VIRGINIA:

IN THE CIRCUIT COURT FOR ARLINGTON COUNTY

FALLS CHURCH MEDICAL CENTER, LLC, d/b/a Falls Church Healthcare Center

900 South Washington Street, Suite 300
Falls Church, Virginia 222046,

Appellant,

V.

VIRGINIA BOARD OF HEALTH,

109 Governor Street
Richmond, Virginia 23219

Serve: Dr. Cynthia C. Romero,
Virginia Commissioner of Health

and

VIRGINIA DEPARTMENT OF HEALTH

109 Governor Street
Richmond, Virginia 23219

Serve: Dr. William A. Hazel,
Virginia Secretary
Of Health and Human Resources

and

DR. CYNTHIA C. ROMERO,
In Her Official Capacity as
Virginia State Health Commissioner

109 Governor Street
Richmond, Virginia 23219

Appellees.

CASE NO.: CL ~~1362-00~~

CL13-1362

PETITION FOR APPEAL OF THE VIRGINIA BOARD OF HEALTH REGULATIONS

Appellant, Falls Church Medical Center, LLC, by counsel, respectfully brings this Petition for Appeal against Appellees Virginia Board of Health; Virginia Department of Health; and Dr. Cynthia C. Romero, in her official capacity as the Virginia State Health Commissioner; pursuant to the Virginia Administrative Process Act and Part 2A of the Rules of the Supreme Court of Virginia, on the grounds and for the relief set forth below:

I. Nature of the Action

1. This is an appeal by Falls Church Medical Center, LLC, doing business as Falls Church Healthcare Center ("Falls Church Healthcare"), taken under the Virginia Administrative Process Act (VA. CODE ANN. §§ 2.2-4001 to -4031 (2011 & Supp. 2012)) (the "APA") and Part 2A of the Rules of the Supreme Court of Virginia.

2. Since 2002, Falls Church Healthcare has provided affordable, quality gynecological and obstetrical services to patients from the Virginia, Maryland, West Virginia, and Washington, D.C., metropolitan area, in its leased office space in the City of Falls Church. It has always, and continues to, operate as a statutory "small business," as defined by VA. CODE ANN. § 4007.1: it employs fewer than 500 people (indeed, only 12 employees and 6 consultants), and has gross annual sales of less than $6 million (indeed, less than $1 million). As part of its services, it provides safe, sanitary and medically appropriate first-trimester abortions in accordance with Virginia and federal laws.

3. Prior to March 2011, facilities that provided first-trimester abortions could have been classified as "outpatient hospitals" by the Virginia Board of Health ("Board"), the same as all other facilities that performed surgical procedures on outpatients and whose procedures did

not require inpatient hospitalization. Or, these facilities were exempted entirely from the hospital regulations because they qualified as a physician's office providing outpatient services.

4. Since then, over the course of a 24-month regulatory process that included at least four "reviews" by the Virginia Attorney General's office, the Board adopted final regulations that single out and apply only to abortion care providers. These regulations contain 38 separate sections (not including the myriad provisions incorporated by reference), provide no permanent variances or grandfathering for existing facilities whatsoever, and are more exacting in several cases than the Board's corresponding rules for inpatient general hospitals.

5. Falls Church Healthcare appeals from the regulations so adopted: they are contrary to the unambiguous command and underlying purpose of the basic statutes authorizing them; they are the conclusion of a legally flawed process that, among other things, failed to consider the impact on small businesses; and consider and address comments submitted that demonstrated the lack of any rational medical or public health basis for the regulations requiring first-trimester abortion facilities to meet inpatient general hospital standards without exception; and they lack evidentiary support in the record, do not reflect reasoned decision-making and are arbitrary and capricious and an abuse of discretion. Accordingly, Falls Church Healthcare requests this Court to review the regulations and hold them invalid, pursuant to Article 5 of the APA (VA. CODE ANN. §§ 2.2-4025 to -4030).

II. Jurisdiction and Venue

6. This Court has subject matter jurisdiction over this appeal pursuant to Article 5 of the APA (particularly VA. CODE ANN. § 2.2-4026) and Part 2A of the Rules of the Supreme Court of Virginia, in that Falls Church Healthcare is affected by and claiming the unlawfulness

of the regulations discussed below, promulgated by a Virginia agency in a rulemaking subject to the APA.

7. This Court has personal jurisdiction over the Board, the Virginia Department of Health ("Department"), and Dr. Romero, in her official capacity as the Virginia Commissioner of Health ("Commissioner"), pursuant to VA. CODE ANN. §§ 32.1-24 and 2.2-4026, and Part 2A of the Rules of the Supreme Court of Virginia, in that each is either an "agency or its officers or agents," as defined by the applicable statutory provisions.

8. Venue is proper in this Court pursuant to VA. CODE ANN. §§ 2.2-4003 & 8.01-261(1)(a), in that Falls Church Healthcare (i) maintains its principal office, (ii) regularly and systematically conducts its affairs and business activity, and (iii) keeps its property affected by the regulations in the City of Falls Church. VA. CODE ANN. § 17.1-506(17).

III. The Parties

9. Appellant, Falls Church Medical Center, LLC, doing business as Falls Church Healthcare Center ("Falls Church Healthcare"), is a limited liability company and statutory "small business" organized and existing under the laws of the Commonwealth of Virginia. Its principal place of business is 900 South Washington Street, Suite 300, Falls Church, Virginia 22046, which is where Falls Church Healthcare maintains its facility that would be required to comply with the regulations that it is appealing.

10. Falls Church Healthcare provides affordable family and gynecological medical care in its Falls Church office to residents of Northern Virginia and the surrounding communities. At all times relevant hereto, it has complied with all of the Commonwealth's applicable regulations necessary to offer those services. The undersigned are counsel for Falls Church Healthcare in this matter.

11. Since 2002, Falls Church Healthcare has performed more than five first-trimester abortions per month, every month. It intends to continue operating in that manner, at the same location. Falls Church Healthcare is subject to, affected by, and aggrieved by the final regulations because (i) the Board approved them contrary to the express authorization of the General Assembly in amending VA. CODE ANN. § 32.1-127; (ii) they are arbitrary and capricious, and they lack evidentiary support in the record leading to their adoption; and (iii) they otherwise violate the law, all as more specifically set out in this Petition.

12. Before adopting the regulations in issue, the Board adopted emergency regulations (the "Emergency Regulations") on or about September 2011 by using the APA's emergency rule-making procedures. VA. CODE ANN. § 2.2-4011. The Emergency Regulations resulted from the General Assembly's bill, passed and signed into law on or about March 2011, that amended VA. CODE ANN. § 32.1-127(B)(1) and required that the Board adopt, within 280 days of the law's passage, minimum standards in five categories for facilities that provided five or more first-trimester abortions per month. The statute that the bill amended also required the Board to follow a specific process, and to consider expert evidence, when adopting any such regulations. The Emergency Regulations were approved by the Governor and made effective on or about December 29, 2011.

13. From their effective date until now, the Emergency Regulations applied to Falls Church Healthcare; they expire on or about June 29, 2013, unless earlier superseded by the Board's proposed final regulations, which are slated to become effective on June 20, 2013. Falls Church Healthcare complied with all of the Emergency Regulations' standards for organization and management by expanding and revising its Medical Office Policy and Procedures Manual that covered personnel, sanitation, infection prevention, risk management, emergency

procedures, patient rights, disaster preparedness, and functional safety and facility maintenance. It also adapted its Best Practices, or derived new ones, to comply with the Emergency Regulations in the categories of:

A. Administrator's duties;

B. Personnel and their duties;

C. Clinical staff duties;

D. Informed Patient consent;

E. Treating minors;

F. Infection prevention, and reporting and maintaining infection control;

G. In-office sedation;

H. Storing and using drugs;

I. Identifying what emergency equipment and supplies to retain;

J. Securing a transfer agreement with INOVA Hospital;

K. Meeting quality benchmarks;

L. Maintenance of medical records;

M. Reporting to the Board or its agents in a timely fashion;

N. Maintaining a plan for disaster preparedness; and

O. Firefighting

14. This appeal, notice of which was duly and timely filed on May 10, 2013, and this Petition are submitted pursuant to the APA (VA. CODE ANN. §§ 2.2-4000 to -4031) and Part 2A of the Rules of the Supreme Court of Virginia. The regulations are to be codified at 12 VA. ADMIN. CODE §§ 5-412-10 to -370, with minor amendments also to 12 VA. ADMIN. CODE §§ 5-

410-10 and -60. Falls Church Healthcare is now, and will be, an "abortion facility" that is adversely affected and aggrieved by such regulations.

15. Appellee Virginia State Board of Health ("Board") is a statutorily created Virginia executive branch agency, with a principal office in Richmond, Virginia. It maintains an address at 109 Governor Street Richmond, Virginia 23219, and is an "agency" for purposes of the APA, pursuant to VA. CODE ANN. §§ 2.2-4001, 32.1-12, and 32.1-127. It is the agency responsible by law for promulgating the regulations in issue. VA. CODE ANN. §§ 32.1-12, 32.1-127(A).

