Virginia Coalition to Protect Women's Health

March 29, 2013

Dear Members of the Virginia Board of Health,

The Virginia Coalition to Project Women's Health is a group of physicians and medical professionals, community members and advocates. We write to provide you with helpful information to assist in your consideration of the draft permanent regulations of women's health care centers that provide first-trimester abortion in Virginia. In this spirit, we have prepared the enclosed packet of materials.

As your fellow public health and consumer colleagues, we believe that Virginia's Board of Health must be equipped with accurate, sound, clear information to pursue its mission of protecting the health of Virginians, and to do so independently of other government entities, as is the Board's right and mandate to do. We offer here some helpful facts to counter inaccurate information that has been provided to the Board of Health over the past few months.

But first, some context to explain our materials: On June 15, you and your fellow Board members voted on a number of provisions regarding the draft permanent regulations of women's health care centers that provide first-trimester abortion. As you know, one month later, on July 16, the office of Attorney General Ken Cuccinelli sent a memo to Virginia Health Commissioner, Dr. Karen Remley, stating that the Attorney General would not "certify" your amendments, including a crucial decision to grandfather in existing women's health care centers instead of subjecting them to inappropriate building construction.

To be blunt, the Board of Health has been led to believe that its decisions of June 15 were not legal. Quite simply, this is not true on any level. The Board acted precisely within its jurisdiction, its mission, and its expertise – independently. The Attorney General and his office have no legal authority to dictate the precise, explicit letter of *public health regulations* that uphold patient safety in Virginia. The Board acted appropriately.

We have prepared the following documents, and we encourage you to examine all of the direct primary sources offered in these documents – evidence that we are offering you only the facts:

1) **Major findings of a statewide poll**
   Conducted with unquestioned methodology from a nationally reputable polling firm, this poll proves that the people of Virginia overwhelmingly agree argued that the medical regulatory process regarding new regulations on women's health centers must be based on scientific evidence - not political ideology.

2) **Description of the Process by which the federal government incorporates medical expert comment on what procedures can safely be performed in non-inpatient settings**
   Comparable gynecological procedures are, under the CPT codes, able to be performed in outpatient facilities. We believe this shows concretely, through objective evidence, that many similar procedures are performed under non-hospital conditions and that requiring such is not medically necessary.

3) **Fact-checked Attorney General memo of July 16**
   This provides a deep look at the facts in the memo, along with the links to Virginia law and medical documentation to correct the misinformation in this memo.

We respect the Virginia Board of Health as an independent entity that will continue to act within its responsibility and its mandate to make decisions solely on the basis of evidence-based public health and consideration of patients. This public health board cannot succumb to bullying and intimidation by one government office – the slippery slope and political and ideological intrusion into medical and public health decision-making is far too perilous.

Please do not hesitate to contact us if we can be of assistance or provide further information. Thank you for considering these materials.

Respectfully,

The Virginia Coalition to Protect Women's Health

Major findings of a statewide poll

For the past two years, the Coalition has consistently argued that the medical regulatory process regarding new regulations on women's health centers (as initiated by SB924), must be based on scientific evidence - not political ideology. Now a statewide poll, conducted with unquestioned methodology from a nationally reputable polling firm, proves that the people of Virginia overwhelmingly agree with this fact. The survey, conducted by Beck Research, LLC, was conducted by random digit dialing from February 20-24, 2013, among a total of 500 Virginia adults aged 18 and over. The margin of error is +/- 4.4%.

Major findings:

- **The majority of Virginians (58%) oppose the proposed new regulations of women's health care centers that provide first-trimester abortion and annual reproductive health care.**

- **When Virginians heard an explanation of the new building requirements for first-trimester abortion providers, 58 percent of them say they opposed the regulations**, compared to only 35 percent who say they favor the regulations. Opposition to the new regulations carries across partisan boundaries – a majority of **Democrats (63%), Republicans (61%), and Independents (53%) all oppose the regulations.**

- **Virginians say they prefer that medical experts set medical regulations in the commonwealth, not politicians.** Doctors and medical experts are universally trusted about health care in Virginia; 95 percent of Virginians trust doctors (56% very much) and 93 percent trust medical experts (51% very much).

