

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION**

LEE BIRCHANSKY, M.D.; FOX EYE
SURGERY, LLC; KORVER EAR NOSE AND
THROAT, LLC; MICHAEL JENSEN; and
MICHAEL DRIESEN,

Plaintiffs,

vs.

GERD W. CLABAUGH, in his official capacity as
Director of Iowa Department of Public Health and
Administrator of the State Board of Health;
REBECCA SWIFT, in her official capacity as
Administrator of the Health Facilities Council; and
ROBERTA CHAMBERS, CONNIE SCHMETT,
ROGER THOMAS, BRENDA PERRIN, and
HAROLD MILLER in their official capacities as
Members of the Health Facilities Council,

Defendants.

Civil Action No. 4:17-cv-209

**PLAINTIFFS' FIRST AMENDED
COMPLAINT FOR DECLARATORY AND
INJUNCTIVE RELIEF**

COME NOW plaintiffs Dr. Lee Birchansky; Fox Eye Surgery, LLC; Korver Ear Nose and Throat, LLC; Michael Jensen; and Michael Driesen, by their undersigned counsel, and allege as follows:

INTRODUCTION

1. This is a constitutional challenge to Iowa's certificate-of-need requirement, which arbitrarily prevents medical entrepreneurs from offering safer, less costly, and more convenient medical procedures, and also prevents patients from accessing safer, less costly, and more convenient medical procedures.

2. Iowa requires outpatient surgery centers, like those owned by plaintiffs Dr. Birchansky; Fox Eye Surgery, LLC; and Korver Ear Nose and Throat, LLC (physician

plaintiffs), to apply for and receive a “certificate of need.” To obtain a certificate, the medical entrepreneur must convince the Department of Public Health that there is a “need” for the medical services. This certificate can be obtained only through an onerous and costly process, during which competing medical providers can argue there is no “need” for a medical entrepreneur’s new services.

3. But not all medical providers are required to obtain a certificate of need: Existing providers already holding a certificate of need can open an unlimited number of new facilities, provided they spend less than \$1.5 million to do so. These existing providers can also sell their facilities and accompanying certificates of need to other medical providers, and the buyers would not need a new certificate of need, provided that there is a seamless transfer of ownership.

4. This arbitrary certificate-of-need requirement places severe burdens on medical entrepreneurs in Iowa, requiring a difficult and time-consuming application process that offers no reliable way to predict whether a certificate will actually be granted to any given applicant. And the program exists for no reason beyond protecting established businesses from competition.

5. Because—and only because—of the barrier posed by the certificate-of-need requirement, physician plaintiffs may not offer cost-effective surgeries at conveniently located facilities.

6. The certificate-of-need requirement violates the rights of physician plaintiffs and those like them, who simply want to provide safe, effective, and approved medical services, as guaranteed by the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution.

7. And, by imposing certificate-of-need requirements on only some medical

facilities (but not other, similarly situated facilities), defendants violate the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution.

8. Furthermore, Iowa's certificate-of-need requirement infringes on the fundamental right of Americans, like plaintiffs Jensen and Driesen (patient plaintiffs), to access approved medical care from a licensed provider, as protected by the Fourteenth Amendment to the U.S. Constitution.

SUBJECT MATTER JURISDICTION

9. Plaintiffs bring this civil-rights lawsuit pursuant to 42 U.S.C. § 1983 for violations of rights, privileges, or immunities secured by the Fourteenth Amendment to the U.S. Constitution and the Declaratory Judgments Act, 28 U.S.C. § 2201. Plaintiffs seek injunctive and declaratory relief against the enforcement of Iowa's certificate-of-need requirements, Iowa Code §§ 135.61 *et seq.*, its implementing rules and regulations, Iowa Administrative Code §§ 641-202.1 *et seq.* and 641-203.1 *et seq.*, and the policies and practices of the Iowa Department of Public Health and the State Health Facilities Council in enforcing these provisions, which, both facially and as-applied, violate plaintiffs' constitutional rights.

10. Accordingly, this Court has jurisdiction over plaintiffs' claims under 28 U.S.C. § 1331 (federal-question jurisdiction) and § 1343 (civil-rights jurisdiction).

VENUE

11. Venue is appropriate in this Court under 28 U.S.C. § 1391(b) and Local Rule 3(b). As described more fully below, two defendants are domiciled in Polk County and all defendants operate in their official capacities within Polk County, which is located in the Southern District of Iowa in the Central Division, 28 U.S.C. § 95(b)(1).

12. Additionally, all defendants are domiciled in the State of Iowa and at least four

are domiciled in the Southern District of Iowa.

THE PARTIES

I. THE PLAINTIFFS

A. Physician Plaintiffs

13. Plaintiff Dr. Lee Birchansky is a board-certified ophthalmologist licensed to practice in the State of Iowa.

14. Dr. Birchansky is a United States citizen, domiciled in Linn County, Iowa.

15. Dr. Birchansky is the organizing member and Chief Executive Officer of Plaintiff Fox Eye Surgery.

16. Plaintiff Fox Eye Surgery is an Iowa limited liability company. Its registered office is located at 1138 H Avenue NE, Cedar Rapids, Iowa 52402.

17. Dr. Birchansky intends to perform cataract and other outpatient eye surgeries in a fully equipped, custom-built surgery center adjacent to his medical office at 1138 H Avenue NE in Cedar Rapids, Iowa. But Iowa's certificate-of-need requirement has stymied his efforts to do so.

18. Dr. Birchansky would also like to open a new outpatient surgery center in the Quad Cities area. Another physician has already contacted Dr. Birchansky about opening a new outpatient surgery center. But to do so, Dr. Birchansky would need to apply for and obtain a certificate of need, a process which has previously cost him hundreds of thousands of dollars and twenty years to navigate.

19. Plaintiff Korver Ear Nose and Throat (Korver ENT) is an Iowa limited liability company. Its registered office is located at 907 Lincoln Circle SE, Orange City, Iowa 51041.

20. Korver ENT owns a recently constructed medical facility at 907 Lincoln Circle

SE, in Orange City, Iowa.

21. Korver ENT would like to convert the lower level of this facility into an outpatient surgery center to perform tonsillectomies and other ENT surgeries. But it cannot do so without applying for and obtaining a certificate of need.

B. The Patient Plaintiffs

22. Patient plaintiff Michael Jensen has been a patient of Dr. Birchansky since 2001.

23. Plaintiff Jensen wants to receive future cataract or other outpatient eye surgeries from Dr. Birchansky at Fox Eye Surgery's center because it is a safe, cost-effective, convenient, and familiar environment. But Iowa's certificate-of-need requirement has prevented him from doing so because Dr. Birchansky cannot open an outpatient cataract surgery center before obtaining a certificate of need.