16. Appellee Virginia Department of Health ("Department") is a statutorily created Virginia executive branch department with a principal office in Richmond, Virginia, and is responsible for performing duties required of it by the State Commissioner of Health. VA. CODE ANN. §§ 32.1-16, -19(A). It maintains an address at 109 Governor Street, Richmond, Virginia 23219. The Department is responsible, in part, for enforcing the regulations appealed here.

17. Appellee Dr. Cynthia C. Romero, in her official capacity as the Virginia State Commissioner of Health ("Commissioner"), is an appointee of the Governor of Virginia and serves as the statutory executive officer of the Board. VA. CODE ANN. §§ 32.1-17, -18. The Commissioner maintains an address at 109 Governor Street, Richmond, Virginia 23219. The Commissioner is responsible, in part, for enforcing the regulations appealed here.

18. Upon information and belief, pursuant to VA. CODE ANN. § 2.2-507, the Board, the Department, and the Commissioner will be represented in this matter by the Office of the Attorney General of Virginia, whose address is 900 East Main Street, Richmond, Virginia 23219.

IV. The Regulations Being Appealed.

19. Falls Church Healthcare is appealing the final regulations, titled "Regulations for the Licensure of Abortion Facilities," that the Board adopted on or about April 12, 2013, to regulate medical care facilities that provide five or more first-trimester abortion procedures per month (called "abortion facilities") (collectively, the "Appealed Regulations"). They are to be codified at 12 VA. ADMIN. CODE §§ 5-412-10 to -370. 29 Va. Reg. Regs. 2,329, 2,330–41 (May 20, 2013).

A. The General Assembly Gives the Board a Specific, Unambiguous Command

20. In March 2011, the Virginia General Assembly passed, and the Governor signed into law, Senate Bill 924. It became Chapter 670 of the Virginia Acts of Assembly, 2011 Session ("Senate Bill 924"). A true and correct copy of this act is attached as **Exhibit A**.

21. Section 1 of the two-section Senate Bill 924 amended VA. CODE ANN. § 32.1-127 ("Section 127") as follows, by adding the text in italics and deleting the text stricken through (and items unchanged in plain text):

> A. The regulations promulgated by the Board to carry out the provisions of this article shall be in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.) of this chapter.
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> B. Such regulations:
>
> 1. Shall include minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to assure the environmental protection and the life safety of its patients, ~~and~~ employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; ~~and~~ (iv) conditions under which a

> hospital or nursing home may provide medical and nursing services to patients in their places of residence; *and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities. For purposes of this paragraph, facilities in which 5 or more first trimester abortions per month are performed shall be classified as a category of "hospital";*
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> * * * * *

22. The second section of Senate Bill 924 required the Board to promulgate regulations to be effective within 280 days of the law's enactment.

23. The scope of Senate Bill 924 commanded the Board only to "include minimum standards for" abortion facilities in the following areas:

A. "[C]onstruction and maintenance . . . to assure the environmental protection and the life safety of patients, employees, and the public;

B. "Operation, staffing and equipping;

(C) "Qualifications and training of staff . . ., except those professionals licensed or certified by the Department of Health Professions;

(D) "Conditions under which [it] may provide medical and nursing services to patients in their places of residence; and

(D) "Policies related to infection prevention, disaster preparedness, and facility security."

VA. CODE ANN. § 32.1-127(B)(1).

24. Section 127 also required that the regulations be in "substantial conformity" with standards "established and recognized by medical and health care professionals and by specialists in matters of public health and safety," and federal Medicare and Medicaid standards. VA. CODE ANN. § 32.1-127(A).

25. A related section of the Virginia Code, VA. CODE ANN. § 32.1-127.001 ("Section 127.001"), was not amended along with Senate Bill 924. The Board, however, incorporated it into the debate over the Emergency and Appealed Regulations because, at all times relevant hereto, it provided that:

> Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health.

26. Section 127.001 was originally adopted by the General Assembly in March 2005, when the General Assembly passed, and the Governor signed into law, House Bill 2366; it was codified as § 1 of Chapter 177 of the Virginia Acts of Assembly, 2005 Session. When the Board adopted regulations on or about January 25, 2006, to comply with this command for general hospitals (the "2006 Implementing Amendment"), it interpreted the law to require, and amended the relevant regulation, as follows (additions in italics, deletions stricken through):

> A. ~~The requirements set forth herein have been established under authority of §§ 32.1-127 and 32.1-132 of the Code of Virginia and constitute minimum requirements for designing, constructing, and equipping of hospitals built in Virginia after the effective date of this chapter.~~ *All construction of new buildings and additions, renovations, alterations or repairs of existing buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code.*
>
> *In addition, hospitals shall be designed and constructed according to sections 1 through 7 of the 2001 Guidelines for Design and Construction of Hospital and Health Care Facilities of the American Institute of Architects. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.*
>
> B. ~~Additions, alterations or renovations to existing licensed hospitals or existing buildings to be occupied as a hospital shall conform to these~~

~~minimum requirements, except where variances are granted by the Commissioner in accordance with 12 VAC 5-410-30 A of this chapter.~~ *All buildings shall be inspected and approved as required by the appropriate building regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.*

~~C. Conversions of existing buildings to hospital occupancy shall be considered only in those buildings which were originally constructed for institutional occupancy. Variances may be considered by the Commissioner in accordance with 12 VAC 5-410-30 A of this chapter provided patient care and safety to life from fire are not adversely affected by such variance.~~

~~D. Additions, alterations and renovations to existing buildings shall be programmed and phased so that on site construction will minimize disruptions of existing patient care services. Access, exitways, and fire protection shall be maintained so that the safety of the occupants will not be jeopardized during construction.~~

See **Exhibit B**, 12 VA. ADMIN. CODE § 5-410-650, 22 Va. Reg. Regs. 1,071, 1,130 (Dec. 26, 2005) (publishing final regulations that amended, among other sections, § 650 of the hospital regulations).

B. The Appealed Regulations Contravene the General Assembly's Command

27. Falls Church Healthcare appeals the Appealed Regulations on alternative grounds, and seeks relief in the alternative. Principally, it appeals because legal and procedural errors infected the entire process, and the Appealed Regulations must be set aside as a whole. They are part of a comprehensive scheme to regulate "abortion facilities," and the regulations are not severable because "it is apparent that two or more regulations or provisions must operate in accord with one another." VA. CODE ANN. § 2.2-4004.

28. The Appealed Regulations as a whole violate the law for the following reasons:

A. They violate Section 127, as they are not "in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of

public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.) of [Chapter 5 of Title 32.1 of the Code of Virginia]."

B. They treat abortion facilities much more harshly than general hospitals, in a way that is arbitrary and capricious and in violation of the due process clause of the Virginia Constitution, VA. CONST. art. I, § 11, because Section 127 requires the Board to classify abortion facilities "as a category of hospital," but there is no evidence in the record that they should be treated more harshly than the other facilities classified as categories of hospitals, including general hospitals.

C. In adopting the Appealed Regulations, the Board abdicated its statutory duty by failing to consider "less intrusive or less costly" requirements, "the establishment of performance standards for small businesses," or "the exemption of small businesses" in violation of §§ 2.2-4007.04 & 2.2-4007.1 of the APA, and the duty imposed by the Governor to consider less costly impacts, in violation of Governor Robert F. McDonnell's Executive Order No. 14 (June 29, 2010).

D. The Board failed to appropriately consider the information provided by medical and health care professionals, and by specialists in the field of public health and safety. This, despite Section 127's requirement that the Board's regulations "substantially conform" to the standards recognized and established by such individuals. VA. CODE ANN. § 32.1-127(A). The Board was also statutorily required by the APA, but failed, to consider and substantially address comments from such individuals. VA. CODE ANN. §§ 2.2-4007.02 & 2.2-4007.1.

E. The Board failed to substantially conform the Appealed Regulations to those promulgated for Medicare and Medicaid reimbursement under Title XVII and Title XIX of the Social Security Act, because the latter provides that first-trimester abortions should be performed in an outpatient setting and not in a general hospital.

F. The Board failed also to properly convene interested stakeholders, as it is required to do by VA. CODE ANN. § 2.2-4007.02 and its own public participation guidelines, located at 12 VA. ADMIN. CODE § 5-11-10 to -110, particularly by failing to convene a regulatory advisory panel or negotiated rulemaking panel under 12 VA. ADMIN. CODE §§ 5-11-70 & 5-11-80.

