IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

COLON HEALTH CENTERS OF AMERICA, LLC, and WASHINGTON IMAGING ASSOCIATES—MARYLAND, LLC (d/b/a PROGRESSIVE RADIOLOGY),

Plaintiffs,

vs.

BILL HAZEL, in his official capacity as Secretary of Health and Human Resources; BRUCE EDWARDS, in his official capacity as Chairman of the Virginia State Board of Health; PAUL CLEMENTS; KAY R. CURLING; ERIC DEATON; JOHN DETRIQUET; JAMES E. EDMONDSON, JR.; STEVEN R. ESCOBAR; H. ANNA JENG; CHARLES K. JOHNSON; BENNIE MARSHALL; MARY MCCLUSKEY; BHUSHAN PANDYA; M. CATHERINE SLUSHER; GAIL TAYLOR; AMY VEST, in their official capacities as members of the Virginia State Board of Health; KAREN REMLEY, in her official capacity as State Health Commissioner; ERIK O. BODIN, in his official capacity as Acting Director of the Office of Licensure and Certification and Director of the Division of Certificate of Public Need; and DEAN MONTGOMERY, in his official capacity as Executive Director of Health Systems Agency of Northern Virginia, Inc.,

Defendants.

Civil Action No. 1:12cv615 CMH/TCB

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COME NOW Plaintiffs Colon Health Centers of America, LLC and Washington Imaging Associates—Maryland, LLC ("Progressive Radiology"), by its undersigned counsel, and alleges as follows:

INTRODUCTION

This is a constitutional challenge to a Virginia law that arbitrarily prevents Plaintiffs and other doctors from offering the safe, cost-effective, and innovative medical services in Virginia that they successfully offer in other states.

Both Plaintiffs are out-of-state companies that have established out-of-state offices offering medical services that are perfectly legal to offer in Virginia. The only obstacle to Plaintiffs expanding their services into Virginia is the state's "certificate-of-need" program, which makes it illegal to open many (but not all) medical offices or purchase many (but not all) types of medical equipment without first obtaining a determination from the State Health Commissioner that there is a "need" for the medical services. This program places severe burdens on medical entrepreneurs in Virginia, requiring a difficult and time-consuming application process that offers no reliable way to predict whether a certificate actually will be issued to any given applicant. And the program exists for no reason beyond protecting established businesses from competition.

Because—and only because—of the barrier posed by the certificate-of-need process, Plaintiffs' out-of-state medical services are not expanding into Virginia. And they are not importing goods, like MRI machines or CT scanners, into Virginia through interstate commerce, again only because of the state's certificate-of-need requirement. Imposing burdens like this on interstate commerce for no better reason than enriching local interests violates the dormant aspect of the Commerce Clause of the United States Constitution. Imposing them on

some medical services (and equipment) but not similarly situated services (and equipment) violates the Fourteenth Amendment to the Constitution, as does imposing these burdens for no purpose other than economic protectionism. This lawsuit seeks to vindicate the basic economic liberties of Plaintiffs (and those like them) who simply want to provide safe, effective, and approved medical services using safe, approved medical equipment to willing patients in Virginia without the crushing cost, delay, and uncertainties imposed by Virginia's unconstitutional certificate-of-need requirement.

SUBJECT MATTER JURISDICTION

1. Plaintiffs bring this civil-rights lawsuit pursuant to 42 U.S.C. § 1983 for violations of rights, privileges, or immunities secured by Article I, Section 8 and the Fourteenth Amendment to the United States Constitution and the Declaratory Judgments Act, 28 U.S.C. § 2201. Plaintiffs seek injunctive and declaratory relief against the enforcement of Virginia's Medical Care Facilities Certificate of Public Need, Va. Code §§ 32.1-102.1 *et seq.*, its implementing rules and regulations, 12 Va. Admin. Code §§ 5-220-10 *et seq.*, and the policies and practices of the State Health Commissioner, State Board of Health, and the Department of Health in enforcing these provisions, which, facially and as- applied, violate Plaintiffs' constitutional rights.

2. Accordingly, this Court has jurisdiction over this action under 28 U.S.C. § 1331 (federal question jurisdiction) and § 1343 (civil rights jurisdiction).

VENUE

3. Venue is appropriate in this Court under 28 U.S.C. § 1391(b) and Local Civil Rule 3(C). As described more fully below, a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in Fairfax, Loudoun, and Prince William Counties which are

located in the Eastern District of Virginia, 28 U.S.C. § 127(a), in the Alexandria Division, Local Civil Rule 3(B)(1).

4. Additionally, all Defendants are domiciled in the Commonwealth of Virginia, and at least one of the Defendants is domiciled in Fairfax County, located in the Eastern District of Virginia, Alexandria Division.

THE PARTIES

I. THE PLAINTIFFS

5. Plaintiff Colon Health Centers of America, LLC is a Delaware limited-liability company. Its registered office is located at 537 Stanton-Christiana Road, Newark, Delaware 19713.

6. Dr. Mark J. Baumel is the President and Chief Executive Officer of Colon Health Centers of America.

7. Dr. Baumel earned a Bachelor of Science from the University of Notre Dame in 1985. In 1989, he earned his M.D. from the University of Chicago Pritzker School of Medicine. In 1996, he earned a Master of Science in Clinical Epidemiology and Biostatistics from the University of Pennsylvania.

8. Dr. Baumel is a United States citizen, domiciled in Kennett Square, Pennsylvania.

9. Plaintiff Washington Imaging Associates—Maryland, LLC is a Maryland limited-liability company. Its registered administrative office is located at 7799 Leesburg Pike, Suite 1000 North, Falls Church, Virginia 22043. Together with related limited-liability companies, it conducts business under the name "Progressive Radiology." (For ease of reference, Washington Imaging Associates—Maryland, LLC, is simply referred to as

"Progressive Radiology" throughout this Complaint.)

10. Progressive Radiology employs thirteen board-certified radiologists (doctors that specialize in reading and interpreting images of the human body in order to diagnose and treat diseases). Progressive Radiology staffs nine medical offices in Maryland and one in the District of Columbia. As alleged above, it also has an administrative office in Falls Church, Virginia that does not provide any radiology or diagnostic medical imaging services.

11. Dr. Mark Monteferrante is the registered agent and managing partner of Washington Imaging Associates—Maryland, LLC.

12. Dr. Monteferrante graduated from John Hopkins University in 1983 with a Bachelor of Science. During his studies at John Hopkins, he conducted research at the Laboratory of Neurosciences at the National Institutes of Health. In 1987, he earned his M.D. from the University of Maryland. In 1990, Dr. Monteferrante served as chief resident during his residency at Bridgeport Hospital in Connecticut, where he also won the hospital's Resident Research Award.

13. Dr. Monteferrante is a board-certified radiologist and a senior member of the American Society of Neuroradiology.

14. Dr. Monteferrante is licensed to practice radiology in Maryland, the District of Columbia, and Virginia. He actively has been practicing radiology in Maryland and the District of Columbia for the past 19 years and had practiced radiology in Virginia until 2011.

15. Dr. Monteferrante is a United States citizen, domiciled in Potomac, Maryland.

II. THE DEFENDANTS

16. Each Defendant is sued in his or her official capacity.

17. Defendant Bill Hazel is the Secretary of Health and Human Resources for the

Commonwealth of Virginia. Secretary Hazel oversees twelve state agencies including the Virginia Department of Health. His offices are located at 1111 East Broad Street, Richmond, Virginia 23219.

