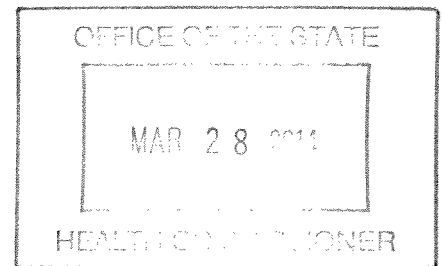


*Virginia Women's Wellness*  
224 Groveland Road  
Virginia Beach, Virginia



March 14, 2014

Marissa J. Levine, M.D.  
State Health Commissioner  
9960 Mayland Drive; Suite 401  
Henrico, Virginia 23233

Re: Request for Variance

Dear Dr. Levine,

Please kindly accept this letter as Virginia Women's Wellness formal request for a temporary variance waiving the enforcement of a portion of the Regulations for the Licensure of Abortion Facilities ("abortion regulations"). Our license expires on April 30, 2014 and we are respectfully requesting a variance commencing May 1, 2014 and continuing for a ten-year term, until April 30, 2024. In the event that the Department will not grant a variance for a ten-year term, then we respectfully request a variance for as long a term as the Department will grant.

I apologize that this request for a variance is being submitted only forty days before the expiration of our license. We delayed in submitting this request for a variance from these abortion regulations in order to wait until the new administration had taken office and most official appointments had been made. We thought this was important because we hoped that this request for a variance from the abortion regulations might receive a fairer and more balanced treatment under the new administration.

This request will follow the format suggested in the Virginia Department of Health's ("Department") "Guidance Document: Granting a Temporary Variance to Regulations for the Licensure of Abortion Facilities" ("Guidance Document") (enclosed).

- A. The facility for which the variance is being requested is Virginia Women's Wellness, an Abortion Facility currently licensed by the Department.
- B. The specific regulation for which we are seeking a variance is 12 VAC 5-412-380 and any related regulations creating design and construction requirements. We are only requesting a variance from the design and construction requirements of the abortion regulations, nothing more. We believe that we are in compliance with all other aspects of the abortion regulations.
- C. The reason why enforcement of 12 VAC 5-412-380 creates an impractical hardship is that it is financially impossible for Virginia Women's Wellness to afford to comply with these requirements. We obtained estimates of the cost of carrying out the construction needed to bring our facility into compliance with the regulation, and it

was estimated that the cost might possibly be \$300,000 and even possibly as much as \$500,000. These are impossible numbers for us. Consequently, forcing VWW to comply with these construction requirements would prove to be the “ultimate hardship” for VWW – it would probably put us out of business. That is why 12 VAC 5-412-380 creates an impractical hardship for us.

- D. The reason why “patient safety, patient care, and the services we offer will not be adversely affected if the variance is granted” is because these construction requirements are not medically necessary and compliance with them has never been scientifically shown to improve patient safety in the performance of first trimester abortion procedures. Furthermore, Virginia Women’s Wellness has been safely providing first trimester abortion care in our existing facility since 1997 without a single, solitary serious complication. This seventeen-year track record of safety proves beyond doubt that our facility is safe. There is no basis to think that granting us a variance on constructing wider hallways or larger rooms, or requiring air to be changed twice per hour in a procedure room where non-sterile procedures are performed (and where we have never had an infection), or installing public pay phones, or forcing us to increase the size of janitorial closets, or any of the other construction requirements, would have any impact on “patient safety, patient care, or the services that we offer”. There is no rational basis or scientific evidence that denying variances to these construction requirements would improve safety for abortion providers in general. And for VWW in particular, our facility already has, essentially, a perfect safety record. Complication rates of zero cannot be improved to “below zero” by construction requirements.

There is substantial evidence supporting our statement that these design and construction requirements are not medically necessary. First, they are not supported by any nationally accredited legitimate medical or scientific authority as improving patient safety for the performance of first trimester abortion procedures. Specifically, they are not endorsed by the American College of Obstetricians and Gynecologists; they are not supported by the National Abortion Federation; they are not supported by the World Health Organization, they are not endorsed by the Society for Family Planning; they are not supported by the Planned Parenthood Federation of America standards; and they are not the standard of the Association of Reproductive Health Professionals. Nor is there any published medical literature producing any scientific data that these construction requirements have any beneficial effect, whatsoever, for first trimester abortion care, on “patient safety, patient care, or the services that we offer”. No doubt it is because of the complete lack of any scientific data or medical evidence supporting these construction requirements that none of these recognized medical organizations endorse them.

It is remarkable that no less than two former Virginia Commissioners of Health have spoken out publicly against these regulations. First, it is well known former Commissioner of Health, Dr. Karen Remly, resigned her position as Commissioner of Health in protest over the politicization of these abortion regulations and the construction requirements for which we now seek a variance (see attached).

The view that these construction requirements are not medically necessary or scientifically supported is further expressed in the attached letter by former Virginia Commissioner of Health under four governors, Dr. James B. Kenley, M.D., M.P.H. Dr. Kenley writes about the temporary regulations (that later became the permanent regulations from which we are now requesting a variance):

*“the temporary regulations, specifically the time and resources required to physically alter health centers for no medical reason, are likely to increase financial barriers for patients as well as reduce women’s ability to find a health care provider. The current temporary regulations require extensive, medically unnecessary and inappropriate renovations to meet building standards intended only for the design and construction of new outpatient surgical hospitals, not existing health centers.”* (emphasis added)

Former Virginia Commissioner of Health Kenley concludes his letter:

*“Abortion is a safe and legal procedure. Studies show that the vast majority of women seeking abortion care are in the first trimester, and 97% report no medical complications. The proposed regulations would likely require every women’s health center in the Commonwealth to make extensive structural modifications that have no proven medical benefit to patients.”*

*“As the former Commissioner of Health under four governors, I urge the members of the Virginia Department of Health and the Board of Health to adhere to their charge – to protect the public health and safety of the people of the Commonwealth by adopting only those regulations that are medically appropriate and based in science”.* (emphasis added)

- E. Under section “e” of the Guidance Document, the Department asks that we “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”.