G. The Board also failed to properly consider the impact of the Appealed Regulations on the family. Instead, the agency statement issued with the Emergency Regulations said the regulations governing the accessibility and affordability of first-trimester abortion services, "[W]ill not have any impact on the institution of the family and family stability." **Exhibit C**, Virginia Department of Health, Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document for Regulations for Licensure of Abortion Facilities (Sept. 19, 2011), available at *http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\58\3563\6006\AgencyStatement_VDH_6006_v6.pdf*

H. The Attorney General gave the Board incorrect legal advice on the required content and form of the Appealed Regulations, mistakenly advising that all existing facilities had to comply with the Facilities Guidelines Institute's 2010 Guidelines for the Design and Construction of Health Care Facilities (the "*2010 Guidelines*").

i. As noted by several lawmakers of the General Assembly that passed Senate Bill 924, the Board founded its decision on an incorrect directive from the Attorney General about the meaning of Section 127 and Senate Bill 924, and the effect of Section 127.001 on both. Section 127 stated only that abortion facilities shall be "classified as a category of hospitals for purposes of *this paragraph*," *i.e.*, Paragraph B of Section 127, and not any other section in the Virginia Code. VA. CODE ANN. § 32.1-127(B)(1) (emphasis added). In turn, Section 127.001 required the Board to adopt regulations "that shall include *minimum* standards for the *design and construction* of hospitals . . . consistent with [the *2010 Guidelines*]." Va. Code Ann. § 32.1-127.001 (emphasis added).

ii. Further, the *2010 Guidelines* themselves expressly state that they apply only to new construction, or additions, renovations, alterations or repairs of existing buildings. They do not apply to existing facilities that have not voluntarily elected to undergo physical changes. *E.g.*, *2010 Guidelines* ¶¶ 1.1-1.3.2; 1.1-3.1.

iii. Section 127 unambiguously provided that the *2010 Guidelines* were to apply to new design or construction, and the minimum standards were for maintenance and construction, not to apply indiscriminately to all existing facilities in all cases. VA. CODE ANN. § 32.1-127(A), -127.001. To the extent this was ambiguous, the Board had already interpreted these two statutory sections to

apply to new facilities, not existing ones *in toto*, when the adopted the 2006 Implementing Amendments per Section 127.001. Accordingly, the Attorney General's advice was against the Board's own interpretation of the statutes, as well as their plain meaning.

iv. The Attorney General instructed the Board, however, that it had no choice but to apply the *2010 Guidelines* to every existing abortion facility. This was wrong under both the unambiguous statutory language of Section 127 and the *2010 Guidelines* themselves.

I. On or about July 16, 2012, the Attorney General also gave incorrect legal advice in refusing to "certify," pursuant to VA. CODE ANN. § 2.2-4013(A), that the Board had "statutory authority" to adopt a version of the Appealed Regulations that proposed to exempt, or "grandfather," existing facilities from compliance with the *2010 Guidelines*.

J. The Attorney General not only erred in his legal advice on the Appealed Regulations, but also incorrectly answered the Board's question about future legal service as follows:

> **Are Board members required to follow the advice of the Attorney General?**
>
> As in the case with any state entity represented by the Office of the Attorney General, Board members may refuse to follow the advice of the Attorney General. Should a Board member choose to disregard the Attorney General's advice and subsequently be named in a lawsuit related to the particular Board action taken, such as the recent litigation challenging the certificate of public need program which named every Board member as an individual defendant, the Attorney General is not obligated to provide representation and it is within the discretion of the Attorney General to decline both representation of the Board member and the appointment of special counsel. *See* Virginia Code §§ 2.2-507 and 2.2-510. Such decisions are made on a case-by-case basis. In

> a case where the Office of the Attorney General declines to represent a Board member because of the member's refusal to follow legal advice, it would be the responsibility of the Board member to obtain and pay for his or her own legal representation if representation was desired.

A true and correct copy of the Office of the Attorney General's September 12, 2012, Memorandum containing that advice is attached as **Exhibit D**, and incorporated by reference (AG's September 2012 Memorandum). As a result, the Board did not follow the mandate specified in Section 127(A), or the APA.

29. Alternatively, Falls Church Healthcare appeals three specific sections of the Appealed Regulations, which suffered the most error in both their content and their adoption, and requests that at least these be held invalid or set aside (the following three, collectively, the "Three Specific Sections"):

A. The "License Renewal Regulation": 12 VA. ADMIN. CODE § 5-412-60, titled "License expiration and renewal," sets a harsher standard for license renewal that that for general hospitals. It states:

> A. Licenses shall expire at midnight April 30 following the date of issue and shall be renewable annually, upon filing of a renewal application and payment of the appropriate nonrefundable renewal application fee. Renewal applications shall only be granted after a determination by the OLC that the applicant is in substantial compliance with this chapter.
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> B. The annual license renewal application shall be submitted to the OLC at least 60 days prior to the expiration date of the current license. A renewal application submitted more than 60 days past the expiration of the current license shall not be accepted.
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> C. Any abortion facility failing to submit an acceptable plan of correction as required in 12VAC5-412-110 shall not be eligible for license renewal.

B. The "Variance Regulation": 12 VA. ADMIN. CODE 5-412-80, titled "Allowable variances," is narrower in the scope for granting variances than that for general hospitals by providing that:

> A. The commissioner may authorize a temporary variance only to a specific provision of this chapter. In no event shall a temporary variance exceed the term of the license. An abortion facility may request a temporary variance to a particular standard or requirement contained in a particular provision of this chapter when the standard or requirement poses an impractical hardship unique to the abortion facility and when a temporary variance to it would not endanger the safety or well-being of patients. The request for a temporary variance shall describe how compliance with the current standard or requirement constitutes an impractical hardship unique to the abortion facility. The request should include proposed alternatives, if any, to meet the purpose of the standard or requirement that will ensure the protection and well-being of patients. At no time shall a temporary variance be extended to general applicability. The abortion facility may withdraw a request for a temporary variance at any time.
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> B. The commissioner may rescind or modify a temporary variance if: (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the abortion facility fails to meet any conditions attached to the temporary variance; or (iv) results of the temporary variance jeopardize the safety or well-being of patients.
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> C. Consideration of a temporary variance is initiated when a written request is submitted to the commissioner. The commissioner shall notify the abortion facility in writing of the receipt of the request for a temporary variance. The licensee shall be notified in writing of the commissioner's decision on the temporary variance request. If granted, the commissioner may attach conditions to a temporary variance to protect the safety and well-being of patients.
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> D. If a temporary variance is denied, expires, or is rescinded, routine enforcement of the standard or requirement to which the temporary variance was granted shall be resumed.

C. The "Building Regulation": 12 VA. ADMIN. CODE 5-412-370, titled "Local and state codes and standards," requires abortion facilities to comply with all

building codes and the *2010 Guidelines*, whether compliance in the facility's present building is possible or not.

i. General hospitals and nursing facilities only need to comply with such codes in new construction or "additions, renovations, alterations or repairs" of existing buildings. 12 VA. ADMIN. CODE § 5-412-650. Likewise, as discussed above, the *2010 Guidelines* only apply to new construction or, for existing buildings, to additions, renovations, alterations or repairs. Provisions "grandfathering" existing facilities under new building regulations have been the Board's rule since its original adoption of hospital regulations in 1948. *See* **Exhibit E**, Rules and Regulations Governing General and Special Hospitals ¶ II.A (1948).

ii. Also, for "abortion facilities, the *2010 Guidelines* take precedence over state and local building and zoning codes. They do not take precedence over such laws in the case of hospitals and nursing homes. The Building Regulation requires that:

> Abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over the Virginia Uniform Statewide Building Code pursuant to § 32.1-127.001 of the Code of Virginia.
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> Entities operating as of the effective date of this chapter as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12VAC5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full

compliance with this provision within two years from the date of licensure.

In order to determine whether the abortion facility is in compliance with this provision, the commissioner may obtain additional information from the facility or its architect concerning the design and construction of the facility.

VI. Application of the Appealed Regulations to Falls Church Healthcare.

30. The office space rented by Falls Church Healthcare in the City of Falls Church, located at 900 S. Washington Street, is about five thousand (5,000) square feet. It is on the top (fifth) floor of an office building constructed almost fifty years ago. The facility cannot meet the full breadth of the standards for new construction in the *2010 Guidelines*, which are incorporated by reference in the Appealed Regulations at 12 VA. ADMIN. CODE § 5-412-370. Via the Hobson's Choice put to it by the Appealed Regulations, Falls Church Healthcare was authorized to submit a Plan of Correction ("POC") obligating it — within two years of submitting it — to either change its facility (by renovation or moving to a new office) or cease operating.

31. Falls Church Healthcare received a license to operate an "abortion facility" under the Emergency Regulations. Falls Church Healthcare's license is valid through April 30, 2014.

32. The Emergency Regulations will be replaced by the Appealed Regulations. The Appealed Regulations, as of their effective date of June 20, 2013, will apply to Falls Church Healthcare. In order to operate, Falls Church Healthcare must renew its Board license under the Appealed Regulations. Falls Church Healthcare intends to continue to offer services at its offices that make it an "abortion facility" under the Appealed Regulations. Renovation of its existing facility is prohibitively expensive, and moving to a new location is not economically or practically feasible. *See* ¶ 79, below.

