September 14, 2011

Karen Remley, M.D.
Commissioner of Health
Commonwealth of Virginia
Virginia Department of Health
109 Governor Street
Richmond VA 23219

RE: ACOG Response to Draft Regulations for Licensure of Abortion Facilities in Virginia, Chapter 412

Dear Dr. Remley,

Please enter this document as a written public comment in relation to the above referenced draft regulations regarding the operation of abortion clinics in the Commonwealth of Virginia. Our comments are sent as the elected officers of the Virginia section of the American Congress o f Obstetricians and Gynecologists. As women's health physicians, we support all efforts to maximize patient safety in all domains of women's health. As the elected officers of the Virginia section, we represent the majority opinion of obstetrician-gynecologists in the Commonwealth.

We have reviewed the draft regulations thoroughly and offer the following comments:

I. 12VAC5-412-240-A-2: We recommend that the proposed regulation mandating the use of a "recognized pregnancy test" be modified to mandate the use of *either* an ultrasound or the use of a recognized pregnancy test. Many, but not all clinics utilize ultrasound as part of the pre-operative assessment to ascertain the location of a pregnancy and to be certain that the gestational age is appropriate for an outpatient procedure. In a clinic where ultrasound is performed, the findings of the ultrasound are sufficient to verify the presence of a pregnancy, and a urine or blood pregnancy test would only add to the cost of the care without enhancing safety.

II. 12VAC5-412-260-B: We recommend that the proposed regulation requiring that medications to induce a termination of pregnancy be administered *by a physician* be modified to indicate that such medications may be administered *by a licensed independent practitioner.* This will allow for appropriate delegation of medication administration by the responsible physician to a nurse practitioner or physician assistant working under his or her supervision.

III. 12VAC5-412-240-D: Regarding the requirement for a pathologic examination of uterine contents when visual confirmation of a pregnancy cannot be obtained, we have the following comments. Many women undergoing elective termination of pregnancy are low income and are paying for the service out of pocket. A histopathologic examination in cases where villi fail to be identified would add a significant additional financial burden to these women and potentially prevent a barrier to them obtaining a safe, legal, first trimester abortion. Recognizing the potential that uterine contents which do not appear to contain placental villi or fetal tissue could represent an ectopic pregnancy, we recommend this portion of the regulation be revised to include a requirement that the responsible physician should notify the patient that pregnancy tissue was not identified, explain the possibility of ectopic pregnancy and the potential serious nature of this condition, offer pathologic examination of the tissue including a disclosure of the cost, and make a referral to an

appropriately qualified practitioner who can further evaluate for the possibility of an ectopic pregnancy.

IV. 12VAC5-412-290-C: We contend that the requirement for a written emergency services agreement with a licensed general hospital is onerous and unnecessary. The excessive burden arises from the circumstance where the nearest general hospital may not agree to enter into an emergency services agreement with an abortion clinic, leaving the clinic in violation of the law if it continues to operate without such an agreement. We believe federal EMTALA law supersedes this requirement in that any patient presenting to the emergency room of a licensed general hospital for emergency care must be provided a medical screening exam and any necessary treatment. We support the following provision: *when an emergency transfer is necessary, the responsible physician at the abortion clinic must provide direct communication to the emergency department staff regarding the status of the patient and the suspected complication.*

V. 12VAC5-412-380: We believe the building requirements create an unnecessary barrier for some women seeking elective first trimester abortion. This is an extremely safe procedure with a very low risk of complications, generally performed in a clinic setting under minimal sedation. Requiring a clinic providing first trimester abortions to meet the 2010 Facilities Guidelines Institute standards (the same requirements as an ambulatory surgery center performing much more invasive and risky procedures under deep sedation or general anesthesia) seems unnecessary. We recognize the need to be able to provide a safe transfer for emergency services in the rare circumstances that a complication does occur, however for most facilities it would be cost prohibitive either to make the mandated architectural changes or to construct a new facility. We are aware that the South Carolina legislation related to regulation of abortion clinics included provisions that allowed for older facilities to meet the standards. We recommend the Board of Health consider the following elements for building standards taken from the South Carolina regulations on Licensure of Abortion Clinics, where both first and second trimester abortions are performed in clinic settings:

> Section 807 H: Procedure and recovery room(s) shall be located on an exit access corridor that provides unimpeded, rapid access to an exit of the building. This exit must accommodate emergency transportation vehicles and equipment.
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> Section 807 I: In multi-storied buildings where the facility is not located on the floor of entry to/exit from the building, there must be at least one elevator that serves the clinic floor(s). The elevator must accommodate emergency transportation equipment.
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> Section 807 K: Doors providing access into the facility and procedure room(s) shall be at least 36 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least 48 inches wide.

These less proscriptive guidelines would allow for patient safety in first trimester abortions to be preserved without making the building standards so demanding that many clinics could not meet them. Alternatively, we encourage the Board of Health to consider requiring facilities which do not meet the 2010 FGI architectural standards to have available a

transport device such as a medical recliner or other maneuverable, wheeled patient transfer device that could allow the transfer of a patient from the procedure or recovery area to a public area where she would be accessible to emergency medical personnel.

We thank you for the opportunity to comment on the draft regulations and urge you to adopt the modifications we have suggested above in the interests of optimizing safety of first trimester abortion procedures in the Commonwealth while maintaining access to abortion services for all women.

Most sincerely yours,

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