24. Patient plaintiff Michael Driesen has been a patient of Korver ENT since 2014.

25. Plaintiff Driesen wants to receive future ENT surgeries from Korver ENT at its proposed surgery center because it is a safe, cost-effective, convenient, and familiar environment. He also wants his children to receive future ENT surgeries from Korver ENT at its proposed facility for the same reasons. But Iowa's certificate-of-need requirement prevents him and his children from doing so because Korver ENT cannot open its proposed surgery center before obtaining a certificate of need.

II. THE DEFENDANTS

26. Defendants are all officials of two state entities that have responsibility for implementing or enforcing Iowa's certificate-of-need statutes. These entities are the Iowa Department of Health (including its State Board of Health) and the State Health Facilities Council.

27. The Iowa Department of Public Health administers the statutes that establish Iowa's certificate-of-need requirement. Iowa Code § 135.62. The Department also promulgates administrative rules and regulations implementing Iowa's certificate-of-need requirement. *See* Iowa Admin. Code §§ 641—202.1(135) *et seq.* and 641—203.1(135) *et seq.*

28. Defendant Gerd W. Clabaugh is the Director of the Iowa Department of Public Health. Director Clabaugh oversees 20 state boards including the Iowa State Board of Health and the Health Facilities Council. His offices are located at Lucas State Office Building, 321 E. 12th Street, Des Moines, IA 50319. On information and belief, Defendant Clabaugh is domiciled in Polk County, Iowa.

29. All rules adopted by the Department of Public Health are subject to approval by the State Board of Health. Iowa Code § 136.3(10).

30. The State Board of Health is composed of 11 Iowans appointed by the Governor for terms of three years each. Iowa Code §§ 136.1-136.2. The Board of Health's purpose is to "provide a forum for the development of public health policy in the state of Iowa," and it has the following duties: (i) establish policies governing the performance of the Department of Public Health in the discharge of any duties imposed on it by law; (ii) assure that the Department of Public Health complies with the Iowa code and administrative rules; and (iii) "[a]dopt, promulgate, amend, and repeal rules and regulations consistent with law for the protection of the public health and prevention of substance abuse, and for the guidance of the department." Iowa Code § 136.3. The Board's policy-setting duties include proposing rules and regulations implementing Iowa's certificate-of-need requirement.

31. Defendant Clabaugh also serves as the Administrator of the State Board of Health.

32. The State Health Facilities Council is administered under the Department of Public Health. The Council makes final decisions with respect to each application for a certificate of need, sets regulatory policy to administer Iowa's certificate-of-need requirement, directs staff personnel of the Department of Public Health assigned to review applications for certificates of need, advises and counsels with the Director of the Department of Public Health concerning administration of the certificate-of-need requirement, and reviews and approves, prior to promulgation, all rules adopted by the Department of Public Health concerning the certificate-of-need requirement. Iowa Code § 135.62(2)(f).

33. Defendant Rebecca Swift is the Department of Public Health Administrator for the Health Facilities Council. Upon information and belief, her domicile is in Jasper County, Iowa.

34. Defendant Roberta Chambers is a member of the Health Facilities Council. Her term expires on April 30, 2019. Upon information and belief, she is domiciled in Wayne County, Iowa.

35. Defendant Connie Schmett is a member of the Health Facilities Council. Her term expires on April 30, 2019. Upon information and belief, she is domiciled in Polk County, Iowa.

36. Defendant Roger Thomas is a member of the Health Facilities Council. His term expires on April 30, 2021. Upon information and belief, he is domiciled in Clayton County, Iowa.

37. Defendant Brenda Perrin is a member of the Health Facilities Council. Her term expires on April 30, 2023. Upon information and belief, she is domiciled in Cherokee County, Iowa.

38. Defendant Harold Miller, M.D., is a member of the Health Facilities Council. His term expires on April 30, 2023. Upon information and belief, he is domiciled in Scott County, Iowa.

39. Each and every defendant is sued in his or her official capacity.

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

STATEMENT OF FACTS

41. Plaintiff Fox Eye Surgery and its organizing member, Plaintiff Dr. Birchansky, want to provide cataract and other eye surgeries at a state-of-the-art facility adjoining Dr. Birchansky's current ophthalmological practice in central Cedar Rapids. They would also like to open a new facility elsewhere in Iowa.

42. Plaintiff Korver ENT wants to custom-build a new outpatient facility in Orange City, Iowa, in the lower level of its current ENT offices, in order to provide low-cost and convenient tonsillectomies, sinus surgeries, and other outpatient ENT surgeries.

43. Iowa prohibits the physician plaintiffs from opening outpatient surgery centers and offering their services unless they first obtain a certificate of need from the Health Facilities Council.

44. Iowa requires the physician plaintiffs to obtain a certificate of need, even though:

- a. all of the medical services they seek to offer would be provided by individuals properly licensed by the State of Iowa;
- 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 Iowa hospitals and outpatient surgery centers;

c. plaintiffs Dr. Birchansky and Fox Eye Surgery already have a facility and the necessary equipment, have been allowed to operate in the past when associated with a local hospital, and are ready to begin operations as soon as is legally possible;

d. plaintiff Korver ENT has a facility and the funds required to finish constructing an outpatient surgery center; and

e. the cost of building and opening physician plaintiffs' facilities would be entirely privately financed and would not involve any taxpayer money.

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

46. Physician plaintiffs are permitted to offer surgery at an already opened institutional health facility in Iowa. Iowa requires physician plaintiffs to obtain a certificate of need only because they plan to open their own independent facilities, which would compete with established businesses.

47. This lawsuit challenges the constitutionality of requiring physician plaintiffs to undergo the burdens, delays, and uncertainties of Iowa's arbitrary certificate-of-need requirement before opening new outpatient surgery centers in the state.

48. Plaintiff Jensen wishes to receive high-quality, low-cost cataract surgeries from Dr. Birchansky.

49. Iowa's certificate-of-need scheme forces Plaintiff Jensen to receive surgery from Dr. Birchansky at a local hospital or hospital-affiliated surgery center where Dr. Birchansky has privileges. This forces Plaintiff Jensen and other Iowans like him to inconvenience themselves, pay more, receive lower quality care, and, in the case of hospital procedures, unnecessarily expose themselves to an increased risk of infection.

50. Plaintiff Driesen wishes to receive, and wants his children to receive, high-quality, low-cost ENT surgeries from Korver ENT.