18. The Virginia State Board of Health ("State Board") is composed of 15 residents of the Commonwealth appointed by the Governor for terms of four years each. Va. Code § 32.1-5. The purpose of the State Board is to provide leadership in healthcare planning and policy for the Virginia Department of Health. Among its many statutory duties, the State Board is authorized to promulgate regulations for implementing Virginia's certificate-of-need program, including establishing procedures to review applications, delineating specific criteria for determining need, and setting application fees. Va. Code § 32.1-102.2. By statute, each member of the State Board represents a specific interest group. Va. Code § 32.1.-5.

19. Defendant Bruce Edwards serves as Chair of the State Board and represents the interests of providers of emergency medical services. His term expires on June 30, 2013. Upon information and belief, his domicile or principal place of business is 2441 Windward Shore Drive, Virginia Beach, Virginia 23451.

20. Defendant Paul Clements is on the Executive Committee of the State Board and represents the interests of the nursing home industry. His term expires on June 30, 2013. Upon information and belief, his domicile or principal place of business is 619 Liberty Lane, Madison, Virginia 22727.

21. Defendant Kay R. Curling is a member of the State Board representing the interests of corporate purchasers of healthcare. Her term expires on June 30, 2014. Upon information and belief, her domicile or principal of place of business is 4000 Legato Road, Suite 1100, Fairfax, Virginia 22033.

22. Defendant Eric Deaton is a member of the State Board representing the interests of the hospital industry. His term expires on June 30, 2012. Upon information and belief, his domicile or principal place of business is 142 South Main Street, Danville, Virginia 24541.

23. Defendant John DeTriquet is a member of the State Board representing the interests of local government. His term expires on June 30, 2014. Upon information and belief, his domicile or principal place of business is 3020 Princess Anne Crescent, Chesapeake, Virginia 23321.

24. Defendant James H. Edmondson, Jr. is a member of the State Board representing the interests of consumers. His term expires on June 30, 2013. Upon information and belief, his domicile or principal place of business is 7804 Ariel Way, McLean, Virginia 22102.

25. Defendant Steven R. Escobar is a member of the State Board representing the interests of the Virginia Veterinary Medical Association. His term expires on June 30, 2015. Upon information and belief, his domicile or principal place of business is 4416 Springfield Road, Glen Allen, Virginia 23060.

26. Defendant H. Anna Jeng is a member of the State Board representing the interests of public environmental health. Her term expires on June 30, 2013. Upon information and belief, her domicile or principal place of business is 1147 Surrey Crescent, Norfolk, Virginia 23508.

27. Defendant Charles K. Johnson is a member of the State Board representing the interests of the Virginia Dental Association. His term expires on June 30, 2014. Upon information and belief, his domicile or principal place of business is 1405 Westover Hills Boulevard, Suite 1, Richmond, Virginia 23225.

28. Defendant Bennie Marshall is on the Executive Committee of the State Board and represents the interests of the Virginia Nurses Association. His term expires on June 30, 2013. Upon information and belief, his domicile or principal place of business is 1425 Cole Drive, Chesapeake, Virginia 23320.

29. Defendant Mary McCluskey is a member of the State Board representing the interests of managed care health insurance plans. Her term expires on June 30, 2014. Upon information and belief, her domicile or principal place of business is 4425 Corporation Lane, Virginia Beach, Virginia 23462.

30. Defendant Bhushan Pandya is the Vice Chair of the State Board and represents the interests of the Medical Society of Virginia. His term expires on June 30, 2012. Upon information and belief, his domicile or principal place of business is 134 Newbury Way, Danville, Virginia 24541.

31. Defendant M. Catherine Slusher is a member of the State Board representing the interests of the Medical Society of Virginia. Her term expires on June 30, 2015. Upon information and belief, her principal place of business is Harrisonburg OB/GYN Associates, 2291 Evelyn Byrd Avenue, Harrisonburg, Virginia 22801.

32. Defendant Gail Taylor is a member of the State Board representing the interests of consumers. Her term expires on June 30, 2013. Upon information and belief, her domicile is 4304 Hanover Avenue, Richmond, Virginia 23221.

33. Defendant Amy West is a member of the State Board representing the interests of the Virginia Pharmacists Association. Her term expires on June 30, 2012. Upon information and belief, her domicile or principal place of business is 4768 Shore Drive, Virginia Beach, Virginia 23455.

34. Defendant Karen Remley is the State Health Commissioner for the Commonwealth of Virginia. Commissioner Remley is responsible for supervising and managing the Virginia Department of Health in accordance with the policies, rules, and regulations of the State Board. Va. Code § 32.1-16. Additionally, under Virginia's certificate-of-need program, Commissioner Remley is authorized to grant, deny, amend, or revoke a certificate. Va. Code §§ 32.1-102.3 to -.4. Commissioner Remley's office is located at 109 Governor Street, Richmond, Virginia 23219.

35. Defendant Erik O. Bodin serves as both the Acting Director of the Office of Licensure and Certification and Director of the Division of Certificate of Public Need. The Virginia Department of Health's Office of Licensure and Certification administers Virginia's CON program through its Division of Certificate of Public Need. Defendant Bodin's office is located at 9960 Mayland Drive, Suite 401, Richmond, Virginia 23233.

36. Upon information and belief, Director Bodin is also responsible for overseeing four of the five health planning regions and/or regional health planning agencies corresponding to Northwestern, Eastern, Central, and Southwest Virginia.

37. Defendant Dean Montgomery is Executive Director of Health Systems Agency for Northern Virginia, the regional health planning agency for Northern Virginia (Health Planning Region II). The Health Systems Agency of Northern Virginia is a nonprofit organization established under Virginia law to conduct an independent review of CON applications in Northern Virginia. Defendant Montgomery's office is located at 7245 Arlington Boulevard, Suite 300, Falls Church, Virginia 22042.

38. At all times alleged, Defendants and their agents have acted under color of state law.

STATEMENT OF FACTS

39. Plaintiffs are out-of-state medical providers who want to offer the medical services that they already provide in other states to patients in Virginia. Plaintiff Colon Health Centers of America wants to open several centers in Virginia that would combine the two prevailing methods of colon-cancer screening and treatment in a "one-stop shop" just like it offers in Delaware and New Jersey. Separately and independently, plaintiff Progressive Radiology wants to open a medical imaging center in Virginia that would allow its radiologists to diagnose patients with injuries of the joints, bones, brain, and spine, just as it currently does in Maryland and the District of Columbia.

40. Virginia prohibits Plaintiffs from opening these medical centers and offering their services or even buying the necessary medical equipment unless each Plaintiff obtains a certificate of need from the Commissioner.

41. Virginia requires Plaintiffs to obtain a certificate of need even though:

a. all of the medical services they seek to offer would be provided by individuals licensed by the Commonwealth of Virginia;

b. all of the medical services they seek to offer are uncontroversial and considered accepted medical practice by leaders in their respective fields, and are available in other states; and

c. the cost of opening Plaintiffs' facilities and purchasing the necessary equipment would be privately financed and not involve any taxpayer money.