33. As of the date of this Petition, the Appealed Regulations have not yet been officially codified. So, for ease of reference, a true and correct copy of the Appealed

Regulations and official commentary of the Board published in the Virginia Register of Regulations on January 28, 2013, at pages 1,523–1,541 are attached to this Petition as **Exhibit F**, and incorporated by reference.

34. The Appealed Regulations were adopted by the Board on or about April 12, 2013, and were unchanged from those set out in **Exhibit F**. The final adopted regulations were published in the Virginia Register of Regulations on May 20, 2013, at pages 2,329–2,341, a true and correct copy of which is attached to this Petition as **Exhibit G**, and incorporated by reference.

35. Falls Church Healthcare principally seeks to set aside the Appealed Regulations in their entirety: they violate the law as a whole because of the legal and procedural errors committed in adopting them.

36. Alternatively, Falls Church Healthcare claims that at least the Three Specific Sections, which single out abortion facilities for harsher treatment than the comparable regulations that apply to general hospitals, are unreasonable, arbitrary and capricious, violate Section 127 and Section 127.001, and otherwise violate Virginia law.

37. The Three Specific Sections set out above are the prime examples of these, in particular the Building Regulation, 12 VA. ADMIN. CODE § 5-412-370, which requires existing and licensed abortion facilities to comply with the *2010 Guidelines*. The *2010 Guidelines* are much more demanding than local building and zoning codes, and the Uniform Statewide Building Code. Moreover, under the Building Regulation, the *2010 Guidelines* take precedence for abortion facilities over the state and local building and zoning codes.

38. The regulations governing design and construction of general hospitals and outpatient hospitals on the other hand (12 VA. ADMIN. CODE § 5-410-650 and 12 VA. ADMIN.

CODE § 5-410-1350) only apply the state building code and *2010 Guidelines* to *new* construction. And, the Uniform Statewide Building Code, and local zoning and building ordinances, take precedence over the *2010 Guidelines*. Thus, the Building Regulation is harsher for abortion facilities than comparable regulations for general hospitals and outpatient hospitals. It is also contrary to the Board's previous interpretation of the applicable statutory command of Section 127.001, despite being founded on the same provision.

39. The Building Regulation is also contrary to the express language of the *2010 Guidelines* themselves, and therefore it violates Section 127.001, to the extent it applies (which, of course, it does not by the unambiguous language of Section 127(B)). The *2010 Guidelines* explicitly state that they are "intended as minimum standards for designing and constructing new health care facility projects." *2010 Guidelines* ¶¶ 1.1-1.3.2, 1.1-3.1, 1.1-3.2, & 1.1-3.3 (2010). Further, they are applicable only based on the facility's functional program. *Id.* ¶¶ 3.1-1.1.1 & 3.7-1.2 ("The extent (number and type) of the diagnostic, clinical, and administrative facilities to be provided will be determined by the services contemplated and the estimated patient load as described in the functional program. Provisions shall be made for medical and nursing assessment, nursing care, preoperative testing, and physical examination for outpatient services."). To make this point even clearer, the *2010 Guidelines* state at ¶ 1.1-3.2 that, "In renovation projects and additions to existing facilities, only that portion of the total facility affected by the project shall be required to comply with the applicable section of these Guidelines."

40. Treating existing abortion facilities more harshly than hospitals in this way has no basis in Virginia law, and is not in "substantial conformity" with Section 127(A) regarding "the standards of health, hygiene, sanitation, construction and safety as established and recognized by

medical and health care professionals and by specialists in matters of public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.) of this chapter."

41. In the proposal stages that led to the Appealed Regulations, the Board proposed and adopted a regulation that would have "grandfathered" existing abortion facilities from compliance with the then-current versions of local ordinances and the Uniform Statewide Building Code, and, most importantly, from the *2010 Guidelines*. This was discussed at length at the June 15, 2012, Board meeting. The proposed amendment to 12 VA. ADMIN. CODE § 5-412-370 (the "Grandfather Clause") provided that:

> All construction of new buildings and additions, renovations, alterations and repairs of buildings for occupancy as abortion facilities shall comply with state and local codes, zoning, and building ordinances and the Uniform Statewide Building Code. In addition, abortion facilities shall be designed and constructed according to Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. A building that meets the standards of the local government and the Uniform Statewide Building Code will be deemed to be in compliance until it is required or chooses to undergo substantial renovation.

See Virginia Regulatory Town Hall, Proposed Regulation Agency Background Document 8 (Jan. 8, 2013), a true and correct copy of which is attached hereto as **Exhibit H**, and incorporated by reference.

42. At the June 15, 2012, Board meeting, the Attorney General's office told the Board that it objected to the content of the Grandfather Clause and would not certify any regulations that contained it.

43. Despite the Attorney General's statement, the Board received recommendations from a state-appointed group of respected university physicians and from nationally recognized

experts. Based on their experience and medical judgment, these experts — who had earlier been convened by the Commonwealth and charged with the task of drafting regulations to implement Senate Bill 924 — had previously drafted and recommended that the Board adopt regulations for abortion facilities that did not require compliance with *2010 Guidelines*. These experts, plus many other medical and healthcare professionals, all recommended that existing clinics be exempt from the *2010 Guidelines*. They noted that the Grandfather Clause was entirely consistent with previous Board rulings covering similar types of facilities, as well as with the prevailing expert consensus concerning medically appropriate building standards for medical facilities.

44. The Board had also made clear in 2006 that facility requirements for hospitals would apply only to new construction. *See* Memorandum from the Office of Licensure and Certification, Virginia Department of Health, Design and Construction of Health Care Facilities (effective July 1, 2006), a true and correct copy of which is attached as **Exhibit I** and incorporated by reference.

45. On or about June 15, 2012, the Board voted 7–4 to amend the proposed regulations to include the Grandfather Clause then voted to adopt the Amended Regulations. The American Civil Liberties Union of Virginia submitted a letter dated June 20, 2012, to Dr. Karen Remley, then the State Health Commissioner, that refuted the guidance of the Attorney General. *See* Letter from Claire Guthrie Gastañaga, Executive Director, American Civil Liberties Union of Virginia, to Karen Remley, State Health Commissioner, Virginia Department of Health (June 20, 2012), a true and correct copy of which is attached as **Exhibit J**, and incorporated by reference.

46. Thereafter, on or about July 16, 2012, the Attorney General refused to "certify" the regulations by alleging that the Board had no "statutory authority" to include a grandfather clause. The Office set out its reasoning in a letter dated July 16, 2012, to the Commissioner, Dr. Remley. **Exhibit K**, Memorandum from Allyson K. Tysinger, Senior Assistant Attorney General/Chief, to Dr. Karen Remley, Commissioner, Virginia Department of Health (July 16, 2012).

47. This action was erroneous, both procedurally and as a characterization of Virginia law, as the Board clearly has the authority to set minimum standards of design and construction. Section 127.001 states that the Board "shall include minimum standards for the design and construction of hospitals, nursing homes and certified nursing facilities consistent with the current edition of the Guidelines for the Design and Construction of Hospital and Health Care Facilities . . . ." Likewise, Section 127 requires regulations of health care facilities to be "in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety . . . ." The current edition of the referenced *2010 Guidelines* states that they are "intended to as minimum standard for designing and constructing *new* health care facility projects." *2010 Guidelines* ¶ 1.1-1.3.2 (emphasis added).

48. As set out in paragraph 45 above, The American Civil Liberties Union of Virginia submitted a letter dated June 20, 2012, to Dr. Karen Remley, then the State Health Commissioner, that refuted the guidance of the Attorney General. *See* Letter from Claire Guthrie Gastañaga, Executive Director, American Civil Liberties Union of Virginia, to Karen Remley, State Health Commissioner, Virginia Department of Health (June 20, 2012), a true and correct copy of which is attached as **Exhibit J**, and incorporated by reference. The Attorney General is

an elected constitutional officer of the Commonwealth, who has no authority to "approve" or "veto" the content of the Appealed Regulations. The Attorney General can only perform those duties imposed by law (*See* VA. CONST. art. V, § 15, *and* VA. CODE ANN. § 2.2-500) and his only role in the administrative process is to "review" the regulations to ensure statutory authority for them. VA. CODE ANN. § 2.2-4013 (A). He has no power to "recommend" or to "suggest" any changes. That is the exclusive province of the Governor. VA. CODE ANN. § 2.2-4013.

49. On or about August 12, 2012, a new draft of the Appealed Regulations was proposed to the Board for consideration at its September 15, 2012, meeting. The new draft did not contain the Grandfather Clause that had been adopted by the Board in June 2012.

50. The Board was scheduled to meet on or about September 15, 2012, at which time it would determine whether to approve the August 2012 draft of the Appealed Regulations and publish them for public comment in the Virginia Register, and at the electronic Virginia Regulatory Town Hall forum ("Regulatory Town Hall"). Three days prior to the hearing the, Attorney General's office delivered a memo to each of the members of the Board in which he asserted informing them that:

A. The Attorney General is the sole legal advisor to Board;

B. The Board members were not obligated to follow his advice, but if they chose not to, he could in turn choose not to represent them in any litigation that might ensue from the Board's decisions (meaning they would be responsible for any costs of litigation);

C. The Attorney General cannot veto a Board decision, such as the inclusion of a grandfather clause, but he could refuse to certify the decision as being without authority;

D. The General Assembly can delegate rule-making to the Board, but the Board could not exceed that delegation; and

E. That, in this situation, the bill that amended Section 127 to make abortion facilities a category of hospital prohibited the grandfather clause adopted by the Board in June 2012.