51. Iowa's certificate-of-need scheme forces Plaintiff Driesen to receive surgery from Korver ENT at a local hospital where Dr. Korver has privileges. This forces Plaintiff Driesen and other Iowans like him to inconvenience themselves, pay more, receive lower quality care, and unnecessarily expose themselves to an increased risk of infection.

52. This lawsuit challenges the constitutionality of requiring Iowans, like Plaintiffs Jensen and Driesen, to incur additional cost and medical risk for no reason other than to increase existing healthcare facilities' bottom lines.

I. PHYSICIAN PLAINTIFFS WANT TO OFFER COST-EFFECTIVE AND CONVENIENT OUTPATIENT CATARACT SURGERIES.

A. Plaintiffs Dr. Birchansky and Fox Eye Surgery want to offer cost-effective, convenient, and safer outpatient surgeries.

53. Plaintiffs Dr. Birchansky and Fox Eye Surgery want to perform cataract and other eye surgeries in an outpatient surgery center in Iowa.

54. Dr. Birchansky earned his M.D. from the University of Miami School of Medicine in 1985, graduating with high honors. In 1986, he completed his residency at the Department of Ophthalmology at University of Iowa Hospitals and Clinics. Dr. Birchansky received board certification from the American Board of Ophthalmology in 1991. Since then, he has received further board certification in both LASIK and Cataract and Lens Implant Surgery from the American Board of Eye Surgery.

55. Recognized as one of the top ophthalmologists in the country in 2011, Dr. Birchansky is an innovator in his field. Many of the cataract surgery techniques that Dr. Birchansky adopted early in his career have become the standard of care nationwide.

56. After learning “no-stitch” cataract surgery in 1991 directly from the pioneer of the procedure, Dr. Birchansky introduced this technique to Eastern Iowa and has performed over 30,000 no-stitch cataract surgeries. No-stitch cataract surgery involves using smaller, self-sealing incisions in order to achieve a faster recovery, and it is now considered the field’s standard of care.

57. Dr. Birchansky is currently performing cataract surgeries at hospitals and other facilities where he has privileges, but he wants to perform them at Fox Eye Surgery’s outpatient surgery center.

58. Fox Eye Surgery’s outpatient surgery center will operate in a fully equipped but currently unused space adjoining Dr. Birchansky’s medical office.

59. The surgery center features ceiling-mounted, ophthalmology-specific microscopes, operating rooms decorated with murals painted by a local artist, and a patient viewing room in which family can observe the procedure. The extensive waiting room can easily accommodate 30 people.

60. St. Luke’s Hospital rented and used this surgery center between 1998 and 2003, during which Dr. Birchansky performed thousands of surgeries at the surgery center. In 2007, the Iowa Supreme Court declared that, after St. Luke’s ceased using the facility, Fox Eye Surgery needed to obtain a certificate of need. *Birchansky Real Estate, L.C. v. Iowa Dep’t of Pub. Health, State Health Facilities Council*, 737 N.W.2d 134 (Iowa 2007).

61. On the advice of his attorney, Dr. Birchansky performed cataract surgeries in the proposed outpatient surgery center from 2009 to 2011, pursuant to the provision of Iowa’s certificate-of-need scheme that excludes in-office procedures. *See* Iowa Code § 135.61 (excluding in-office procedures from definition of “[o]utpatient surgical facility”).

62. The surgery center has not been used since the Department of Public Health determined that cataract surgery did not fall under the in-office exclusion. *See Birchansky v. Iowa Dep't of Pub. Health*, 838 N.W.2d 680 (Iowa Ct. App. 2013).

63. The outpatient cataract surgery center that plaintiffs Dr. Birchansky and Fox Eye Surgery wish to open will decrease patient and payor costs, increase flexibility for doctors and patients in scheduling surgeries, and improve patient care.

64. When Dr. Birchansky was performing in-office cataract surgeries, the only fee he charged in addition to his surgeon's fee was the \$200 it cost him to purchase the prosthetic lens.

65. The total cost for Dr. Birchansky's cataract procedure at Fox Eye Surgery's outpatient surgery center would be \$975 for Medicare patients and \$1,950 for non-Medicare patients. For comparison, one local hospital, Mercy Medical Center, charges \$8,372 for its facility fee alone.

66. Additionally, if plaintiffs Dr. Birchansky and Fox Eye Surgery were allowed to open their outpatient surgery center, they would provide free services to indigent cataract patients from 14 Iowa counties.

67. Dr. Birchansky can at present offer completely free services only if the hospital or other surgery center is willing to waive its facility fee.

68. In one instance, Mercy Medical Center refused to provide a free facility for cataract surgery to one of Dr. Birchansky's young diabetic patients who rapidly became blind from severe cataracts. Dr. Birchansky's surgical expertise was free, but he was unable to provide his service without a facility in which to operate. Dr. Birchansky's patient was ultimately sent to the University of Iowa, which agreed to waive the facility fee for his surgery. This delayed his visual rehabilitation by several months.

69. There would be at least a 35 percent decrease in payor costs for cataract surgeries in an outpatient surgery center compared to doing the same surgeries in hospitals.

70. Fox Eye Surgery's facility is conveniently located next to Dr. Birchansky's ophthalmological office.

71. The surgery center would allow his elderly patients to receive outpatient cataract surgery from their own ophthalmologists, in a single-story location that they are used to navigating, instead of having to travel to a large, unfamiliar hospital.

72. Research has established that mornings are the best time for surgery. Mercy Medical Center, the local hospital, is unable to provide reasonable and optimal operating room times for Dr. Birchansky's elderly patients. Dr. Birchansky's patients have been assigned surgery times from 11:00 AM to 7:00 PM.

73. Patients today receive and have come to expect a higher level of medical care. Today's facilities need to offer the latest technologies and accommodate a patient's preference, desire, schedule, and requested surgical time. The patients at the plaintiffs' surgery center will choose the day of the week, Monday through Saturday, and the time of their surgery. Fox Eye Surgery's proposed surgery center will be the only facility in Cedar Rapids to offer cataract surgery on weekends.

74. There are distinct safety advantages to performing outpatient surgeries in single-specialty centers like Fox Eye Surgery's facility instead of in hospitals. First, because hospitals treat many different illnesses and conditions, hospital surgeries face an increased risk of infection. Second, hospitals require surgeons to follow their unique procedures and work with staff assistants who may not be familiar with the operating surgeon's methods. When performing surgeries in a specialized facility, patients can avoid intra-hospital infection, and

surgeons like Dr. Birchansky can use the same trained staff and established procedures for each cataract surgery.

75. Dr. Birchansky performed over 10,000 cataract surgeries at Fox Eye Surgery's outpatient cataract surgery center when it was operational. Under his leadership, there were no eye infections.