42. Virginia requires Plaintiffs to obtain a certificate of need to buy the medical imaging equipment they would need to offer their services even though such equipment is completely legal and routinely sold in interstate commerce.

43. Virginia would not require Plaintiffs to obtain a certificate of need if they chose to offer their medical services by working for an established business in Virginia that already owns the necessary equipment. Virginia requires Plaintiffs to obtain a certificate of need only because they plan to open facilities that would compete with established businesses.

44. As alleged in detail in Section III below, obtaining a certificate of need is a burdensome, time-consuming, costly, and unpredictable process.

45. But for the fact that Virginia's certificate-of-need program requires Plaintiffs to weather the huge costs and uncertain rewards of applying for a certificate of need, Plaintiffs would be able to open their proposed facilities, buy the necessary medical equipment, and offer their medical services to patients in Virginia.

46. This lawsuit challenges the constitutionality of requiring Plaintiffs to undergo the burdens, delays, and uncertainties of the state's certificate-of-need process before opening new facilities in Virginia or importing equipment into Virginia.

I. COLON HEALTH CENTERS OF AMERICA WANTS TO OFFER INNOVATIVE COLON-CANCER SCREENING SERVICES THAT WILL SAVE LIVES.

47. In 2007, Dr. Baumel founded Colon Health Centers of America in order to provide individuals with a new model of cancer screening that would save lives. His model, trademarked as Integrated Virtual Colonoscopy, combines the advantages of the two prevailing colon-cancer screening methods in a "one-stop shop" that screens, diagnoses, and treats colon cancer. By increasing the percentage of people who get screened for colon cancer, Dr. Baumel's model reduces the number of deaths caused by colon cancer.

A. Proper Screening is Vital To Preventing Colon Cancer, the Second-Leading Cause of Cancer Deaths in the United States.

48. According to the American Cancer Society, colorectal cancer ("colon cancer") is

the second leading cause of cancer deaths in the United States. Each year 150,000 Americans are diagnosed with colon cancer and approximately 50,000 die from the disease. In Virginia, nearly 1,400 people die each year from colon cancer.

49. However, 90 percent of colon cancer deaths are preventable through proper screening methods. Screening is effective because pre-cancerous polyps, or an abnormal growth of tissue, develop and grow for years before they transform into cancer.

50. According to the American Cancer Society's guidelines for the early detection of colon cancer, every person should get screened by the time he or she reaches the age of 50, and every five to ten years thereafter. Nevertheless, fewer than 50 percent of at-risk individuals get screened for colon cancer.

51. There are two methods of screening for colon cancer: (i) optical colonoscopy, the traditional method; and (ii) virtual colonoscopy, a relatively newer method. Both optical and virtual colonoscopies are widely accepted medical practices in Virginia.

B. Optical Colonoscopy, the Traditional Method of Colon-Cancer Screening, Is Invasive and Poses Some Medical Risks.

52. One of the major reasons for the dismal rate of colon-cancer screening is the invasive nature of the traditional method of screening, optical colonoscopy.

53. In medical terms, an invasive procedure is one which involves entering the body by incision or by inserting an instrument through a body cavity.

54. The traditional method of screening, optical colonoscopy, involves administering anesthesia intravenously, and then inserting an approximately six-foot tube attached to a camera (known as an endoscope) into a patient's rectum. As the tube advances through the colon (large intestine), the doctor can see the inner lining of the patient's colon on a screen. If a polyp or other abnormality is detected during the optical colonoscopy, which

occurs in about 15 to 20 percent of patients, the doctor can immediately either remove a tiny piece of the polyp for direct examination under a microscope (take a biopsy), or if large enough, remove the entire polyp. No external incision into the skin is required.

55. As an invasive procedure, colonoscopies are performed most commonly by gastroenterologists ("GI physicians") as well as other physicians trained in endoscopic procedures.

56. Optical colonoscopy poses several medical risks. First, the anesthesia poses a risk of an adverse reaction. Second, as with any invasive procedure, there is a risk of infection from the endoscope or other instruments. Third, there is a risk of bleeding which may require hospitalization. Finally, there is a slight risk of tearing the inner lining of the colon (perforation) or puncturing a hole in the bowel, both of which can be life-threatening and would require an immediate operation.

57. In addition to the physical discomfort, optical colonoscopy requires a recovery period of several hours and patients are advised not to resume normal work, driving, or other activities for the remainder of the day.

C. The New Noninvasive Screening Method of Virtual Colonoscopy Also Has Its Disadvantages.

58. Advances in diagnostic medical imaging technology offer a new, noninvasive method to screen for colon cancer. Diagnostic medical imaging refers to the use of various technologies that create images of the human body to reveal, diagnose, and treat medical conditions.

59. In the new noninvasive screening method, called computed tomographic colonography ("CTC"), or more commonly "virtual colonoscopy," the patient lies down on an examination table while a 16-slice or greater Computed Tomography (CT or CAT) scanner

uses low-dose radiation to take approximately 250 cross-sectional images in a sequence of 16 or more images at a time. A computer then combines all the two-dimensional images to create three-dimensional images of the patient's colon and surrounding abdominal cavity in a "virtual" scan.

60. As a medical imaging technique, virtual colonoscopies are performed by radiologists or other specialized doctors trained to read and interpret the CT scans.

61. As with optical colonoscopy, virtual colonoscopy requires patients to prepare for the screening by fasting and using laxatives the night before in order to purge their bowels.

62. There are five primary advantages that virtual colonoscopy offers over traditional optical colonoscopy:

a. First, the main advantage to virtual colonoscopy is that it allows the 80 to 85 percent of screened individuals without any detected abnormality to avoid an invasive procedure, the accompanying anesthesia, and all the attendant risks and inconveniences associated with both, as described in ¶ 56.

b. Second, because virtual colonoscopy is noninvasive, it also is an excellent alternative for the elderly or patients with factors that increase the risk of complications from an invasive procedure, such as those taking blood thinner medications.

c. Third, there is no recovery period needed for a virtual colonoscopy.

d. Fourth, virtual colonoscopy can often catch abnormalities in the surrounding abdominal cavity, which are not visible in a traditional optical colonoscopy.

e. Fifth, virtual colonoscopies are less costly than optical colonoscopies.

63. Due to these advantages of virtual colonoscopy, a greater number of patients

choose to get screened for colon cancer. Indeed, one study has shown that approximately 30 percent of virtual colonoscopy patients previously had refused to be screened through the more invasive optical colonoscopy method.

64. Despite its advantages, virtual colonoscopy has the drawback of requiring a second visit by the patient to treat any detected abnormality. Because virtual colonoscopy usually is performed by radiologists who are unaffiliated with GI physicians, the 15 to 20 percent of patients who have a detected abnormality must be referred to a GI or other physician for the invasive colonoscopy. Additionally, those patients also must undergo another laxative-based "preparation" the night before their invasive procedure.

D. Dr. Baumel's Innovative Model Combines the Advantages of Both Screening Methods While Eliminating Most of the Disadvantages.

65. In order to deal with this problem of requiring multiple visits to screen for and treat colon cancer, Dr. Baumel has combined the comfort and convenience of noninvasive virtual colonoscopy with the capacity for immediate removal of polyps offered by optical colonoscopy in a "one-stop-shop" for colon health services that he has trademarked as Integrated Virtual Colonoscopy.

