-412 pursuant to Executive Order 14 (2010), §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, and ED-01. The comment period for the periodic review commenced June 16, 2014, and ends on July 31, 2014.

It would be contrary to sound healthcare and business practices – and arguably inappropriate -- to pursue an aggressive and extraordinarily expensive compliance program with respect to Part VII at a time when an Executive Directive of the Commonwealth deems Part VII an unprecedented construction requirement that may negatively impact women's access to necessary health services and the Commonwealth is commencing a process to determine whether Part VII should be amended or repealed.

In addition to the Executive Directive, Part VII is under judicial review before the Circuit Court for Arlington County in *Falls Church Healthcare Center v. Virginia Board of Health, et al.*, Case No. CL 13-1362. The Court overruled a demurrer that had been filed by the Commonwealth and upheld the right of Falls Church Healthcare Center (with respect to the litigation, "FCHC") to be heard on the merits of its challenge to Part VII and other aspects of the emergency regulations adopted by the Board of Health. The Office of the Attorney General has asked that the case be continued pending completion of the Board of Health's pending periodic review and small business impact review. FCHC has consented to that request.

In its appeal, FCHC has asked the Court to set aside the Regulations for Licensure of Abortion Facilities (12 VAC5-412.10 to .370) in their entirety. Alternatively, FCHC has asked the Court to set aside the portions of the regulations pertaining to license renewal, temporary variances, and the building regulations contained in Part VII.

The Healthcare Provider understands that this ongoing litigation may resolve whether undertaking compliance with Part VII is necessary and, at the very least, may provide additional guidance with respect to compliance.

In sum, it would be unreasonable to require the Facility or Healthcare Provider to expend exorbitant sums of money that have no bearing on patient safety, care or service offerings given the pendency of an Executive Directive and litigation that would render such expenditures unnecessary – expenditures that would undermine the principal purpose of the Facility and Healthcare Provider to provide access to reproductive health services and to spend resources on medically appropriate means of assuring patient health and safety.

During the pendency of the periodic review initiated pursuant to the Executive Directive and the litigation commenced by FCHC, the Healthcare Provider requests that this letter, its license

RECEIVED

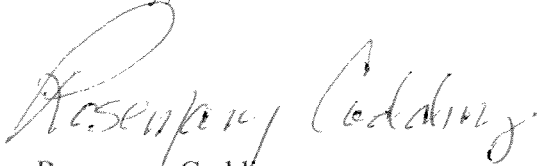
VDH/OLC

(3)

renewal application, and its Plan be deemed to satisfy the Guidance Document dated October 25, 2012, issued by the Virginia Department of Health Office of Licensure and Certification.

Accordingly, the Healthcare Provider requests grant of a temporary variance for the Facility until April 30, 2015.

Sincerely,



Rosemary Coddling
Director, Falls Church Healthcare Center

cc: David Lasso, Esq.
Counsel to Falls Church Healthcare Center

RECEIVED

4/29/15
VDH/OLC

(4)