76. Outpatient surgery centers like Fox Eye Surgery's also improve the quality of care by permitting their doctors to readily adopt the newest technologies.

77. Dr. Birchansky and Fox Eye Surgery, should they be allowed to open their proposed outpatient surgery center, intend to adopt laser-assisted cataract surgery. There is currently only one other facility in Iowa with this technology available.

78. Dr. Birchansky has asked local hospitals to adopt laser-assisted cataract surgery, even offering to buy the equipment and lease room in the hospitals. But the hospitals have refused to adopt this technology.

79. On August 24, after over 20 years of effort on Dr. Birchansky's part, the Health Facilities Council issued a decision granting Dr. Birchansky and Fox Eye Surgery's application for a certificate of need for their Cedar Rapids facility. That approval is not the end of the process—the existing businesses with which Dr. Birchansky seeks to compete still have a right of appeal—but Dr. Birchansky hopes that the Cedar Rapids facility will be up and running within three weeks.

80. Dr. Birchansky also wants to perform cataract surgeries at a new outpatient surgery centers in the Quad Cities area.

81. Over the past 10 years, Dr. Birchansky has discussed plans with another Iowa physician to offer cataract surgeries in the Quad Cities area in a new outpatient surgery center.

The planned outpatient surgery center would consist of an approximately 7,500-square-foot multi-specialty center, with facilities equipped for both pain-relief treatment and cataract surgery. Referring optometrists in the Quad Cities area currently want to send Dr. Birchansky approximately 20 patients requiring cataract surgery per month.

82. But Dr. Birchansky and Fox Eye Surgery cannot provide cataract surgeries at a new outpatient surgery center without first obtaining a certificate of need.

83. Before even filing an applying for a new certificate of need, Dr. Birchansky would have to spend hundreds of thousands of dollars preparing a new facility.

84. Before applying, Dr. Birchansky would have to consult with a real estate consultant and architect to find a suitable location. The location would need to satisfy zoning restrictions and building requirements. Any building would need to have 6,000 square feet of useable space.

85. Because financial feasibility will be considered by the Council, Dr. Birchansky would have to hire an accountant to present an estimated cost breakdown.

86. In order to file an application, Dr. Birchansky would have to hire an attorney to both file the application and present the proposed outpatient surgery center to the Council.

87. Because his last facility required over 20 years and hundreds of thousands of dollars to obtain a certificate of need, Dr. Birchansky believes it will be both prohibitively expensive and futile to spend time and money on further compliance with Iowa's unconstitutional certificate-of-need program.

88. But for Iowa's certificate-of-need requirement, Dr. Birchansky would immediately begin searching for a location in the Quad Cities area to establish a new outpatient surgery center.

B. Plaintiff Korver ENT wants to provide cost-effective, safe, and convenient outpatient ENT procedures.

89. Plaintiff Korver ENT wants to open an outpatient surgery center to perform tonsillectomies, sinus surgeries, and other outpatient ENT surgeries in Orange City, Iowa.

90. The lower floor of Korver ENT's split-level facility contains 3,168 square feet of unused space. Korver ENT intends to convert this space into a surgery center to provide tonsillectomies and other outpatient ENT surgeries. The intended surgery center will feature a separate entrance and easy access to parking.

91. Dr. Kurtis Korver is the organizing member and president of Korver ENT.

92. Dr. Korver received his M.D. from the University of Iowa, Carver College of Medicine. He has been practicing for 17 years and is certified by the American Board of Otolaryngology.

93. The outpatient surgery center that Korver ENT wishes to open will decrease patient and payor costs, increase flexibility for both Dr. Korver and his patients in scheduling surgeries, and improve patient care.

94. When Dr. Korver performs outpatient ENT surgeries at hospitals, the hospital facility fees are commonly around \$4,500. Korver ENT projects that it can provide outpatient ENT surgeries with facility fees of around \$1,500 or less in an independent outpatient facility.

95. Under current Iowa law, Korver ENT would be required to apply for and receive a certificate of need before operating an outpatient ENT surgery center.

96. If Iowa's unconstitutional certificate-of-need scheme did not apply, Korver ENT could convert the unused space on the lower level of its offices into a certified outpatient surgery center.

97. Korver ENT possesses the investment capital, knowledge, and ability to construct

a surgery center within a year's time and at a cost of less than \$200,000.

98. The completed surgery center will meet any and all federal, state, and local requirements for the construction of an outpatient ENT surgery center.

II. IOWA'S CERTIFICATE-OF-NEED REQUIREMENT IS A VESTIGE OF A FEDERAL POLICY THAT WAS ABANDONED MORE THAN 30 YEARS AGO.

99. Certificate-of-need requirements for medical facilities originated in the mid-1960s, when state and local governments made efforts to allocate federal funding for the creation of hospitals in order to ensure the financial viability of taxpayer-funded hospitals.

100. 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.

101. 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.

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

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

104. Congress took note of the American Hospital Association's lobbying efforts. At the time, Medicare and Medicaid reimbursed for services based on a hospital's actual expenditures. Because this system allowed hospitals receiving federal funds to recoup expenditures even when those hospitals were inefficient, Congress believed it could hold

hospitals accountable for costs by requiring new medical facilities to demonstrate that they were needed by the community.

105. Congress passed the National Health Planning and Resources Development Act of 1974 (NHPDA), which required states to adopt a certificate-of-need program in order to receive federal healthcare subsidies.

106. NHPDA also guaranteed federal funding for the administration of state certificate-of-need programs that met federal guidelines.

107. As a result of NHPDA's federal subsidy prerequisites and funding guarantees, by 1980 all states but Louisiana had implemented a certificate-of-need requirement.

108. 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 served regardless of the hospital's actual expenditures.

109. In 1986, Congress repealed NHPDA, 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."

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

111. 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 certificate-of-need-restricted) services and equipment in favor of less-efficient (but certificate-of-need-exempt) services and equipment.

112. 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).

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

114. 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 34 states, including Iowa.

115. There is no evidence of any negative effects in the 16 without certificate-of-need

programs.

116. Studies show that certificate-of-need requirements are associated with lower hospital quality and higher mortality rates.

117. There is no evidence that certificate-of-need requirements like Iowa's limit or reduce healthcare costs.

III. IOWA'S BURDENSOME AND UNEQUAL CERTIFICATE-OF-NEED PROGRAM

A. Iowa Imposes a Restrictive and Burdensome Certificate-of-Need Requirement.

118. The primary goal of Iowa's certificate-of-need program is to provide established healthcare businesses with a government-backed shield from competition.