66. Dr. Baumel's innovative approach to colon-cancer screening is premised on the belief that if colon-cancer screening is made simple, convenient, noninvasive, and comprehensive, many more Americans will get appropriate screening, which, in turn, will decrease the number of colon cancer deaths.

67. Under Dr. Baumel's Integrated Virtual Colonoscopy model, a locally based GI physician purchases the CT scanner for his office and then contracts with Plaintiff Colon Health Centers of America's team of (state-licensed) radiologists to provide same-hour evaluations of the patients' scans. With the addition of a CT scanner and the dedicated services

of specialized radiologists, the GI physician's office becomes a "one-stop shop" colon health center that is fully equipped to perform both virtual and optical colonoscopy in a single visit by a patient.

68. Upon arriving at a colon health center, a patient gets screened with a noninvasive virtual colonoscopy, which takes approximately 10 to 15 minutes. The images of the CT scan are immediately sent electronically to Colon Health Centers of America's team of radiologists based in Ohio. Unlike typical radiologists, Colon Health Center of America's team of radiologists has specialized experience in reading and interpreting CT scans from virtual colonoscopies; the team contains radiologists who are licensed to practice in every state in which Integrated Virtual Colonoscopy is offered. Within 30 to 45 minutes, the radiologists would read and interpret the CT scan and report the results to the local colon health center. If the results of the scan show no detected abnormality, as is the case with approximately 80 to 85 percent of the population, the patient is free to drive to work or home. If the results of the scan reveal a polyp or other abnormality, as is the case with approximately 15 to 20 percent of the population, the GI physicians would remove the abnormality through an immediate invasive colonoscopy on the same day.

69. With this model, patients with detected abnormalities are ready for treatment within an hour of arriving at the center, and are consequently able to take less time away from work or other activities. Additionally, these patients need to undergo only one bowel preparation instead of two.

70. Dr. Baumel's innovative border-crossing technique reduces the costs (both financial and personal) of colon-cancer screening, which will result in more at-risk individuals getting screened.

71. Dr. Baumel currently offers Integrated Virtual Colonoscopy at his flagship facility at the Colon Health Centers of Delaware where he has partnered with Delaware- based GI physicians. Since its opening in 2008, approximately 4,000 patients have received virtual colonoscopies at that facility with the option of receiving same-day treatment. Dr. Baumel also offers Integrated Virtual Colonoscopy in partnership with New Jersey-based GI physicians.

72. Dr. Baumel plans to partner with more GI physicians to create similar facilities in other states, beginning on the East Coast including in Virginia. These partnerships involve the purchase of equipment, including a CT scanner by the partner GI physician.

73. Virginia prohibits Dr. Baumel from offering fully integrated colon screening and treatment services by opening a colon health center or even purchasing a CT scanner without obtaining a certificate of need.

II. PLAINTIFF PROGRESSIVE RADIOLOGY WANTS TO OFFER COST-EFFECTIVE MEDICAL IMAGING SERVICES IN VIRGINIA.

74. Plaintiff Progressive Radiology offers cost-effective diagnostic medical imaging services throughout Maryland and the District of Columbia.

75. Progressive Radiology specializes in interpreting orthopedic imaging (pictures of the bones and joints) and neurological imaging (pictures of the brain and spine). Dr. Mark Monteferrante has particular expertise in neurological imaging and pediatric neuroradiology.

76. Primarily, Progressive Radiology uses magnetic resonance imaging ("MRI"), a type of medical imaging technology that uses a powerful magnetic field, radio frequency pulses and a computer to produce detailed pictures of organs, soft tissues, bones, joints, and virtually all other internal body structures without exposing the patient to radiation. A typical MRI scanner is a large cylinder-shaped tube surrounded by a circular magnet. The patient lies on a moveable examination table that slides into the center of the magnet.

77. Generally MRI scans are noninvasive, but some forms may require a patient to receive an injection of contrast material into the bloodstream. This injection allows the radiologist to better see internal processes in the body and better diagnosis certain conditions.

78. MRI images allow physicians to better evaluate various parts of the body and determine the presence of certain diseases that may not be assessed adequately with other imaging methods such as x-ray, ultrasound, or conventional CT scanning.

79. Aside from the administrative office in Falls Church, each of Progressive Radiology's current offices has one MRI scanner.

80. In 1987, Progressive Radiology opened its first and only diagnostic medical imaging office in Virginia at 7799 Leesburg Pike in Fairfax County (the "Tyson office"). It spent nearly $2 million investing in the Tyson office, which was equipped with an MRI scanner. At that time, Virginia did not require a certificate of need to purchase an MRI scanner.

81. In 1995, Progressive Radiology sold the Tyson office to a non-physician group called HealthSouth. Under the terms of the sale, Progressive Radiology entered into a long-term contract with HealthSouth to provide radiology physician services in the Tyson office.

82. In 2009, HealthSouth was acquired by Diagnostic Health Corporation, a venture capital group, which resold the Tyson office in 2011 to the highest bidder. Although Progressive Radiology submitted a bid to re-acquire the Tyson office, Diagnostic Health Corporation rejected its bid in favor of a much larger bid by Virginia-based Inova Health Systems. Subsequently, Inova Health Systems brought in its own radiologists and terminated Progressive Radiology's contract to provide radiology physician services at the Tyson office.

83. As a result, Progressive Radiology is no longer providing MRI services in

Virginia, even though all thirteen radiologists in its employ are licensed to practice in Virginia.

84. Dr. Monteferrante and Progressive Radiology have concrete plans to open a new MRI office in Fairfax County near its former Tyson office in order to continue to serve the patients of Virginia with its specialty in orthopedic and neurological imaging.

85. The proposed office would include an MRI scanner, costing approximately $1.7 million. Dr. Monteferrante estimates that the cost of building and furnishing the office would run approximately $500,000 and the projected monthly expenses and costs of operation would be between $50,000 and $100,000. Based on his prior experience in the Virginia market, Dr. Monterferrante estimates that the new office would serve approximately 400 patients per month.

86. However, Virginia prohibits Progressive Radiology from opening this new MRI office or even purchasing the MRI scanner unless it first obtains a certificate of need.

III. VIRGINIA'S CERTIFICATE-OF-NEED PROGRAM IS A RELIC FROM A FEDERAL POLICY ABANDONED MORE THAN 25 YEARS AGO.

A. The Federal Government Abandoned its Short-Lived Experiment with Certificate-of-Need Requirements.

87. Certificate-of-need requirements originated in the mid-1960s from state and local efforts to allocate federal funding for the creation of hospitals in order to ensure the financial viability of hospitals paid for by taxpayers.

88. These requirements were premised on the purported ability to control healthcare costs by restricting supply and dividing the provision of healthcare services into discrete geographical regions. But by constraining the supply of hospital beds and dividing the market for healthcare services, certificate-of-need requirements effectively insulated existing hospitals from new competition.

89. Hospitals were quick to recognize that they would benefit financially from the prevalence of state certificate-of-need requirements and their inherent restriction of competition.

90. In 1968, the American Hospital Association began a nationwide lobbying campaign to pass state certificate-of-need programs and even drafted model legislation.

91. By 1975, twenty states had enacted certificate-of-need regimes as a result of American Hospital Association's lobbying efforts.