- **The Virginia Legislature, Governor Bob McDonnell, and Attorney General Ken Cuccinelli are the least trusted sources on health care in Virginia.** Just 37 percent trust the Virginia legislature, 41 percent trust the governor, and 38 percent trust the AG; 52 percent do not trust McDonnell or Cuccinelli very much or at all on health care.

- **Virginians think abortion should be legal – and a decision left between a woman and her doctor.** The majority of Virginians (56%) think that abortion should be "legal in all cases." By a wide three-to-one margin (75%-to-22%), Virginians agree "private medical decisions should be made by a woman, her family and her doctor."

The perspectives of most Virginians match with the professional opinions of Virginia's doctors and medical experts, hundreds of whom have publicly denounced the regulations over the past year.

In June 2012, Dr. James "Jef" Ferguson of the University of Virginia School of Medicine, one of six top medical experts from across Virginia asked to review the draft regulations (http://www.wjla.com/articles/2011/12/medical-experts-virginia-abortion-regulations-based-on-politics-not-safety-69899.html) in 2011, publicly denounced the final regulations and called them "politically motivated," (http://www.nbc29.com/story/18794646/uva-gynecologist-speaks-out-ahead-of-abortion-regulation-approval?clienttype=printable) saying that "arbitrary and capricious decisions like this – in my opinion – have no place in the practice of medical care and disruption that's occurring…women's health care should not be politically motivated." He asked for his name to be removed from the final regulations.

In September 2012, a diverse group of almost 200 doctors and medical experts from across the state organized and independently funded a public letter and *Richmond Times-Dispatch* advertisement (http://www.medicinenotpolitics.com/), writing that "We must not travel down a dangerous slippery slope where we allow political forces to dictate medical care." And in October 2012, Dr. Karen Remley, the Virginia Health Commissioner, resigned her position (http://www.usatoday.com/story/news/ondeadline/2012/10/18/virginia-health-commissioner-resigns/1642197/) due to the intrusion of politics into women's health care.

Description of the Process by which the federal government incorporates medical expert comment on what procedures can safely be performed in non-inpatient settings

Proposed Regulations for Licensure of Abortion Facilities, 12VAC5-412 (the "Regulations"), impose unnecessary clinical, financial, and administrative burdens on providers of first-trimester abortion services that are not necessary medically or to promote or protect patient health and safety.

The approach embodied in the Regulations flies in the face of the medical movement since the 1990s to move surgical procedures to the outpatient setting rather than the hospital setting. Today more than 65% of all elective surgeries are performed in the outpatient setting, and this number is expected to continue to rise in the coming decade.

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 needless financial burden on such women's health clinics. Many provisions in the Regulations on their face have no relationship to protecting the health of women undergoing first-trimester abortions; examples include requiring clinics to build five-foot wide hallways; add covered entrances, public telephones, and public bathrooms and drinking fountains in waiting rooms; incorporate new ventilation systems; regulate the size of janitorial closet; and provide four

parking spaces for each room that is routinely used for surgical procedures plus one space for each staff member.

The lack of any rational basis for such regulations, and the needless, undue burden they will place on clinics that provide first-trimester abortions and not later-term abortions, is confirmed by reference to federal Medicare program regulations. Each year the Medicare program, in consultation with appropriate medical organizations as required by the Social Security Act, promulgates rules regarding its payment policy for services performed in the hospital inpatient setting, the hospital outpatient setting, and in physician offices. *See* 42 U.S.C. § 1395(i)(1) (stating that the Secretary of Health and Human Services "shall, in consultation with appropriate medical organizations" specify those surgical procedures which may be safely performed in an ambulatory surgical center or a physician's office). Medicare's process is open to public comment, including from health care providers and experts regarding current medical practice and standards of care. Based on those comments, Medicare develops a listing referred to as the "inpatient only list" that enumerates those procedures Medicare will pay for only when performed in the inpatient hospital setting. Similarly, the Medicare Physician Fee Schedule, which sets out payments to physicians based on whether a procedure is performed in a physician's office or at a facility (such as a free-standing ambulatory surgery center or hospital), identifies procedures Medicare will not pay for if performed in the office setting.