119. The certificate-of-need requirement has nothing to do with health or safety.

Other laws regulate the licensing and safety of outpatient surgery centers:

- a. Life and safety building codes for outpatient surgery centers are regulated by Iowa Administrative Code sections 661-205.1(100) and 661-205.20(1);
- b. Iowa licenses physicians and surgeons under Iowa Code Chapter 148; and
- c. facilities that accept Medicare funds must be certified in accordance with federal standards under 42 C.F.R. § 416(A)-(C).

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

121. The crux of Iowa's regulatory scheme is found in Iowa Code § 135.63, which broadly prohibits establishing any new or changed "institutional health service" without first applying for and receiving a "certificate of need" from the Department of Public Health.

122. Offering any institutional health service without the required certificate of need carries a civil penalty of up to \$300 for each day the facility is in violation. Iowa Code § 135.73.

123. “New . . . or changed institutional health service” is defined broadly, including: “The construction, development or other establishment of a new institutional health facility.” Iowa Code § 135.61(18). An outpatient surgery center, or “outpatient surgical facility,” is defined to be an institutional health facility. Iowa Code § 135.61(14).

124. The first step in the application process is to file a letter of intent with the Department of Public Health, briefly describing the proposed new or changed service, its location, and its estimated cost. Iowa Code § 135.65. This letter initiates a “30-day waiting period,” after which the applicant may submit an application for a certificate of need. Iowa Admin. Code § 641—202.2(135).

125. Certificate-of-need applicants must also pay a fee of 0.3% of the anticipated cost of the project. The total cost of the project is calculated by adding site costs, land improvements, facility costs, movable equipment, and financing costs. Iowa Admin. Code § 641—202.4(2)(a). The minimum fee is \$600 and the maximum fee is \$21,000. Iowa Code § 135.63(1); Iowa Admin. Code § 641—202.4(2).

126. Within 15 calendar days, the Department of Public Health must acknowledge receipt of the application and notify the applicant if the application is incomplete. Iowa Admin. Code § 641—202.4(3).

127. After accepting a complete application, the Department must notify all “affected persons” in writing of the application, including those persons who are or will be competitors. Iowa Code §§ 135.61(d) and 135.66(2); Iowa Admin. Code § 641—202.4(4).

128. While consumers or third-party payers may receive notice by the Department's furnishing the information to news media, competitor health facilities must receive written notice.

129. After notice is given, the Department will conduct a formal review of the application. Formal review includes, first, a public hearing and, second, evaluating the application against the non-exhaustive criteria in Iowa Code § 135.64.

130. The public hearing, which must be held before evaluating the application against the relevant statutory criteria, is conducted by the Health Facilities Council. Iowa Code § 135.66(3).

131. The Council must give 10 days' notice before the hearing and must allow any "affected person," including the proposed facility's potential competitors, to testify in favor of or against the application. Iowa Code § 135.66(4).

132. The hearing format, in descending order, is as follows:

- i. Announcement of application under review.
- ii. Presentation of department report.
- iii. Applicant presentation.
- iv. Affected persons' presentation.
- v. Applicant's rebuttal.
- vi. Council discussion, motion, and final decision.

Iowa Admin. Code § 641—202.6(1). This format requires an applicant to "rebut[]" the presentations of affected persons, including the applicant's potential competitors.

133. After the hearing, Iowa Code § 135.64(1) instructs the Department of Public Health and the Health Facilities Council to consider 18 different, non-exhaustive criteria in

evaluating certificate-of-need applications, including:

- “[t]he relationship of the proposed institutional health services to the existing health care system of the area in which those services are proposed to be provided”;
- “[t]he appropriate and efficient use or prospective use of the proposed institutional health service, and of any existing similar services, including but not limited to a consideration of the capacity of the sponsor’s facility to provide the proposed service, and possible sharing or cooperative arrangements among existing facilities and providers”;
- “[t]he appropriate and nondiscriminatory utilization of existing and available health care providers”; and
- “[t]he impact of relocation of an institutional health facility . . . on other institutional health facilities.”

134. Even if the Council finds that the applicant satisfies the 18 statutory criteria in Iowa Code § 135.64(1), the Council cannot grant a certificate of need without making written findings that:

- (1) “[l]ess costly, more efficient, or more appropriate alternatives” to the applicant’s facility do not exist and cannot be otherwise developed;
- (2) similar, existing facilities “are being used in an appropriate and efficient manner”;
- (3) alternatives to new construction “including . . . modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable”; and

(4) “[p]atients will experience serious problems in obtaining care of the type which will be furnished” by the applicant’s facility. Iowa Code § 135.64(2).

135. Before issuing a decision, the Council must conduct a public hearing on the propriety of the certificate. Iowa Code § 135.66(3)(b).

136. All affected persons or their representatives have the opportunity to present testimony to the Council at the public hearing. Iowa Code § 135.66(4); Iowa Admin. Code § 641—202.6(3).

137. Once the final decision is made on the certificate-of-need application, “any dissatisfied party who is an affected person with respect to the application” may seek judicial review. Iowa Code § 135.70. This means that established facilities that will be in competition with the new facility may appeal the Council’s decision to grant a certificate of need.

138. The Health Facilities Council possesses vast discretion in determining whether to grant a certificate of need. Not all of the 18 statutory criteria must be satisfied, no one factor is controlling, and factors other than the statutory ones may be considered. Thus, it is effectively impossible for an applicant to determine in advance whether his application for a certificate of need will be granted or denied.

139. The Health Facilities Council must make a final decision on an application within 90 days or, in certain circumstances, within 150 days. Iowa Code §§ 135.69, 135.72(4); Iowa Admin. Code § 641—202.8(135).

140. In sum, the initial application and review process can potentially take up to five months and cost up to \$21,000 in fees, not including the cost of hiring lawyers or consultants to assist with the application, the hearing, and any appeals.

141. Thus, the duration and cost (and therefore the burden) of the certificate-of-need

approval process is onerous.

142. Moreover, the certificate-of-need hearing format ensures that the application process is strongly influenced by existing medical providers who have an economic interest in preventing would-be competitors from receiving certificates of need.

143. Iowa's certificate-of-need scheme does not control costs, spending, or the construction of medical facilities. Existing providers who already have outpatient surgery centers may build and open (or buy and reopen) an unlimited number of new outpatient surgery centers without applying for a certificate of need, provided that they operate within the same county and that opening the facility or facilities costs less than \$1.5 million per year.

144. Iowa's certificate-of-need scheme does not control who may operate a medical facility. Any person can purchase an already existing and operational facility and continue to operate it without first applying for a certificate of need.