The alleged purpose of 12 VAC 5-412-380 is to provide a facility that is physically safe for patients. As previously mentioned, VWW has a seventeen-year documented track record of safety in our current facility. In this time frame, we have safely provided abortion care to more than 40,000 women, without a single serious complication. This extremely strong record of outstandingly safe medical care proves that our physical facility, as it is, is safe. Consequently, our proposed alternative that meets the Abortion Regulation’s goal of a physically safe facility is to continue to provide safe care to the women of Virginia in our already-safe medical facility. Furthermore, we maintain that continuing to serve the public in our safe medical facility will continue to “ensure the protection and well-being of patients”, just as we have done for the past 17 years.

F. Under section “f” the Guidance Document asks us to provide a “plan for the long-term compliance with the specific regulation to which variance is sought”. Our long-term plan is several-fold:

- i. First, these construction requirements are currently being challenged in the Virginia Courts and may be reversed. If the Virginia courts overturn these construction requirements, then it will not be necessary for VWW to comply with them.
- ii. Second, the Virginia Board of Health previously voted to grandfather in existing providers from compliance with these construction requirements. This was consistent with the abortion regulations themselves, since they incorporated the requirements from the Facility Guideline Institute’s *2010 Guidelines for Design and Construction of Health Care Facilities* (“Guidelines”). However, these Guidelines are not intended to apply to existing facilities. Specifically, the Guidelines plainly state that they’re “*intended as minimum standards for designing and constructing new health care facility projects*” (emphasis added). Pressure from the previous administration, coupled with the previous Governor’s appointment of a new Board of Health member who also served as Vice President of a prominent Pro-life organization, resulted in the Board of Health reversing themselves on grandfathering existing facilities. Since the Board of Health has already voted once to grandfather in existing facilities, we are hopeful that, free from political pressure, cooler heads may prevail and the Board may return to their original position and grandfather in existing facilities, including VWW.
- iii. The staff of VWW heard, and applauded, then gubernatorial candidate Terry McAuliffe’s campaign promises to support women’s rights and his criticism of the previous administration’s “war on women”. As previously stated, these design and construction requirements are politically motivated and not supported by either science or medicine. We are hopeful that now Governor McAuliffe, and you as his appointed Commissioner of Health, will breathe fairness and reason into the enforcement of the abortion regulation in Virginia, and that either you or he will somehow lift these unreasonable and medically inappropriate construction requirements.
- iv. If neither the legal challenges, nor the Board of Health, nor the Commissioner of Health, nor the Governor of Virginia can stop the enforcement of these construction requirements on existing women’s health care facilities in Virginia, then VWW will continue to ask for variances to them.
- v. If the abortion regulations are upheld, and if the Department vigorously enforces them, and if the Governor cannot intervene to protect women’s

health care facilities from these regulations, and if you deny our requests for a variance, then most likely we will be forced to close our doors and go out of business.

- vi. If this variance is granted for a period of ten years, and if the abortion regulations are upheld and the Department is continuing to enforce this construction requirement, then VWW will attempt to save \$50,000 per year and put that into a “construction account” so that by the end of the ten-year period we will have the amount of money needed to complete the construction and to come into compliance with the regulation.

Because vigorous enforcement of regulation ultimately threatens the survival of VWW, I believe that it is important to point out that Virginia Women’s Wellness fulfills an important public health function for the people of Virginia. For seventeen years we have provided quality, safe medical care to the women of Virginia Beach in a kind, caring, and compassionate manner. With the closure of Hillcrest, we are now one of only three facilities struggling to meet the demand for pregnancy termination services in this area. As it is, patients report to us that lately Planned Parenthood is overwhelmed by demand and is unable to offer many patients an appointment less than several weeks into the future, which for these time-sensitive procedures may not be fast enough to meet the 14 week deadline. That leaves only VWW and Tidewater to serve Planned Parenthood’s overflow patients. If VWW went out of business, then Tidewater would probably also be overwhelmed trying to handle their own patients, plus Planned Parenthood’s over-flow patients, plus all of VWW’s patients. The net result would most likely be that many women of this region of Virginia might not be able to access abortion services locally, if at all. Indeed, that may well have been the original intention of the pro-life promoters of this regulation – to stop women from accessing their legal right to freedom of choice through denial of women’s access to an abortion provider - by putting abortion providers out of business.

In conclusion, Commissioner Levine, I respectfully ask you to please kindly do as former Commissioner Kenley urges: “to adhere to your charge – to protect the public health and safety of the people of the Commonwealth” by enforcing “only those regulations that are medically appropriate and based in science”. In the interest of justice, fairness, and protecting women’s access to safe reproductive health services, I beg you to please grant us this variance.

Thank you very much for your time and consideration in reviewing this request. If you have any questions or concerns about this request, or if I can be of any service to you in any way, please do not hesitate to contact me immediately.

Respectfully submitted,



Michelle E. Nelson, L.P.N.  
Administrator  
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