Exhibit 1 sets forth Medicare's reimbursement rates for those procedures it will pay for in the physician office and hospital outpatient sites of service. Notably, these regulations show that many obstetrics and gynecology procedures, including abortions, are routinely performed on an outpatient basis in the ambulatory care setting and are not required to be performed in a hospital setting. This means that neither the Medicare program nor the hundreds of commenters that respond to Medicare's annual rulemaking believe that it is unsafe or medically inappropriate to perform such services in physician offices that do not meet hospital facility construction requirements. These Medicare regulations refute the purported rationale of the Regulations to promote patient safety.

Moreover, the targeting only of first-trimester abortion providers by the Regulations confirms the lack of any medical justification for them. If the purported justification for promulgating the Regulations were accepted, that would mean that literally hundreds of far more complex and risky surgical services that currently are performed safely and successfully in the ambulatory care setting should be required to be performed in a physical plant that is the equivalent of an inpatient hospital setting. Not surprisingly, such an outcome is not contemplated by Virginia law or regulation, since it makes no medical or economic sense. The targeting only of first-trimester abortion clinics for such physical plant regulations in contravention of the modern trend in medical practice, which is confirmed by the Medicare regulations, compels the conclusion that the requirements have nothing to do with patient safety.

Exhibit 1.

		National Payment		
		Physician Office		Inpatient Only
CPT		Status	Non-Facility PE RVUs	
56620	Partial removal of vulva	A	NA	Not Listed
56625	Complete removal of vulva	A	NA	Not Listed
57106	Remove vagina wall partial	A	NA	Not Listed
57107	Remove vagina tissue part	A	NA	Not Listed
57288	Bladder Sling	A	NA	Not Listed
57505	Endocervical curettage	A	1.69	Not Listed
57510	Cauterization of cervix	A	1.73	Not Listed
57511	Cryocautery of cervix	A	2.10	Not Listed
57513	Laser surgery of cervix	A	2.05	Not Listed
58120	Dilation and Curettage (D&C)	A	3.54	Not Listed
58145	Myomectomy vag method	A	NA	Not Listed
58260	Vaginal hysterectomy	A	NA	Not Listed
58262	Vag hyst including t/o	A	NA	Not Listed
58263	Vag hyst w/t/o & vag repair	A	NA	Not Listed
58270	Vag hyst w/enterocele repair	A	NA	Not Listed
58353	Endometrial Ablation/ Endometr ablate thermal	A	26.75	Not Listed
58356	Endometrial cryoablation	A	50.31	Not Listed
58552	Laparo-vag hyst incl t/o	A	NA	Not Listed
58555	Hysteroscopy dx sep proc	A	1.79	Not Listed
58558	Hysteroscopy biopsy	A	2.43	Not Listed
58559	Hysteroscopy lysis	A	3.04	Not Listed
58560	Hysteroscopy resect septum	A	3.38	Not Listed
58561	Hysteroscopy remove myoma	A	4.67	Not Listed
58562	Hysteroscopy remove fb	A	2.58	Not Listed
58563	Hysteroscopy ablation	A	3.03	Not Listed
58565	Hysteroscopy sterilization	A	4.69	Not Listed
59840	Abortion	R	2.70	Not Listed
59841	Abortion	R	4.27	Not Listed
59866	Abortion (mpr)	R	NA	Not Listed

Notes

1. The Status column indicates whether the CPT code is included in the PFS. The presence of an "A" indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. A "R" in the status column, means "Restricted Coverage" and indicates that special coverage instructions apply. If the service is covered and no RVUs are shown, it is contractor-priced.
2. "NA" in the Non-Facility PE RVUs column means that CMS has not developed a PE RVU in the non-facility setting for the service because it is typically performed in the hospital (for example, open heart surgery is generally performed in the hospital setting and not a physician's office). So, in other words, if there is an NA in this column and the contractor determines that this service can be performed in the non-facility setting, the service will

be paid at the facility PE RVU rate.