B. Iowa's Certificate-of-Need Requirement Is Applied Unequally.

145. Despite the broad scope, large cost, and heavy burden of Iowa's certificate-of-need requirement, Iowa does not apply the requirement evenhandedly.

146. Already established facilities may spend up to \$1.5 million to build new medical facilities in the same county, including outpatient surgery centers, without requiring a new certificate of need. *See* Iowa Code §§ 135.61(18)(c), 135.63(1); Iowa Admin. Code § 641—202.1(135).

147. Existing medical providers may, without obtaining certificates of need, construct new facilities that are exactly the same as physician plaintiffs' proposed surgery centers except that the new facilities are owned by entities who already have certificates of need.

148. There is no limitation on the number of new facilities that already existing

providers can construct in the same county. So long as they spend less than \$1.5 million per year, providers who already have certificates of need can build an unlimited number of outpatient surgery centers.

149. Indeed, in July 2017, Mercy Medical Center opened the Hiawatha Medical Park—a three-story, 80,000-square-foot medical building, just four miles from Plaintiff Fox Eye Surgery’s currently unused center. Mercy Medical Center will be leasing the second and third floors of this building to an outpatient surgery center and eye clinic.

150. At the Health Facilities Council’s February 25, 2016, meeting, the Council determined that Mercy’s proposed outpatient surgery center did not require a certificate of need under an exemption for expansions of existing facilities requiring less than \$1.5 million in expenditures.

151. Once a provider has a certificate of need for its facility, it can then sell its facility and accompanying certificate of need to another provider, provided the services offered remain unchanged during the transfer of ownership. *See* Iowa Code § 135.63(2)(o).

152. Under Iowa’s certificate-of-need scheme, physician plaintiffs could *buy* their proposed facilities from already existing providers who have certificates of need for the facilities and then begin operating those facilities as soon as possible. It is only because physician plaintiffs do not already have certificates of need, like their competitors do, that they cannot begin operating their proposed facilities.

153. Furthermore, the Department has discretion to waive certain requirements, like the letter-of-intent requirement and its 30-day waiting period. Iowa Code § 135.67.

IV. PLAINTIFFS DR. BIRCHANSKY AND FOX EYE SURGERY HAVE FIRST-HAND EXPERIENCE WITH HOW IOWA’S CERTIFICATE-OF-NEED SCHEME INHERENTLY ALLOWS EXISTING BUSINESSES TO BLOCK NEW COMPETITION.

154. Plaintiffs Dr. Birchansky and Fox Eye Surgery have directly experienced how prohibitively expensive, time-consuming, and fruitless the certificate-of-need process is. They are thus challenging having to apply for a certificate of need in the first place, not the outcome of any particular application.

155. For the past 20 years, Dr. Birchansky has been trying to establish an outpatient surgery center to perform eye surgeries in a facility adjacent to his current ophthalmological offices.

156. Dr. Birchansky has submitted five certificate-of-need applications, four of which were denied. The fifth was granted on August 24, 2017, and it is subject to appeal by “affected persons,” including Dr. Birchansky’s competitors.

157. At each and every step, the two area hospitals—Mercy Medical Center and St. Luke’s—have opposed Dr. Birchansky’s efforts, even intervening in the actions concerning whether his cataract surgeries qualified under the statute’s in-office exemption.

158. After first being denied a certificate of need in 1996, Dr. Birchansky shared his blueprints for the proposed outpatient surgery center with St. Luke’s to partner with it to create a surgery center next to his office location.

159. Because the surgery center would operate as an off-campus department of the hospital that already offered the service (and therefore would be considered an extension of St. Luke’s hospital that fell below the \$1.5 million threshold for capital expenditures) no certificate of need was required. *See* Iowa Code § 135.61(18)(c).

160. Under the terms of the partnership agreement, St. Luke’s rented the facility from

Dr. Birchansky for five years with an option to renew.

161. In 1998, the custom-built outpatient surgery center that Dr. Birchansky had envisioned in his original application was completed.

162. When the lease term expired in 2003, St. Luke's refused to renew the lease because of a restrictive covenant it had with other physicians building a competing outpatient surgery center in Cedar Rapids—the Outpatient Surgical Center of Cedar Rapids.

163. Recognizing the uncertainty of his partnership with St. Luke's, Dr. Birchansky and Fox Eye Surgery applied for a certificate of need in August 2004.

164. Initially, the Department of Public Health determined that Dr. Birchansky and Fox Eye Surgery did not require a certificate of need to operate their facility following a transfer of ownership from St. Luke's to Fox Eye Surgery.

165. Later, however, the Department clarified its determination, stating that the transfer had to be seamless; otherwise a certificate of need was necessary. St. Luke's, in an anti-competitive effort to prevent a seamless transfer of ownership and trigger the certificate-of-need requirement, abruptly closed the center to prevent Dr. Birchansky from continuing to use the outpatient surgery center. This forced Dr. Birchansky to reschedule 27 patients' surgeries.

166. On February 26, 2005, the Department formally reconsidered its earlier determination that Dr. Birchansky did not need a certificate of need and denied Dr. Birchansky's application, finding that additional surgery space was not needed in Cedar Rapids.

167. Dr. Birchansky appealed, arguing that it was not within the Department's authority to reconsider its earlier determination that he did not require a certificate of need.

Both St. Luke's and Mercy Medical Center intervened. The district court reversed the denial. While on appeal, the Iowa Hospital Association successfully lobbied the legislature to amend the law to require that the transfer of ownership be consensual. In August 2007, relying on the amended law, the Iowa Supreme Court held that Dr. Birchansky required a certificate of need and that the Department did not unreasonably deny his application. *Birchansky Real Estate, L.L.C. v. Iowa Dep't of Pub. Health*, 737 N.W.2d 134, 140-41 (Iowa 2007).

168. Dr. Birchansky and Fox Eye Surgery filed additional certificate-of-need applications, one in late 2007 and one in late 2008. The 2007 application limited his request to a single-specialty (ophthalmology) surgical center and the 2008 application requested approval for only one operating room.

169. Each application was opposed by both Mercy and St. Luke's. And the Council denied each application, finding there was no "need" for Dr. Birchansky's services.

170. Tired of the denials, Dr. Birchansky informed the Department that he was planning to perform cataract surgeries as part of his in-office practice, not under the proposed surgery center.

171. Under an exclusion for in-office procedures, the Department permits other surgeries (such as LASIK, plastic surgery, and ob-gyn procedures) to be conducted in facilities without a certificate of need.

172. Dr. Birchansky requested a formal determination that cataract surgeries qualify as office-based procedures that do not require certificates of need. Due to pending appeals of his applications, the Department stated it would not respond to his request for a determination.