92. Congress took note of the American Hospital Association's lobbying efforts and passed the National Health Planning and Resources Development Act of 1974 ("NHPRDA") which required states to adopt a certificate-of-need program in order to receive certain federal healthcare subsidies. NHPRDA also guaranteed federal funding for state certificate-of-need programs that met federal guidelines.

93. At the time, Medicare and Medicaid reimbursed for services based on a hospital's actual expenditures. Because this system allowed hospitals to recoup expenditures regardless of whether the hospital was inefficient, Congress believed it could hold hospitals accountable for costs by requiring new medical facilities to demonstrate that they were needed by the community before getting federal dollars.

94. As a result of NHPRDA's federal requirement and funding guarantee for state certificate-of-need programs, by 1980 all states but Louisiana had implemented a certificate-of-need requirement.

95. In 1984, Congress restructured the Medicare and Medicaid reimbursement system to a fee-for-service model under which hospitals received a fixed amount for each patient regardless of the hospital's actual expenditures.

96. In 1986, Congress repealed NHPRDA, eliminating the federal requirement and funding for state certificate-of-need programs for three reasons. First, restructuring the Medicare and Medicaid reimbursement system to a fee-for-service model eliminated the rationale for encouraging states to adopt certificate-of need programs. Second, Congress found there was no evidence that certificate-of-need programs advanced their goal of lowering healthcare costs or even slowing the growth of healthcare costs. In fact, the evidence showed that certificate-of-need programs resulted in increased costs. Third, Congress determined that certificate-of-need requirements were beginning to produce detrimental effects as local officials took myopic or parochial views of what kind of medical services a community "needed."

97. The federal government has reaffirmed its conclusion that certificate-of-need programs raise costs and harm patients on two separate occasions.

98. A 1988 Staff Report of the Bureau of Economics in the Federal Trade Commission ("FTC") concluded that certificate-of-need programs harm consumers and raise healthcare costs by: (1) serving as a barrier to entry of new healthcare providers; and (2) encouraging hospitals to avoid using more-efficient (but CON-restricted) services and equipment in favor of less-efficient (but CON-free) services and equipment.

99. In 2004, the FTC and United States Department of Justice ("DOJ") issued a joint report reaffirming the 1988 study. Based on 27 days of joint hearings held from February through October 2003, an FTC-sponsored workshop in September 2002, and independent research, the federal agencies concluded that:

> States with Certificate of Need programs should reconsider whether these programs best serve their citizens' health care needs. The [FTC and DOJ] believe that, on balance, **CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits.** Market incumbents can too easily use CON procedures to forestall competitors from entering an

> incumbent's market. . . . [T]he vast majority of single-specialty hospitals—a new form of competition that may benefit consumers—have opened in states that do not have CON programs. **Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry.** Other means of cost control appear to be more effective and pose less significant competitive concerns.

(emphasis added).

100. Since 1986, there has been no federal authorization for certificate-of-need programs.

101. However, despite the end of the federal authorization of certificate-of-need programs, local lobbying efforts have kept some form of certificate-of-need requirements in place in 36 states, including Virginia.

102. There is no evidence of any negative effects in the 14 states that have entirely eliminated their certificate-of-need programs.

B. Virginia Imposes a Particularly Restrictive Certificate-of-Need Requirement.

103. The primary goal of Virginia's certificate-of-need program is to provide current healthcare providers with a government-backed shield from competition.

104. According to the Department of Health's website, Virginia's CON program "seeks to contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost." A guiding principle of Virginia's CON program is to "discourage[] the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability." 12 Va. Admin. Code § 5-230-30.

105. The crux of Virginia's complex regulatory scheme is found in Section 32.1-102.3 of the Virginia Code which broadly prohibits commencing any healthcare "project" without first demonstrating to the Commissioner a "public need" for the project.

106. The statutory definitions of those terms highlight the broad scope of Virginia's

regulatory scheme.

107. For example, the statute broadly defines "project" to include nine categories of activity, including but not limited to:

- establishing a medical care facility;
- introducing into an existing medical care facility any new healthcare service, including CT scanning and MRI; and
- adding specified medical equipment to a medical care facility, including a CT or MRI scanner.

Va. Code § 32.1-102.1.

108. Virginia also broadly defines "medical care facility" to include any institution, place, building or agency which offers healthcare services. Va. Code § 32.1-102.1. The statute enumerates types of medical care facilities subject to review, including "[s]pecialized centers or clinics or that portion of a physician's office developed for the provision of . . . computed tomographic (CT) scanning, . . .[and] magnetic resonance imaging." *Id.*

109. However, despite the broad scope of Virginia's certificate-of-need requirement, it does not apply evenhandedly.

110. For example, "nuclear cardiac imaging" is specifically exempted from Virginia's certificate-of-need requirement. Va. Code § 32.1-102.1 ("'Medical care facility' shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging."); *id.* (defining project to include "[i]ntroduction into an existing medical care facility of any . . . nuclear medicine imaging, except for the purpose of nuclear cardiac imaging").

111. "Nuclear cardiac imaging" is similarly situated to other types of nuclear imaging and other types of medical imaging.

112. In addition to the certificate-of-need requirement, Virginia mandates that certain

medical equipment including CT and MRI scanners be registered with the Commissioner and the appropriate regional health planning agency within thirty (30) days of purchase. Va. Code § 32.1-102.1:1.

113. In approving a certificate of need, the Commissioner must consider some twenty different statutory factors and conclude that a "public need has been demonstrated" for the new service or equipment. The burden is on the applicant to produce information and evidence that the project meets these statutory criteria including demonstrating a need. 12 Va. Admin. Code § 5-230-40.

114. Because not all of the statutory factors must be satisfied and no one factor is controlling, the Commissioner possesses a vast amount of discretion in determining whether or not to grant a certificate of need. Thus, it effectively impossible for an applicant to determine in advance whether his application for a certificate of need will be granted or denied.

115. Once a certificate of need has been issued, no significant change to a project may be made without prior written approval of the Commissioner. 12 Va. Admin. Code § 5-220-130. Additionally, the certificate of need is not transferable. Va. Code § 32.1-102.5.

116. Commencing any project without the required certificate of need is a misdemeanor, punishable by fines of up to $1,000 for each day the facility is in violation. Va. Code. §§ 32.1-27 to -27.1. On petition of the Commissioner, the State Board or the Attorney General may request a court to enjoin any project undertaken without a certificate. Va. Code §32.1-102.8.

C. Virginia's Certificate-of-Need Process Is Complicated and Onerous.

117. Virginia's certificate-of-need approval process is time-consuming and involves multiple steps before various subdivisions within the Department of Health.

118. The Virginia Department of Health has prepared a flowchart that summarizes its lengthy and complex certificate-of-need process. A copy of this flowchart is attached to the Complaint at Appendix A.

119. Upon information and belief, the Department of Health uses "regional health planning agencies," defined by Va. Code § 32.1-102.1, to facilitate review of and make initial recommendations on certificate-of-need applications.

120. For purposes of state health planning, Virginia is divided into five health planning regions as defined by Va. Code § 32.1-102.1.

121. Upon information and belief, Northwestern Virginia Health Systems Agency, Inc. is the regional health planning agency for Health Planning Region I covering Northwestern Virginia.