See **Exhibit D**, AG's September 2012 Memorandum.

51. On or about September 15, 2012, after receiving the AG's September 2012 Memorandum, the Board convened to consider the most recent draft of the Appealed Regulations, among other things. A public comment session was held. It included testimony from the head of the Virginia chapter of the American Congress of Obstetricians and Gynecologists, who explained that the Grandfather Clause was medically appropriate for facilities providing first-trimester abortions. Despite this testimony, the Board voted 13–2 to adopt the draft of the Appealed Regulations that failed to include the previously adopted Grandfather Clause and to require all existing abortion facilities to meet current building and zoning codes, and the *2010 Guidelines*.

52. On or about October 18, 2012, Dr. Remley resigned as the Virginia State Health Commissioner. In her resignation letter, Dr. Remley said that the Attorney General's effective veto of the Board's June 2012 decision to adopt the Appealed Regulations including the Grandfather Clause and interpretation of the law applicable to "abortion facilities" caused her to resign after a five-year term that spanned administrations from both political parties:

> I personally committed to you when I accepted your appointment that I would lower abortion rates in our state by both the application of evidence based approaches and also the thoughtful implementation of abortion regulation if authorized to do so by the General Assembly and signed into law by yourself. I have honored those commitments on both accounts. I have worked to guarantee the process of survey and licensure

> would be fairly and thoughtfully applied across the Commonwealth. As of today, all twenty abortion facilities that are eligible for licensing have been inspected, where necessary, plans of correction were received and approved, and within the next few days all will be fully licensed for the coming year.
>
> Unfortunately, how specific sections of the Virginia Code pertaining to the development and enforcement of these regulations have been and continue to be interpreted has created an environment in which my ability to fulfill my duties is compromised and in good faith I can no longer serve in my role.

53. The actions of the Board were caused directly by the erroneous legal guidance provided by the Attorney General and by the implication that, if the Board did not agree with the advice, the Attorney General's office would refuse to represent the Board or its members if they were sued because of the Appealed Regulations and adopted by the Board at the June 12, 2012, meeting including the Grandfather Clause.

54. The Attorney General's actions caused the Board to violate the standard of conduct required of it in carrying out its administrative rule-making function, set out in Section 127(A).

55. After that, the Appealed Regulations — approved by the Board on September 15, 2012, which did not include a grandfather clause — were posted on the electronic Regulatory Town Hall. Among the more than 2,950 comments was a letter dated March 26, 2013, signed by 177 health care professionals and by the Virginia Section of the American College of Obstetrics and Gynecology. That letter summarized the consensus of "the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety opinion" that the Board had previously received — that the application of the current design and construction standards for healthcare facilities was "onerous and medically unnecessary," and contrary to the standards of conduct set out in Section 127(A) governing the Board. Comment of Andrew M. Klein, M.D.,

et al., to the Virginia Board of Health (March 26, 2013), a true and correct copy of which is attached as **Exhibit L** and incorporated by reference

56. The Board also received comments during the Town Hall from Dr. James E. Ferguson II, M.D., M.B.A., a Board-certified obstetrician and gynecologist with a subspecialty in maternal fetal medicine and the W. Norman Thornton, Jr., Professor and Chair of the Department of Obstetrics and Gynecology at the University of Virginia. Comment of James E. Ferguson II, M.D., to the Virginia Board of Health (March 29, 2013), a true and correct copy of which is attached as **Exhibit M** and incorporated by reference. Dr. Ferguson participated in the initial drafting of the Regulations that would be applicable to abortion facilities. He stated as follows:

* * * * *

> 6. The original regulations focused on good medicine and medical practices, and addressed issues such as appropriate follow-up monitoring of patients, methods for establishing gestational age, and ensuring appropriate patient care. The panel's regulations also offered guidelines on patient confidentiality, screening for sexually transmitted diseases if undergoing an abortion, provider credentialing, and appropriate follow-up care.
>
> 7. During this process, we were also asked to review building requirements from South Carolina pertaining to facilities that perform both first- and second-trimester abortions. Second-trimester abortions must be performed in hospitals in Virginia; therefore, the panel concluded that most of South Carolina's guidelines were unnecessary.
>
> 8. After the panel had concluded drafting its version of the regulations, it submitted its version of the regulations for review.
>
> 9. When the draft permanent regulations were returned from Virginia Attorney General Kenneth Cuccinelli's office, the regulations were heavily edited and vastly different from those developed by our committee of physicians and submitted for review by officials. I concluded that I could not support the regulations and asked to have my name removed from them.
>
> 10. Many aspects of the Draft Permanent Regulations, which are currently under review for final approval by the Virginia Board of Health, are unnecessary from a medical perspective to protect patient health and safety. In particular, the requirements that clinics that provide first trimester abortions maintain physical plants that satisfy building requirements for new hospitals are not

reasonably designed or necessary to promote patient health and safety. These requirements will, instead, impose a significant and unnecessary financial burden on such women's health clinics.

11. The clinics subject to the Regulations perform first trimester abortions. The Draft Permanent Regulations, however, require these clinics to meet the facilities requirements applicable to hospitals.

12. Many provisions in the Draft Permanent Regulations have nothing to do with patient care and safety, do not improve patient outcomes, and do not serve to better and/or protect the health of women undergoing first trimester abortions, which are outpatient procedures. For example, the regulations require clinics to build five-foot wide hallways throughout the women's health care centers; add new covered entrances, public telephones, and public bathrooms and drinking fountains in waiting rooms; incorporate new ventilation systems; and even regulate the size of janitorial closets. The regulations require these clinics to provide four parking spaces for each room that is routinely used for surgical procedures plus one space for each staff member. Such regulations do not address medical concerns relevant to protecting the health of such patients.

13. The lack of any reasonable connection between the Draft Permanent Regulations and patient health is further confirmed by the fact that other clinics and ambulatory surgical facilities performing comparable or more medically significant procedures, including dentistry and liposuction, are not regulated to the extent these women's health clinics will be regulated.

14. As rewritten, the Draft Permanent Regulations went well beyond what the advisory panel recommend. The revised Regulations from the Attorney General's office include many provisions taken from regulations adopted by South Carolina, which cover facilities providing first- and second-trimester abortions. However, those regulations are inappropriate for Virginia because Virginia already has rules governing second trimester abortions, which are regulated differently from first trimester abortions. Under existing regulation in Virginia, second-trimester abortions must be performed in hospitals. Accordingly, there is no need for regulations imposing a hospital facility level standard for such abortions. And because first trimester abortions are a significantly different procedure, there is no medical basis for imposing the same requirements on first trimester abortions as second trimester abortions. The Revised Draft Permanent Regulations ignore this difference.

15. When talking about regulations involving medical care, the focus should be on evidence that they are medically necessary and reasonably calculated to enhance patient health and safety. Here, rather than improving patient health and safety, the Regulations impose requirements on these clinics that are not medically necessary and will adversely affect patients by increasing the cost of services or reducing the availability of services where clinics and/or their patients cannot absorb the substantial additional costs that must be incurred to meet hospital facility

standards. Thus, in my judgment, the net result of the Regulations will be counterproductive to patient health and safety.

16. In sum, the Regulations currently under review do not represent the opinions of the medical community or reflect sound medical practice. To the contrary, they are medically unnecessary and will, if anything, adversely affect women's health care in the Commonwealth. It is regrettable that an important issue of public health is not being addressed on the merits, but instead based on political considerations.

57. Also submitting a letter was Dr. Stephen H. Bendheim, M.D. Comment of Stephen H. Benheim, M.D., to the Virginia Board of Health (Mar. 29, 2013), a true and correct copy of which is attached as **Exhibit N** and incorporated by reference. Among his many credentials, Dr. Bendheim served as the immediate past chair of the Virginia Section of the American Congress of Obstetricians and Gynecologists ("ACOG"), which is the nation's leading group of professionals providing health care for women. He reviewed the draft permanent regulations and he stated as follows:

* * * * *

6. The Draft Permanent Regulations are not grounded in medical facts or sound medical practices. The Regulations require health care facilities that only perform first-trimester abortion procedures to unnecessarily overhaul their existing facilities and comply with the building and construction requirements applicable to new hospitals. Such onerous and expensive structural facility requirements are not rationally related to enhancing the safety of first-trimester abortion procedures, nor prevent potential patient complications. For example, requirements as to the width of hallways, HVAC systems, or numbers of parking spaces bear no logical connection to the health and welfare of patients undergoing first trimester abortion procedures, which are performed on an outpatient basis.