173. In March 2009, St. Luke's and the Outpatient Surgery Center of Cedar Rapids complained that Dr. Birchansky was performing cataract surgeries without a certificate of need.

174. In June 2009, the Department issued an opinion stating that cataract surgery was not an office-based procedure and, consequently, Dr. Birchansky was operating a surgical facility without the required certificate of need.

175. On April 22, 2010, the Department issued a cease-and-desist order, expressing its intent to impose \$20,000 in fines unless Dr. Birchansky immediately stopped performing cataract surgery in his office.

176. Dr. Birchansky sought judicial review of the Department's determination that cataract surgeries are not in-office procedures. The Iowa Court of Appeals dismissed the challenge because Dr. Birchansky had not properly served the intervenor hospitals in violation of the notice provisions of the Iowa Administrative Procedure Act.

177. Despite opposing Dr. Birchansky and Fox Eye Surgery's past certificate-of-need applications, both Mercy Medical Center and St. Luke's have constructed additional outpatient surgery facilities and were able to do so without a certificate of need due to the exemption for existing facilities.

178. In May 2017, Dr. Birchansky and Fox Eye Surgery filed their fifth certificate-of-need application.

179. Following Dr. Birchansky and Fox Eye Surgery's application, Defendant Swift sent a memorandum to "Affected and Interested Parties" who are "provider[s] or potential provider[s] of similar services in the same geographic area." The memorandum indicates that the affected parties "are invited to voice [their] support or opposition to this proposal."

180. Five existing providers filed letters opposing Fox Eye Surgery's application. Each letter argues that the application should be denied because existing facilities can accommodate Dr. Birchansky's patients.

181. One letter, by the Surgery Center of Cedar Rapids (a surgery center jointly operating with St. Luke's Hospital), even points out that "Mercy has announced that it is nearing completion of a new multi-specialty outpatient surgical facility in Hiawatha that will also provide eye surgery" and, therefore, that area "facilities have sufficient excess capacity to accommodate all of the procedures Fox [Eye Surgery] currently performs and those [it] proposes to perform if its CON Application is approved." In other words, existing facilities, even those built and opened *after* plaintiffs Dr. Birchansky and Fox Eye Surgery were previously denied certificates of need, can meet the "need" of Iowa patients and should not face competition from an upstart surgery center.

182. On July 19, the Health Facilities Council held a hearing on Dr. Birchansky's most recent certificate-of-need application.

183. Representatives from Mercy Medical Center and St. Luke's opposed Dr. Birchansky's application.

184. Representatives from Mercy Medical Center argued that the Fox Eye Surgery's application should be denied because there was no need for new operating rooms, even though Mercy Medical Center had opened a new outpatient surgery center within a week of the hearing.

185. During the affected parties' statements in opposition, Council Member Roberta Chambers noted the apparent "collusion" between the two large hospitals in Cedar Rapids, St. Luke's and Mercy Medical Center, in order to keep out "the little guy."

186. Another Council Member, Roger Thomas, criticized the loophole under which existing facilities can expand without obtaining a certificate of need.

187. At the hearing, the Health Facilities Council voted 3-2 to grant Fox Eye

Surgery's certificate of need. The "affected persons," including Mercy Medical Center and St. Luke's, may now appeal the Health Facilities Council's decision.

188. Now that he has received a certificate of need, Dr. Birchansky will within two to three weeks begin performing the cataract surgeries in Fox Eye Surgery's facility in Cedar Rapids. But he will do so subject to the possible appeal of the Council's decision to grant his certificate of need.

189. Given Dr. Birchansky's two-decade odyssey within Iowa's unconstitutional certificate-of-need process, and the fact that his current facility's certificate of need is potentially subject to an appeal by one of his competitors, it would be futile and cost-prohibitive to apply for another certificate before opening a new surgery center.

V. INJURY TO PLAINTIFFS

A. But for Iowa's Certificate-of-Need Scheme, Physician Plaintiffs Would Be Able to Provide Innovative and Cost-Effective Surgeries to Patients in Iowa.

190. Iowa's certificate-of-need program imposes a significant barrier to opening a new outpatient surgery center.

191. Plaintiffs Dr. Birchansky and Fox Eye Surgery are currently refraining from offering new medical services in Iowa because their attempts to obtain the required certificate of need have, with one exception, been unsuccessful and very costly.

192. The average cost for each certificate-of-need application by Fox Eye Surgery and Dr. Birchansky exceeds \$40,000. The financial cost of four failed applications and the related legal proceedings totals over \$200,000.

193. Dr. Birchansky and Fox Eye Surgery have spent at least 600 hours trying to comply with Iowa's certificate-of-need requirement.

194. Dr. Birchansky and Fox Eye Surgery do not want to spend additional money or

time to comply with Iowa's certificate-of-need requirement.

195. But for the existence of Iowa's certificate-of-need scheme, Dr. Birchansky and Fox Eye Surgery could legally open their outpatient surgery center without having to first proceed through the unconstitutional certificate-of-need program and, even if successfully obtaining a certificate of need, without facing legal appeals and protracted court battles as a result of the unconstitutional certificate-of-need program.

196. But for the existence of Iowa's certificate-of-need scheme, Dr. Birchansky and Fox Eye Surgery would immediately begin searching for a location in the Quad Cities area in which to open a new outpatient surgical facility.

197. Korver ENT wishes to offer outpatient ENT surgeries in a cost-effective and convenient outpatient surgery center in Orange City, Iowa.

198. Korver ENT has already constructed a building fit for an outpatient surgery center but is refraining from finishing the surgery center's construction because (and only because) of Iowa's certificate-of-need requirement.

199. Korver ENT's projected monetary cost of applying for a certificate of need would include, at least, tens of thousands of dollars for attorneys and other consulting fees, an approximately \$1,000 application fee, and any additional expenses for appeals.

200. But for Iowa's certificate-of-need scheme, Korver ENT would finish the surgery center's construction and begin offering outpatient ENT surgeries.

201. None of the physician plaintiffs has ever opposed any application for a certificate of need.

202. Defendants are responsible for administering and enforcing Iowa's certificate-of-need program.

203. Physician plaintiffs have no adequate remedy at law.

B. But for Iowa's Certificate-of-Need Scheme, Patient Plaintiffs Jensen and Driesen Could Receive Safe, Affordable Outpatient Surgeries from the Provider of Their Choice.

204. Between 2002 and 2003, when Fox Eye Surgery's proposed outpatient surgery center was operational and affiliated with St. Luke's Hospital, patient plaintiff Jensen underwent two corneal replacements in that facility.