122. The Health Systems Agency of Northern Virginia is the regional health planning agency for Health Planning Region II covering Northern Virginia. Defendant Montgomery oversees this health planning agency.

123. Upon information and belief, similar regional planning agencies govern Health Planning Region III (Southwestern Virginia); Health Planning Region IV (Central Virginia); and Health Planning Region V (Eastern Virginia).

124. Upon information and belief, Defendant Bodin oversees regional health planning agencies for Health Planning Regions I, III, IV, and V.

125. In reviewing certificate-of-need applications, the Department of Health uses a "structured batching process" that groups together different applications for different services into a broad category of medical projects to be reviewed in the same 190-day cycle. 12 Va. Admin. Code § 5-220-200 (defining batch groups and setting forth review cycles for each

batch). For example, applications for CT scanners are grouped with applications for MRI scanners and considered in the same review cycle for diagnostic imaging facilities (Batch D). To be considered in the review cycle for a particular batch, an application must be submitted to the Department of Health and the appropriate regional health planning agency at least 40 days before that batch's review cycle begins. 12 Va. Admin. Code § 5-220-180(C). Consequently, an applicant for a CT or MRI scanner must submit a completed application by the deadlines for that review cycle or it will not be considered.

126. According to the Department of Health, this structured batching process makes it easier to identify "competing" applications.

127. The first step in the application process is to file a letter of intent with the Commissioner identifying the type of healthcare project, the owner, and the proposed scope, size, and location of the project. 12 Va. Admin. Code § 5-220-180(A). Within seven days of receiving a letter of intent, the Department of Health must send the applicant the application forms. *Id.*

128. In order to be deemed complete for review, certificate-of-need applicants must pay a fee of one percent of the proposed expenditure for the project up to $20,000. 12 Va. Admin. Code § 5-220-180(B). According to the Department of Health, the average expenditure-based fee paid by applicants to the Virginia certificate-of-need program is approximately $20,000 and application fees generate revenue of about $1 million annually which goes to support the administration of Virginia's certificate-of-need scheme.

129. Within 15 calendar days, the Department must acknowledge receipt of the application and notify the applicant if the application is incomplete. 12 Va. Admin. Code §5-220-190.

130. Within 60 days, the regional health planning agency or the Department of Health must conduct a public hearing to provide applicants, local governing bodies, and anyone else, including existing businesses that would have to compete with the applicant, with an opportunity to comment on the application. 12 Va. Admin. Code § 5-220-230(A).

131. Within 70 days, the Department must complete its review and recommendation of the application. *Id.*

132. Within 75 days, the Department must determine whether an "informal fact-finding conference" is necessary. *Id.*

133. Established businesses can seek to intervene in the application process and request an "informal fact-finding conference" for "good cause" which includes wanting to present information not previously presented at the public hearing, address changed factors or circumstances since the public hearing, or point out a mistake of fact or law in the Department's staff report on the application or in the report submitted by the regional health planning agency. 12 Va. Admin. Code § 5-220-230(A).

134. Despite the "informal" label, this stage of the certificate-of-need process can resemble full-blown litigation, involving attorneys, adversarial parties, and expert witnesses.

135. After the record is closed, the Commissioner has 45 days in which to determine whether to approve the application. If no action is taken by the Commissioner, the application is deemed approved after 25 calendar days.

136. Without an informal fact-finding conference, the entire application process and review can take six to seven months to complete. If an informal fact-finding conference is requested by any person, the certificate-of need process can take significantly longer.

137. Upon information and belief, fact-finding conferences are almost exclusively

requested by entities that would be in economic competition with the entity that is the subject of the certificate-of-need proceeding.

138. Because of this, the duration (and therefore the burden) of the certificate-of-need approval process is largely controlled by entities that have an economic interest in preventing the certificate of need from being granted.

IV. PLAINTIFFS HAVE FIRST-HAND EXPERIENCE WITH HOW VIRGINIA'S CERTIFICATE-OF-NEED SCHEME INHERENTLY ALLOWS EXISTING BUSINESSES TO BLOCK NEW COMPETITION.

139. Both plaintiffs have had direct experiences with the certificate-of-need application process that illustrate how applying for a certificate of need for their proposed Virginia offices would be prohibitively expensive, time-consuming, and fruitless. They are thus challenging having to apply for a certificate of need in the first place, not what happens in any particular application.

A. Established Businesses Blocked Plaintiff Colon Health Centers of America's Prior Efforts To Offer Integrated Virtual Colonoscopy in Virginia.

140. Dr. Baumel's efforts to open three colon health centers in Virginia and offer Integrated Virtual Colonoscopy to Virginians were blocked by established businesses under Virginia's certificate-of-need program.

141. From October 2008 to January 2009, Dr. Baumel took concrete steps to recruit and partner with GI physicians in Virginia to provide Integrated Virtual Colonoscopy. After countless e-mails, phone calls, and half-a-dozen trips to Virginia, he successfully recruited three groups of GI physicians to open three separate colon health centers in Virginia, with one in Fredericksburg, and two in Loudoun and Prince William Counties, respectively.

142. Because the proposed colon health centers would require the purchase of CT scanners, they could not legally be opened without a certificate of need from the

Commissioner.

143. Dr. Baumel attempted to find an attorney to shepherd him through Virginia's complicated application process. However, when he received an estimate that an attorney would cost at least $75,000, not including any appeal, Dr. Baumel decided to prepare the applications himself and spare himself and his GI partners the additional cost.

144. Each of the three GI physician groups had already agreed to pay the approximately $7,000 to $8,000 in application fees for each application.

145. Dr. Baumel spent about one month working full time on completing the three applications, one for each proposed center. During this time, he researched the requirements of Virginia's certificate-of-need program and the application process; spent dozens of hours drafting the applications; found and coordinated exhibits and supporting documentation including videos and medical studies; took numerous follow-up trips to Virginia to find suitable locations for the proposed centers; and developed generalized blueprints for these facilities.

146. On March 31, 2009, Dr. Baumel submitted three applications for Colon Health Centers: one in Fredericksburg and two in Loudoun, and Prince William Counties, respectively. Each application contained approximately 45 pages of detailed information accompanied by 38 supporting exhibits. As part of a required "completeness review" in support of each application, Dr. Baumel submitted approximately an additional 20 pages answering various questions and 16 supporting exhibits.

147. Because Virginia's certificate-of-need program is based on geographically dividing the healthcare market, two different regional health planning agencies were required to review the applications. The proposed Colon Health Center in Fredericksburg fell within the reviewing authority of the Northwestern Virginia Health Systems Agency, while the proposed

centers in Loudoun and Prince William Counties fell within the reviewing authority of the Health Systems Agency of Northern Virginia.

148. With respect to the proposed Fredericksburg Colon Health Center, at least 40 letters of support from physicians and physician associations and 186 letters of community support were received urging the Commissioner to approve the certificate of need.

149. On the morning of the public hearing, the Northwestern Virginia Health Systems Agency received letters of opposition from three established businesses and competitors of the proposed Colon Health Center (Medical Imaging of Fredericksburg, LLC, Radiologic Associates of Fredericksburg, and MediCorp Health). All three established businesses argued that there was no "need" for another CT scanner because they already provided CT services.