4. The "Inpatient Only" column indicates those services that are only paid as inpatient procedures. "C" means Inpatient Procedures and is not paid under OPPS.

FACTUAL BREAKDOWN

Attorney General Cuccinnelli's Letter (July 16, 2012) to Va. Dept. of Health Commissioner Dr. Karen Remley on Board of Health's June 15 Vote

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MEMO:
"I have reviewed the amendments to the Regulations for Licensure of Hospitals in Virginia, 12 VAC 5-410-10 et seq., and the Regulations for Licensure of Abortion Facilities, 12 VAC 5-412-10 et seq., that were adopted by the State Board of Health on June 15, 2012."

FACT CHECK:

- The Regulations for Licensure of Hospitals in Virginia, 12 VAC 5-410-10 et seq, are the entirety of the regulations approved by the Board of Health on June 15, 2012. These regulations include, in part, the provision that "grandfathered in" existing women's health centers, rather than subject them to building requirements that are only meant for the construction of new facilities.

- These regulations also include, in part, provisions that leave several important loopholes in the protections for provider and patient safety and confidentiality.

MEMO:
"The Board does not have the statutory authority to adopt these Regulations."

FACT CHECK:

- Virginia law, § 32.1-127(A)**,** directs the Board's statutory authority. This law directs the Board of Health to create regulations for health care facilities that conform solely to standards established by medical and health professionals. Courts in Virginia have consistently upheld this role to create and approve health regulations established by medical experts.[1]

- The original draft of the regulations for women's health centers did not conform to that statute's purpose. Instead, imposing requirements meant only for new construction on existing facilities contradicted what medical and health professionals and specialists recommended. In fact, the specialists who authored the Guidelines for Design and Construction of Health Care Facilities themselves stated that the Guidelines are intended to apply only to new construction, not to existing facilities.

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[1] See, e.g., *Brown v. United Airlines, Inc.*, 540 S.E.2d 521, 522 (Va. Ct. App. 2001); see also *Avalon Assisted Living Facilities, Inc. v. Zager*, 574 S.E.2d 298, 306 (Va. Ct. App. 2002)

- Thus, it is actually the *original draft* of regulations for women's health centers that exceeded the Board's authority. In amending the regulations to "grandfather in" existing women's health centers, the Board of Health recognized that inconsistency and amended the regulations to apply construction requirements as the experts intended.

MEMO:
"*Because proposed 12 VAC 5-412-370 conflicts with Virginia Code § 32.1-127.001, the Board has exceeded its authority."*

FACT CHECK:

- 12 VAC 5-412-370 is the provision of the regulations allowing for existing women's health centers to be "grandfathered in," rather than subjected to three chapters of a manual called 2010 Guidelines for Design and Construction of Health Care Facilities.

- The Attorney General asserts that 12 VAC 5-412-370 is in conflict with Virginia Code § 32.1-127.001 because § 32.1-127.001 states that the Board of Health shall issue regulations for health care facilities "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."

- The Attorney General's office is incorrect about the Board's obligations in Virginia Code § 32.1-127.001. That section of the Virginia Code, enacted in 2005, has never been interpreted to require existing facilities to meet new construction standards, and a fair reading of its plain text provides no support for such a requirement. While § 32.1-127.001 states that the Board shall issue regulations for health care facilities, "consistent with the current edition of the 2010 Guidelines for Design and Construction of Hospital and Health Care Facilities," the Guidelines explicitly state that they are "intended as minimum standards for designing and constructing *new* health care facility projects." Thus, the Board's refusal to apply the Guidelines to existing facilities is "consistent with" the Guidelines.

MEMO:
"Thus, this Office cannot certify these Regulations."

FACT CHECK:

- The Attorney General has the responsibility to review proposed regulations to determine if the Board has the authority to adopt them.

- Virginia law does not give the Attorney General's office veto power over the Board's policy decisions about what to include in the final rules.

- As an elected official without medical expertise, the Attorney General does not have – and has never had – the legal authority to decide upon the specifics of public health and medical regulations.