7. The lack of any logical connection between new hospital construction standards and patient health and safety is illustrated by the fact that other outpatient procedures that present risks similar to, or greater than, first trimester abortions, are regularly and safely performed in facilities other than hospitals, including private physician's offices, clinics, and surgical centers. These procedures may include breast biopsies, certain plastic surgical procedures, and fibroid removal.

> 8. As a physician, I support all reasonable efforts to minimize health risks to patients and potential complications from medical treatment. With respect to first trimester abortions, such risks can be appropriately addressed through use of proper sterile technique; proper training of personnel, including physicians, nurses, and technicians; proper patient consultation and follow-up; and appropriate storage of supplies and disposal of waste. A hospital grade facility is not required, and I am not aware of any credible medical opinion holding that it is.

58. The former Chair of the Board, Fred Hannett, submitted comments. Comment of Fred Hannett, former Chair of the Board, to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit O**, and incorporated by reference. Among other points, former-Chairman Hannett discussed how the Attorney General's legal guidance was incorrect and how the Board had a long-standing practice based in the law that the *2010 Guidelines* applied only to new construction.

59. In adopting the Appealed Regulations, the Appellees failed to address or analyze the points raised by the comments discussed in paragraphs above. As a result, the decision to adopt the Appealed Regulations was inconsistent with the notice and comment requirements of the APA, was arbitrary and capricious and did not constitute reasoned decision making. It was also not supported by substantial evidence in the record.

60. Further, a number of state legislators submitted letters to the Board that stated their position that the Board's Grandfather Clause was within the Board's authority and the Board would, in fact, be ***inconsistent*** with Virginia law if it applied the *2010 Guidelines* to existing abortion facilities. *See* Comment of Senator Barbara Favola to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit P** and incorporated by reference; Comment of Senator Mark Herring to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit Q** and incorporated by reference; Comment of Senator Janet Howell to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit R** and incorporated by reference; Comment of Senator L. Louise Lucas to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit S** and incorporated by reference; Comment of Senator Henry Marsh to the Virginia Board of Health, a true and correct copy of which is attached as

Exhibit T and incorporated by reference; Comment of Senator Donald McEachin to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit U** and incorporated by reference; Comment of Senator John Edwards to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit V** and incorporated by reference; and Comment of Senator Phillip Puckett to the Virginia Board of Health, a true and correct copy of which is attached as **Exhibit W** and incorporated by reference.

61. In fact, since hospitals were first regulated by rules adopted by the Board in 1948, pursuant to the predecessor statute to Section 127 (Section 32-301 of the Code of Virginia), the standards of construction applied to new "general and special hospitals":

> Before construction is begun, plans and specifications *covering the construction of new buildings, additions, or major alterations to existing building and plants, or any material change in facilities involving patient care,* shall be submitted to the State Department of Health for approval. Unnecessary expense may be avoided if proposed plans in sketch form be submitted to the State Department of Health before final plans are drawn.

Rules and Regulations Governing General and Special Hospitals ¶ II.A (1948) (the "1948 Regulations"), a true and correct copy of which is attached as **Exhibit X** and incorporated by reference.

62. The Board set out in the Virginia Register, and for comment at the electronic Virginia Regulatory Town Hall forum, its analysis and conclusions regarding the potential economic impact of the Appealed Regulations on small businesses. (See **Exhibit F** at 1,526-1,529).

63. Appellant Falls Church Healthcare is a "small business," as that term is defined in VA. CODE ANN. § 2.2-4007.1(A), and also appeals the Appealed Regulations pursuant to VA. CODE ANN. § 2.2-4027 and Va. Sup. Ct. R. 2A:6 for failure to comply with the obligations of VA. CODE ANN. §§ 2.2-4007.04 and 2.2-4007.1. Among other information before the Board were the comments and facts presented by former Chair Hannett, of Arlington; Dr. Wendy S. Klein, M.D., Fellow of the American College of Physicians, Henrico; Dr. Klein, M.D., Henrico;

Dr. Holly S. Puritz, M.D., Norfolk; and Dr. Ferguson II, M.D., M.B.A., Charlottesville (**Exhibit O**).

64. Their letter stated as follows:

> On June 29, 2010, Governor McDonnell signed an important Executive Order (No. 14, 2010) to promote effective and least-burdensome regulation. The order sets out a general policy for executive branch agencies of the Commonwealth, and calls on them to follow a set of common sense principles of good regulatory practice. This order was clearly designed to prevent the sometimes-heavy hand of government from arbitrarily stifling small business and enterprise or interfering with personal freedom without achieving any compelling government interest.
>
> The role of the Virginia government is to make the Commonwealth an even better place to live, work, and raise a family. It is not to shutter legitimate small businesses or to infringe on personal freedom based solely on ideology. Small businesses play a critical role in Virginia's economy, and they are especially susceptible to the negative impacts of arbitrary government action.
>
> Executive Order 14 laid out an extensive process for Virginia regulators, including a mandate to:
>
> - ". . . [Identify] the nature and significance of the problem a regulation is intended to address, including, where applicable, why private markets and institutions cannot adequately address the problem."
> - ". . . [Identify] and assess the least costly means including reasonably available alternatives in lieu of regulation for achieving the goals of a regulation... [including] [the] use of information disclosure requirements, rather than regulatory mandates..."
> - "[Conduct regulatory development] in accordance with statutory provisions related to impact on small businesses."
> - ". . . [Consider] the impact on existing and potential Virginia employers and their ability to maintain and increase the number of jobs in the commonwealth, as well as the cost of compliance by the general public."
>
> Regulations currently proposed under Senate Bill 924 merely pay lip service to these mandates and ideals. The Virginia Department of Health (VDH) did not identify any actual problem requiring the

Commonwealth to intervene in private markets to crush twenty women's health providers arbitrarily. VDH did not demonstrate *any benefits whatsoever,* much less benefits that could plausibly outweigh the enormous costs imposed. In some cases, VDH would force these clinics to spend over $2.5 million in the pursuit of literally zero benefits. And these cost estimates come from the Department of Health's own analysis.

Most strikingly, given the crucial importance of small businesses to the Virginia economy, these regulations fail to offer any reasonable alternatives that might achieve the same goals. These regulations are *designed* to eliminate Virginia jobs, and to make Virginia women less safe and less free.

We call on the Governor, the. Virginia Department of Health, its Board, and members of the Virginia Legislature to fix this regulation to ensure it complies with state statue and Executive Order 14. Specifically, we call upon the Department of Health to focus on informed disclosure instead of the current heavy-handed approach designed to regulate the widths of hallways, mandate special sink handles, and require awnings over the front doors, amongst others. These requirements are intended to apply only to the construction of *new* facilities, and the plain language of SB 924 does not extend them any further.[1] We are unaware of any situation in Virginia where a clinic's sink handles, hallway dimensions, or door awnings have materially affected the life, health, or safety of any woman receiving care in an outpatient setting.

Regulation should protect the health and safety of citizens, and a modern regulatory system can ensure the best possible outcomes with the least possible burden. Executive Order 14 mimics the Federal framework for regulatory oversight that multiple Presidents from both political parties have upheld. This framework recently led the Department of Health and Human Services to actively reduce burdensome regulations for necessary health facilities when doing so would not harm the public interest (in one case providing relief from onerous sprinkler system regulations).

The Virginia Department of Health has never demonstrated that these facilities threaten the health or welfare of Virginia women. These regulations have no medical benefit, and VDH did not even attempt to claim that forcing these clinics to undertake millions of dollars of architectural tweaks would change patient outcomes at all. Meanwhile, this burdensome regulation may well result in the state achieving an effective ban on reproductive health services through regulatory fiat. No rational person would consider this "good government."

A well-functioning regulatory system is designed to work for *all* citizens. It is not the proper role of the Virginia legislature, the Department of Health, or the Governor himself to ban legitimate businesses arbitrarily

based on ideology. *No* small business is safe if regulators can break their own rules in order to attack any small business at will.

65. The Department noted that the cost of compliance for the 20 abortion facilities would range from $75,000 to as much as $6,000,000. In cases of renovation, the Department solely relied on the Department of General Services' ("DGS") expertise, which estimated that it would cost $200 to $447 per square foot "to renovate existing professional office space to meet hospital standards." However, the Department did not specify the methodology used to develop these estimates, and on information and belief they are unsubstantiated and unrealistic because they are not based on any specific analysis of the circumstances of individual abortion clinics, the local market for health care facilities, or other pertinent criteria. In fact, stakeholders were only consulted by e-mail at the last minute with a deadline to reply within hours. A new facility would also cost in that range, but there would be substantial additional land acquisition and potentially demolition costs. If a facility were to move, it would lose business. Also, of course, the option to move assumed that space was available that met current standards and an owner was willing to lease. **Exhibit F**, 29 Va. Reg. Regs. 1,527 (Jan. 28, 2013).