150. At the public hearing, besides the GI doctor applicants and Dr. Baumel, only five individuals offered comments. All five individuals represented established businesses and advocated for denying the certificate of need. One local radiologist noted that the project would move healthcare dollars out of state.

151. The other two applications faced a similar fate. Both proposed colon health centers in Loudoun and Prince William Counties received similar levels of professional and community support as the Fredericksburg Center.

152. However, three established businesses and competitors of the proposed Colon Health Center (Washington Radiology Associates, Potomac Hospital, and Prince William Health System) submitted letters of opposition.

153. Ignoring the unique advantages offered by combining optical and virtual colonoscopy services in one center, both regional health planning agencies determined that the specialty colon health centers were not "needed" because they were "fungible" with "centers

for providing general CT services."

154. Based on a similar rationale, the Division of Certificate of Public Need also recommended denying the certificate-of-need applications.

155. After holding a fact-finding conference on August 12, 2009, the adjudication officer concluded that none of the three proposed colon health centers met a public need and recommended denying all three applications.

156. On November 30, 2009, Defendant Commissioner Remley adopted the recommendation of the adjudication officer and denied all three applications.

157. The only way for Dr. Baumel to open a Colon Health Center in Virginia would be to successfully reapply for a certificate of need.

158. Because of the enormous expense, time, and uncertainty involved in Virginia's multi-step certificate-of-need process, Dr. Baumel cannot afford to enter into partnerships with the same (or different) GI physicians in Virginia to reapply for certificates of need.

159. Based on his prior experience in finding interested GI physicians in Virginia and his success building partnerships in other states, Dr. Baumel believes he would have no problem partnering with GI physicians in Virginia to offer Integrated Virtual Colonoscopy but for the state's certificate-of-need requirement.

B. Plaintiff Progressive Radiology Also Has Prior Experience With the Burdens of Virginia's Certificate-of-Need Scheme and the Way It Protects Existing Businesses from Competition.

160. Plaintiff Progressive Radiology is also familiar with the burdens and barriers imposed by Virginia's certificate-of-need program. Dr. Monteferrante experienced first-hand the complexities and burden of Virginia's regulatory scheme.

161. After Progressive Radiology sold its Tyson office to HealthSouth in 1995,

HealthSouth decided to purchase a second MRI scanner in order to meet increasing demand. By this time in the early 2000s, Virginia had reactivated its certificate-of-need requirement for medical equipment and so HealthSouth applied for a certificate of need.

162. After five years of multiple applications, hearings, and appeals and spending approximately $175,000 in filing fees, consulting fees, and attorney fees, HealthSouth received a certificate of need for a new MRI scanner.

163. Throughout the application process, Dr. Monteferrante and other members of Progressive Radiology played an integral role in trying to obtain the certificate of need. Dr. Monteferrante attended numerous meetings and testified in favor of the certificate of need.

164. At each stage during this five-year process, existing diagnostic imaging centers, which would have had to compete with Progressive Radiology's increased capacity, opposed the applications.

165. Based on Dr. Monteferrante's and Progressive Radiology's previous experience with the certificate-of-need process and the opposition of their competitors to new services, Progressive Radiology cannot afford to spend the huge amounts of money and time required to apply for a certificate of need that is not likely to be granted.

166. The only barrier to Progressive Radiology opening a new office in Virginia is the state's certificate-of-need requirement. But for that requirement, Progressive Radiology would open a Virginia office, purchase at least one new MRI scanner in interstate commerce, and install it in a suitable medical office leased in Fairfax County.

167. As a consequence of Virginia's certificate-of-need requirement, the only way Progressive Radiology's radiologists can practice medicine in the state (as they are licensed to do) is to go to work for an established in-state business. They are effectively barred from

purchasing the equipment necessary to operate as their own business.

V. BUT FOR VIRGINIA'S CERTIFICATE-OF-NEED SCHEME, PLAINTIFFS WOULD BE ABLE TO PROVIDE INNOVATIVE AND COST-EFFECTIVE MEDICAL CARE TO PATIENTS IN VIRGINIA.

168. Virginia's certificate-of-need program imposes a significant barrier to opening a new medical facility or purchasing essential medical equipment to offer medical services in Virginia.

169. All Plaintiffs are currently refraining from offering new medical services in Virginia because (and only because) they cannot afford to invest the enormous resources required for a certificate-of-need application when approval is so unlikely.

170. But for Virginia's certificate-of-need requirement, Plaintiffs would expand their out-of-state businesses into Virginia.

171. But for Virginia's certificate-of-need requirement, Plaintiffs would import medical equipment into Virginia in order to offer their healthcare services to Virginia residents.

172. None of the Plaintiffs has ever opposed any application for a certificate of need.

173. Defendants are responsible for administering and enforcing Virginia's certificate-of-need program.

174. Plaintiffs have no adequate remedy at law.

A. Injury to Colon Health Centers of America.

175. Colon Health Centers of America has successfully partnered with a GI physicians' practice in Delaware and New Jersey in order to offer Integrated Virtual Colonoscopies.

176. Colon Health Centers of America has agreements with other GI physicians to open facilities in other states that will offer Integrated Virtual Colonoscopies.

177. The only reason Colon Health Centers of America is not currently expanding its business into Virginia (as it is in other states) is Virginia's certificate-of-need requirement.

178. But for Virginia's certificate-of-need requirement, Colon Health Centers of America would partner with Virginia-based GI physicians to purchase CT scanners, open colon health centers, and offer Integrated Virtual Colonoscopy to patients in Virginia.

179. Based on Colon Health Centers of America's previous experience in finding GI partners in Virginia, the only barrier to opening a Virtual Integrated Colonoscopy facility in Virginia is the state's certificate-of-need requirement.

180. Currently, most (if not all) Virginians are unable to obtain same-day virtual colonoscopy and treatment.

181. In order to provide Integrated Virtual Colonoscopy, Dr. Baumel or any of his GI partners would need to purchase a CT scanner in interstate commerce and bring it into Virginia. As a direct result of Virginia's regulatory scheme, neither Dr. Baumel nor any of his partners can import CT scanners or other medical equipment into Virginia without obtaining a certificate of need.

182. Based on Colon Health Centers of America's previous experience in applying for a certificate of need in Virginia, it would be financially impossible to invest the resources required for another application given the associated costs, burdens, delay, and complete uncertainty of whether the state would issue a certificate of need for an Integrated Virtual Colonoscopy center.

B. Injury to Progressive Radiology.

183. Progressive Radiology currently offers radiological services in both Maryland and Washington, D.C.

184. Progressive Radiology currently employs Virginia-licensed radiologists who are authorized to practice medicine in the state.

185. Progressive Radiology currently employs Virginia-licensed radiologists who have previously served Virginia patients and would like to serve Virginia patients again.

186. The only way for Progressive Radiology's radiologists to work in Virginia (as they are licensed to do) is either to (1) obtain a certificate of need for a new facility or (2) work for another business that already has a certificate of need.

187. But for Virginia's certificate-of-need program, Progressive Radiology would open an office in Virginia, purchase an MRI, and offer diagnostic radiology services to patients in Virginia.

188. Progressive Radiology's doctors cannot offer radiology services without purchasing an MRI machine, and it cannot purchase an MRI machine without obtaining a certificate of need.

189. Based on Progressive Radiology's previous experience in trying to obtain a certificate of need to purchase a second MRI scanner in an existing facility, it would be financially impossible to invest the resources necessary to apply for a certificate of need to open a new facility given the associated costs, burdens, delay, and complete uncertainty of whether the state would actually grant such a certificate.

CONSTITUTIONAL VIOLATIONS

FIRST CLAIM FOR RELIEF
(Commerce Clause Violation)

190. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through XX above.

191. The Commerce Clause of the U.S. Constitution (Article I, Section 8, clause 3)

creates a unitary national market in goods and services by giving Congress the exclusive power to regulate interstate commerce. Consequently, the Commerce Clause operates as an external restraint on the legislative powers of the states even when Congress has not exercised its power.

192. Under this dormant aspect of the Commerce Clause, states are prohibited from enacting laws that either (i) discriminate against interstate commerce; or (ii) incidentally burden interstate commerce more than they benefit local interests. Virginia's certificate-of-need requirement does both.

193. Virginia's certificate-of-need requirement explicitly applies to imaging technology like CT scanners and MRI machines.

194. There is an interstate market for the sale of imaging technology like CT scanners and MRI machines.

195. Upon information and belief, all or nearly all CT scanners and MRI machines like those Plaintiffs seek to buy are manufactured outside of Virginia.

196. Other states, including New Jersey, Maryland, and Delaware, do not require a certificate of need to purchase imaging technology like CT scanners and MRI machines.

197. As a result of Virginia's applying its certificate-of-need requirement to imaging technology like CT scanners and MRI machines, the flow of those goods into Virginia is substantially burdened or restricted.

198. There is an interstate market in the provision of medical services, including colon-cancer screening and treatment and radiology services. Plaintiffs provide medical services in interstate commerce. Plaintiffs, their employees, and their patients move across state lines to provide these medical services.

199. Virginia's certificate-of-need requirement prevents out-of-state medical

providers like Plaintiffs from offering their independent services without going through the uncertain, costly, and burdensome process of applying for and receiving a certificate of need.

200. Virginia's certificate-of-need requirement has the purpose of discriminating against out-of-state businesses in favor of in-state businesses.

201. Virginia's certificate-of-need requirement has the effect of discriminating against out-of-state businesses in favor of in-state businesses.

202. Virginia's certificate-of-need requirement places substantial burdens on interstate commerce—including interstate commerce in imaging equipment like CT scanners and MRI machines, and interstate commerce in medical services—that are not justified by local benefits.

203. Virginia's certificate-of-need requirement has the purpose of protecting in-state businesses from competition.

204. Virginia's certificate-of-need requirement has the effect of protecting in-state businesses from competition.

205. Protecting in-state businesses from competition is not a legitimate state interest.

206. Virginia's certificate-of-need requirement has the purpose of favoring in-state businesses.

207. Virginia's certificate-of-need requirement has the effect of favoring in-state businesses.

208. Virginia's certificate-of-need requirement does not actually achieve any legitimate local benefits.

209. Upon information and belief, Defendants possess no evidence that Virginia's certificate-of-need requirement actually achieves any legitimate local benefits.

210. Virginia's certificate-of-need requirement violates Plaintiffs' right under the Commerce Clause of the United States Constitution to participate in the national marketplace and the flow of interstate commerce.

211. Plaintiffs have been and continue to be harmed by enforcement of Virginia's certificate-of-need program.

SECOND CLAIM FOR RELIEF
(Equal Protection Violation)

212. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through XX above.

213. Under the Fourteenth Amendment to the U.S. Constitution, no state shall "deny to any person within its jurisdiction the equal protection of the laws."

214. Virginia's certificate-of-need program irrationally treats similar medical services differently, and therefore violates the Constitution's equal-protection guarantee.

215. Virginia's certificate-of-need program irrationally treats similar medical equipment differently, and therefore violates the Constitution's equal-protection guarantee.

216. There is no rational reason to subject Plaintiffs' proposed healthcare services to a certificate-of-need requirement when other services—including similarly situated imaging services, like nuclear cardiac imaging—are exempt.

217. Upon information and belief, Defendants possess no evidence that the exemption of nuclear cardiac imaging from the state's certificate-of-need requirement advances any legitimate state interest that would not apply equally to other kinds of nuclear imaging or other kinds of medical imaging.

218. Upon information and belief, Defendants possess no evidence that the application of the certificate-of-need requirement to services like those Plaintiffs want to

provide advances any legitimate state interest.

219. Plaintiffs have been and continue to be harmed by enforcement of Virginia's certificate-of-need program.

THIRD CLAIM FOR RELIEF
(Substantive Due Process Violation)

220. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through XX above.

221. The Due Process Clause of the Fourteenth Amendment protects people's right to earn a living in the occupation of their choice subject only to reasonable government regulation.

222. Virginia's certificate-of-need program violates the right to earn a living because it does not advance any legitimate purpose.

223. Virginia applies its certificate-of-need requirement to regulate purely private imaging clinics, not just publicly financed "community" providers.

224. Virginia's certificate-of-need program's purpose is to protect established Virginia healthcare businesses from economic competition.

225. Intrastate economic protectionism is not a legitimate state interest under the Fourteenth Amendment.

226. Plaintiffs have been and continue to be harmed by enforcement of Virginia's certificate-of-need program.

FOURTH CLAIM FOR RELIEF
(Privileges or Immunities Violation)

227. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through XX above.

228. The Privileges or Immunities Clause of the Fourteenth Amendment to the U.S. Constitution states that: "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States."

229. The Privilege or Immunity Clause was intended to guarantee citizens' right to earn a living in the occupation of their choice free from unreasonable or unnecessary government regulation.

230. Virginia's prohibition against opening a healthcare facility, offering healthcare services, or purchasing essential medical equipment to practice their livelihood, without prior government approval, on its face and as applied, violates that right because it is arbitrary, unreasonable, and not related to the advancement of any legitimate government interest.

231. Plaintiffs have been and continue to be harmed by enforcement of Virginia's certificate-of-need program.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. For entry of judgment declaring that Virginia's certificate-of-need program (Va. Code §§ 32.1-102.1 *et seq.*, its implementing rules and regulations, 12 Va. Admin. Code §§ 5-220-10 *et seq.*) is unconstitutional on its face and as applied to the extent that it discriminates against interstate commerce in medical equipment and healthcare services, and therefore violates the dormant Commerce Clause of the U.S. Constitution.

2. For an entry of judgment declaring that Virginia's certificate-of-need program is unconstitutional on its face and as applied to the extent it violates the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution;

3. For an entry of judgment declaring that Virginia's certificate-of-need program is

unconstitutional on its face and as applied to the extent it violates the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution;

4. For an entry of judgment declaring that Virginia's certificate-of-need program is unconstitutional on its face and as applied to the extent it violates the Privileges or Immunities Clause of the Fourteenth Amendment to the U.S. Constitution;

5. For entry of a permanent injunction against Defendants prohibiting the enforcement of these statutory provisions, administrative rules and regulations, and practices and policies;

6. For an award of attorney's fees, costs, and expenses in this action pursuant to 42 U.S.C. § 1988; and

7. For further legal and equitable relief as this Court may deem just and proper.

Dated this 5th day of June, 2012.

Respectfully submitted,

INSTITUTE FOR JUSTICE

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** Application for Admission Pro Hac Vice to be filed.*