66. Falls Church Healthcare is located in an almost half-century-old office building that would require additional costs currently estimated at more than $2 million if the Commissioner does not grant it a permanent waiver; such permanent waivers are not allowed under the Appealed Regulations, even though hospitals can receive permanent waivers. *See* Pet. for App. ¶ 29(B), (describing that such disparate treatment of hospitals and abortion facilities on variance or waiver issues is unlawful).

67. The Department accepted the unsubstantiated cost estimates as correct, but stated that it had no choice but to enact the rules in order to fulfill the General Assembly's directive to "establish licensure, requirement for facilities performing five or more first trimester abortions."

Exhibit F 29 Va. Reg. Regs. 1,528–29 (Jan. 28, 3013). No analysis of alternative or less-costly means of achieving licensure were examined or proposed, all in direct violation of Section 127, the APA, Executive Order No. 14, and other provisions of Virginia law.

68. The Appealed Regulations were later certified by the Virginia Attorney General's office by letter dated April 12, 2013, from Allyson K. Tysinger, Senior Assistant Attorney General and Chief of the Health Services Section, to Dr. Cynthia C. Romero, Virginia State Commissioner of Health. **Exhibit Y**

69. The Secretary of Health and Human Resources for Virginia completed his review of the Appealed Regulations on or about April 16, 2013.

70. The Department of Planning and Budget completed its review of the Appealed Regulations on or about April 16, 2013.

71. Virginia Governor Robert F. McDonnell approved the Appealed Regulations on or about April 25, 2013.

72. The Appealed Regulations were published in the Virginia Register of Regulations on May 20, 2013, in Volume 29, Issue 19. 29 Va. Reg. Regs. 2,329 (May 20, 2013). **Exhibit G**.

73. As noted above, Falls Church Healthcare's license is valid through April 30, 2014. Pursuant to the License Renewal Regulation (12 VA. ADMIN. CODE § 5-412-60 (B)), at least 60 days prior to the expiration of its license to operate an abortion facility, Falls Church Healthcare will be forced to apply for a renewal of its license.

74. Section A of the License Renewal Regulation provides that, "Renewal applicants shall only be granted after a determination by [the Office of Licensure and Compliance] that the applicant is in substantial compliance with this chapter." While abortion facilities are now treated as a "category of 'hospital'" under Section 127, neither general hospitals nor outpatient

surgical hospitals are subject to this level of review for license renewals. Section 12 VA. ADMIN. CODE § 5-410-90, applicable to both general hospitals and outpatient surgical hospitals, provides that licenses shall be renewed annually "unless cause appears to the contrary."

75. Pursuant to the License Renewal Regulation, however, in order to have a license renewed, an abortion facility will have to comply with all regulations in Chapter 412, Title 12, agency 5 (12 VA. ADMIN. CODE § 5-412-10 to -370). Therefore, the license renewal standard for abortion facilities of "substantial compliance" is more stringent than the "unless cause appears to the contrary" standard for other categories of hospitals.

76. There is no reasonable basis in fact or in the standards of health, hygiene, sanitation, construction or safety, for treating "abortion facilities" differently — and more harshly — and such treatment is arbitrary and capricious, and in violation of Section 127, the APA, and other provisions of Virginia law.

77. Further, the Building Regulation (12 VA. ADMIN. CODE § 5-412-370) provides that existing abortion facilities are required to comply with state and local codes, zoning and building ordinances, the Virginia Uniform Building Code, and certain design and construction standards in the *2010 Guidelines*.

78. Thus, to continue operating after April 2014, the Appealed Regulations require Falls Church Healthcare to either: modify its 5,000-square-foot facility at an expected cost of $447 per square foot (per the Board's estimate) at the end of those two years, which is not possible; or move to a new facility, which assumes one can be found at a comparable cost that meets all the *2010 Guidelines* standards.

79. For Falls Church Healthcare, moving is just as prohibitively expensive as is renovating. Currently, Falls Church Healthcare leases its offices for about $16 per square foot,

which rate includes utilities. Other medical suites that might comply with the *2010 Guidelines*, viewed over the past year by Falls Church Healthcare, are renting at approximately $28 to $32 per square foot, excluding utilities — assuming that it is available and that a landlord will rent to an abortion facility. On information and belief, a significant percentage of landlords are unwilling to rent to abortion facilities at market rates. It is not even clear that the replacement spaces viewed can comply with the *2010 Guidelines*: most are built as outpatient facilities.

80. Thus, if Falls Church Healthcare moved to another facility at that rental rate, its leasing costs alone would go up by $60,000 to $80,000 per month, before factoring in utilities. A 100% increase in rental costs for a small business that makes less than $1 million in revenue makes this option prohibitively expensive.

81. The Building Regulation also treats abortion facilities differently, and more harshly, than general or outpatient hospitals by requiring existing abortion facilities to comply with current building codes and the *2010 Guidelines*. Other classes of hospitals that operate in existing buildings are not subjected to such rules. This disparate treatment is unreasonable, arbitrary and capricious, and has no basis in logic health, medical science or safety, or the other categories set out in Section 127.

82. The individual parts of the *2010 Guidelines* that are made applicable to "abortion facilities," Part 1, Parts 3.1-1 to 3.1-8, and § 3.7 of Part 3, show that even a large part of these standards are not related to patient safety, health, or sanitation. A sample of these are:

A. Parking requirements, such as:

> **3.7-1.3.2 Parking** Comply with the requirements of Section 1.3-3.3 and the following specific requirements:
>
> **3.7-1.3.2.1** Four spaces shall be provided for each room routinely used for surgical procedures plus one space for each staff member.

3.7-1.3.2.2 Additional parking spaces convenient to the entrance for pickup of patients after recovery shall be provided.

1.3-3.3 Parking

1.3-3.3.1 Health care facilities shall provide sufficient parking capacity to satisfy the needs of patients, personnel, and the public. Parking needs shall be evaluated for each new facility, major addition, or major change in function.

1.3-3.3.2 In the absence of local parking standards or ordinances, refer to individual chapters governing specific facility types for required parking capacity. In all instances, review individual chapters for requirements for dedicated emergency, patient transfer, or service parking.

1.3-3.3.3 Unless otherwise prohibited by individual chapters, reduction of parking requirements shall be permitted, as acceptable to local authorities having jurisdiction, in locations convenient to pedestrians, public transportation, or public parking facilities or where carpool, shuttle bus, or other alternative transportation arrangements have been developed.

B. Requirements for the Heating, Ventilation, and Air Conditioning system that addresses costs, energy efficiency, and acoustics. For instance:

3.7-3.3.6.1 For mechanical system requirements, see 3.1-8.2 (HVAC Systems) and Part 6 (ASHRAE 170).

Part 3.1-8.2 on HVAC systems contains labyrinthine requirements including life-cycle cost-effective design of the HVAC system, acoustic properties, and energy-saving mechanisms.

C. Areas for support staff and personnel, such as:

3.7-3.7 Support Areas for Staff

3.7-3.7.1 Staff Lounge and Toilet Facilities Staff lounge and toilet facilities shall be provided in facilities with three or more operating rooms. The toilet room shall be near the recovery area.

3.7-3.7.2 Staff Clothing Change Area Appropriate change area(s) shall be provided for male and female staff working within the surgical suite (a unisex locker area with one or more private changing rooms shall be permitted).

3.7-3.7.2.1 The area(s) shall contain lockers, toilet(s), hand-washing station(s), and space for donning scrub attire.

3.7-3.7.2.2 For facilities that provide Class B and C surgical services, this area(s) shall be designed to effect a one-way traffic pattern so that personnel entering from outside the surgical suite can change and move directly into the suite's semi-restricted corridor.

3.7-3.7.3 Staff Shower At least one staff shower shall be provided that is conveniently accessible to the surgical suite and recovery areas.

D. A covered entrance at the patient entrance:

3.7-6.1.1 Entrance A covered entrance shall be provided for pickup of patients after surgery. The entrance covering shall not be required to cover the driveway or street areas but only the patient entrance of the building.

83. The parking requirement in ¶ 79(A) above conflicts with the local zoning code in the City of Falls Church, as that Code specifies that parking shall be based upon the type of office where the facility is located. In the case of Falls Church Healthcare, which is located in an almost five-decade-old office building, that building's parking was lawful the time it was constructed in 1964, but now is a legal non-conforming use. Even if it were conforming, parking would be calculated at the rate of 1 space per 300 square feet of office space in the building (City of Falls Church Zoning Code § 48-1004); the individual uses within the office building do not have their own parking requirements.

84. With regard to other classes of hospitals, 12 VA. ADMIN. CODE §§ 5-410 -650 (general hospitals) and -1350 (outpatient hospitals) recognize that parking should be determined by local zoning codes. Not only do those two regulations expressly apply only to "construction of new buildings and additions, renovations, alterations, or repairs of existing buildings . . . .," but also expressly state: "However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence." Such disparate treatment of

"abortion facilities" with regard to building codes and zoning codes, and specifically with regard to parking requirements, is unreasonable, and has no logical health-based, medically-based or safety-based reason for its existence. As such, 12 VA. ADMIN. CODE § 5-412-370 is invalid as it is violates Section 127 of the Code of Virginia, is arbitrary and capricious, and violates Virginia law.

85. Requiring Falls Church Healthcare, or any "abortion facility" in Virginia, to take either option — renovate or move — is not required of other classes of hospitals, is not a reasonable requirement, is arbitrary and capricious, and is not in compliance with Section 127 of the Code of Virginia, the APA, or other Virginia law.

86. The procedure in the Variance Regulation to obtain a temporary variance (12 VA. ADMIN. CODE § 5-412-80) is only available on a "temporary" basis. It is not allowed to exceed the term of the license (*i.e.*, one year), and is allowed only for relief from "an impractical hardship unique to the abortion facility and when a temporary variance would not endanger safety or wellbeing of patients." Once again, all other classes of hospitals are treated less harshly, as 12 VA. ADMIN. CODE § 5-410-30 allows hospitals to obtain variances, and even permanent "waivers," from any regulation whose enforcement would be "clearly impractical."

87. Most importantly, these waivers or variances for other classes of "hospital" can be "either temporarily or permanently" granted. This disparate treatment of abortion facilities is not a reasonable requirement, is arbitrary and capricious, is not in compliance with Section 127, the APA or other Virginia law.

Summary of Errors in Regulatory Process Requiring This Court to Hold the Appealed Regulations Unlawful, and Remand to the Board for further Consideration

88. Falls Church Healthcare incorporates paragraphs 1–87 of the Petition by reference, as if specifically set forth here.

89. Falls Church Healthcare contends the Appealed Regulations are unlawful in their entirety, for the following reasons:

A. They violate Section 127, as they are not "in substantial conformity to the standards of health, hygiene, sanitation, construction and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety, including health and safety standards established under provisions of Title XVIII and Title XIX of the Social Security Act, and to the provisions of Article 2 (§ 32.1-138 et seq.) of [Chapter 5 of Title 32.1 of the Code of Virginia]."

B. They treat abortion facilities much more harshly than general hospitals, in a way that is arbitrary and capricious and in violation of the due process clause of the Virginia Constitution, VA. CONST. art. I, § 11, because Section 127 requires the Board to classify abortion facilities "as a category of hospital," and there is no evidence in the record that they should be treated more harshly than general hospitals.

C. In adopting the Appealed Regulations, the Board abdicated its statutory duty by failing to consider "less intrusive or less costly" requirements, "the establishment of performance standards for small businesses," or "the exemption of small businesses" in violation of §§ 2.2-4007.04 & 2.2-4007.1 of the APA, and the duty imposed by the Governor to consider less costly impacts, in violation of Governor Robert F. McDonnell's Executive Order No. 14 (June 29, 2010).

D. The Board failed to appropriately consider the information provided by medical and health care professionals, and by specialists in the field of public health and safety. This, despite Section 127's requirement that the Board's regulations to "substantially conform" to the standards recognized and established by such individuals. VA. CODE ANN. § 32.1-127(A).

The Board was also statutorily required by the APA, but failed, to consider and respond to comments from such individuals. VA. CODE ANN. §§ 2.2-4007.02 & 2.2-4007.1.

E. The Board failed to substantially conform the Appealed Regulations to those promulgated for Medicare and Medicaid reimbursement under Title XVII and Title XIX of the Social Security Act, because the latter provides that first-trimester abortions should be performed in an outpatient setting and not in a general hospital.

F. The Board failed also to properly convene interested stakeholders, as it is required to do by VA. CODE ANN. § 2.2-4007.02 and its own public participation guidelines, located at 12 VA. ADMIN. CODE § 5-11-10 to -110, particularly by failing to convene a regulatory advisory panel or negotiated rulemaking panel under 12 VA. ADMIN. CODE §§ 5-11-70 & 5-11-80.

G. The Board also failed to properly consider the impact of the Appealed Regulations on the family. Instead, the agency statement issued with the Emergency Regulations said the regulations governing the accessibility and affordability of first-trimester abortion services, "[W]ill not have any impact on the institution of the family and family stability." **Exhibit C**.

H. The Attorney General gave the Board incorrect legal advice on the required content and form of the Appealed Regulations, mistakenly advising that all existing facilities had to comply with the Facilities Guidelines Institute's 2010 Guidelines for the Design and Construction of Health Care Facilities (the "*2010 Guidelines*").

i. As noted by several lawmakers of the General Assembly that passed Senate Bill 924, the Board founded its decision on an incorrect directive from the Attorney General about the meaning of Section 127 and Senate Bill 924,

and the effect of Section 127.001 on both. Section 127 stated only that abortion facilities shall be "classified as a category of hospitals for purposes of *this paragraph*," *i.e.*, Paragraph B of Section 127, and not any other section in the Virginia Code. VA. CODE ANN. § 32.1-127(B)(1) (emphasis added). In turn, Section 127.001 required the Board to adopt regulations "that shall include *minimum* standards for the *design and construction* of hospitals . . . consistent with [the *2010 Guidelines*]." Va. Code Ann. § 32.1-127.001 (emphasis added).

ii. The Attorney General instructed the Board, however, that it had no choice but to apply the *2010 Guidelines* to every existing abortion facility. This was wrong under both the unambiguous statutory language of Section 127 and the *2010 Guidelines* themselves.

iii. Section 127 unambiguously provided that the *2010 Guidelines* were to apply to new design or construction, and the minimum standards were for maintenance and construction, not to apply indiscriminately to all existing facilities in all cases. VA. CODE ANN. § 32.1-127(A), -127.001. To the extent this was ambiguous, the Board had already interpreted these two statutory sections to apply to new facilities, not existing ones *in toto*, when the adopted the 2006 Implementing Amendments per Section 127.001. Accordingly, the Attorney General's advice was against the Board's own interpretation of the statutes, as well as their plain meaning.

iv. Further, the *2010 Guidelines* themselves expressly state that they apply only to new construction, or additions, renovations, alterations or repairs of existing buildings. They do not apply to existing facilities that have not

voluntarily elected to undergo physical changes. *E.g.*, *2010 Guidelines* ¶¶ 1.1-1.3.2; 1.1-3.1.

90. On or about July 16, 2012, the Attorney General also gave incorrect legal advice in refusing to "certify," pursuant to VA. CODE ANN. § 2.2-4013(A), that the Board had "statutory authority" to adopt a version of the Appealed Regulations that proposed to exempt, or "grandfather," existing facilities from compliance with the *2010 Guidelines*.

91. The Attorney General not only erred in his legal advice on the Appealed Regulations, but also incorrectly answered the Board's question about future legal service as follows:

> **Are Board members required to follow the advice of the Attorney General?**
>
> As in the case with any state entity represented by the Office of the Attorney General, Board members may refuse to follow the advice of the Attorney General. Should a Board member choose to disregard the Attorney General's advice and subsequently be named in a lawsuit related to the particular Board action taken, such as the recent litigation challenging the certificate of public need program which named every Board member as an individual defendant, the Attorney General is not obligated to provide representation and it is within the discretion of the Attorney General to decline both representation of the Board member and the appointment of special counsel. *See* Virginia Code §§ 2.2-507 and 2.2-510. Such decisions are made on a case-by-case basis. In a case where the Office of the Attorney General declines to represent a Board member because of the member's refusal to follow legal advice, it would be the responsibility of the Board member to obtain and pay for his or her own legal representation if representation was desired.

Exhibit D,

V. Specific Relief Requested.

92. Enjoin the enforcement of the Appealed Regulations are arbitrary and capricious and an abuse of discretion and contrary to law;

93. Hold that the Appealed Regulations are arbitrary and capricious and an abuse of discretion;

94. The Court should order the Board to produce to this Court the entire record relating to the development and adoption of the Appealed Regulations, pursuant to Va. Sup. Ct. R. 2A:4.;

95. The Court should set a date for a dispositive hearing, and then conduct a hearing where Falls Church Healthcare can present the factual and legal basis for its appeal.

96. Remand this matter to the Board with instructions that clarify that the Board shall adopt regulations that comply with the basic law authorizing them, including Sections 127 and 127.001, as well as the Board's previous interpretations of the language in Sections 127 and 127.001.

97. Accordingly, Falls Church Healthcare requests this relief and such other relief as the Court deems necessary.

Dated: June 10, 2013

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this Petition for Appeal of the Virginia Board of Health Regulations, was filed with the court, and that a true and correct copy of the same was also sent on June 10, 2013, via certified mail, return receipt requested, to all of the parties as follows:

Virginia Board of Health
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Richmond, Virginia 23219

Virginia Department of Health
c/o Dr. William A. Hazel, Secretary
Health and Human Resources
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Richmond, Virginia 23219

Dr. Cynthia C. Romero
Virginia Commissioner of Health
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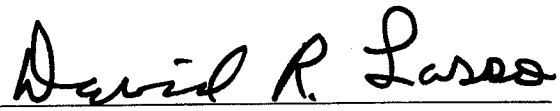

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