205. In 2016, after being diagnosed with cataracts and glaucoma, Jensen underwent cataract surgery in his left eye. Dr. Birchansky performed the surgery at Mercy Medical Center.

206. Instead of interacting with familiar staff in a convenient facility, Jensen endured his surgery in a large, impersonal hospital.

207. Jensen's corneal replacements, glaucoma, and prior cataract surgery all indicate that he will need another cataract surgery in the near future.

208. Jensen wishes to receive future cataract surgeries from Dr. Birchansky in Fox Eye Surgery's outpatient surgery center. He cannot do so because Iowa's certificate-of-need requirement prevents him from seeking surgery at centers that do not have certificates of need.

209. Because of the different rates that Medicare reimburses for facility fees, there would be at least a 35% decrease in costs for doing the same surgery in an ambulatory surgery center compared to a hospital.

210. There are only two facilities where cataract surgery can be performed in the Cedar Rapids area: Mercy Medical Center or the Surgery Center of Cedar Rapids (which is in partnership with St. Luke's Hospital).

211. On information and belief, Mercy Medical Center charges \$8,372 for its facility

fee. The facility fee at St. Luke's is over \$3,500.

212. The total cost for Dr. Birchansky's cataract procedure at Fox Eye Surgery's outpatient surgery center would be \$975 for Medicare patients and \$1,950 for non-Medicare patients. Additionally, Dr. Birchansky would provide free services to indigent cataract patients from 14 Iowa counties.

213. In 2014, patient plaintiff Driesen received sinus surgery from Dr. Korver.

214. Of the cost of Driesen's surgery, the billed cost of the hospital's facility fee was over \$15,000. Korver ENT's fee was only \$2,745.

215. Driesen wishes to receive future ENT surgeries from Dr. Korver in Korver ENT's proposed outpatient surgery center. He cannot do so because Iowa's certificate-of-need requirement prevents him from seeking surgery at centers that do not have certificates of need.

216. Three of Driesen's six children have also been to Korver ENT for ENT surgeries.

217. For one of Driesen's children's surgeries, a tympanostomy tube insertion, Dr. Korver's billed fee was only \$480. The hospital facility fees for this surgery, however, range from \$3,000 to \$4,000.

218. Driesen wants his children to receive surgery at Korver ENT's proposed facility should the need arise.

219. Iowa's certificate-of-need program imposes a significant barrier to opening a new outpatient surgery center.

220. When compared with hospitals, outpatient surgery centers provide less expensive and faster care, better health outcomes, and greater patient satisfaction.

221. Defendants are responsible for administering and enforcing Iowa's certificate-of-need program and thus have caused patient plaintiffs' injuries.

222. Plaintiffs Jensen and Driesen have no adequate remedy at law.

CONSTITUTIONAL VIOLATIONS

FIRST CLAIM FOR RELIEF On Behalf of Physician Plaintiffs (Equal Protection Clause Violation)

223. Physician plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through 222 above.

224. 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.”

225. Iowa’s certificate-of-need program irrationally treats surgery facilities owned by existing medical providers differently from materially indistinguishable facilities proposed by medical entrepreneurs, and therefore violates the Constitution’s equal-protection guarantee.

226. For instance, the only difference in Plaintiff Fox Eye Surgery’s facility between now and when it was allowed to operate (from 1998 to 2003) is the identity of the facility’s licensee.

227. Indeed, a surgery center will be permitted to operate just four miles away from Plaintiff Fox Eye Surgery’s proposed Cedar Rapids facility for no other reason than that the center is owned by an existing institutional health facility.

228. If plaintiffs Dr. Birchansky and Fox Eye Surgery affiliated with an existing provider to run their current facility, as they did between 1998 and 2003 they would be allowed to operate immediately without a certificate of need.

229. If physician plaintiffs built new facilities for less than \$1.5 million, and then affiliated with a provider in the same county who already has a certificate of need, they would be permitted to operate immediately without a certificate of need.

230. If physician plaintiffs were to purchase a facility from an existing provider and continue the services offered at that facility, they would be allowed to operate without a certificate of need.

231. The only reason physician plaintiffs cannot build new facilities or reopen existing facilities without obtaining a certificate of need is because they are new market entrants, who would compete with existing businesses, and therefore do not already have a certificate of need.

232. Already existing outpatient surgery centers may construct and open an unlimited number of new facilities in the same county without obtaining certificates of need.

233. There is no rational reason to subject physician plaintiffs' proposed surgery centers to a certificate-of-need requirement when other facilities—including similarly situated hospitals and other institutions offering similar outpatient surgeries—are exempt.

234. There is no rational basis for exempting existing medical providers who spend less than \$1.5 million in capital expenditures per year to build new facilities from the state's certificate-of-need requirement that would otherwise apply to medical entrepreneurs offering new services.

235. The application of the certificate-of-need requirement to services like those proposed by physician plaintiffs does not advance any conceivable legitimate state interest.

236. The only purpose behind Iowa's certificate-of-need program is to protect established Iowa healthcare facilities from economic competition. This is not a legitimate state interest.

237. Iowa's nakedly protectionist certificate-of-need program harms consumers and deprives medical patients of their rights to choose their own qualified medical provider.

238. Physician plaintiffs have been and continue to be harmed by enforcement of

Iowa's certificate-of-need program.

**SECOND CLAIM FOR RELIEF
On Behalf of Physician Plaintiffs
(Substantive Due Process Violation)**

239. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through 238 above.

240. 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.

241. Iowa's certificate-of-need program violates the right to earn a living because it does not advance any conceivable legitimate government purpose.

242. There is no evidence that Iowa's certificate-of-need requirement advances a legitimate government interest.

243. The only purpose behind Iowa's certificate-of-need program is to protect established Iowa healthcare facilities from economic competition.

244. Economic protectionism is not a legitimate state interest under the Fourteenth Amendment.

245. Iowa's nakedly protectionist certificate-of-need program harms consumers and deprives medical patients of their rights to choose their own qualified medical provider.

246. Physician plaintiffs have been and continue to be harmed by enforcement of Iowa's certificate-of-need requirement for outpatient surgery centers.

**THIRD CLAIM FOR RELIEF
On Behalf of Physician Plaintiffs
(Privileges or Immunities Violation)**

247. Plaintiffs reallege and incorporate by reference each and every allegation set

forth in ¶¶ 1 through 246 above.

248. 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.”

249. The Privileges or Immunities Clause was intended to guarantee citizens’ right to earn a living in the occupation of their choice, free from unreasonable or unnecessary government regulation.

250. Iowa’s prohibition against opening an institutional health facility and offering surgery services 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.

251. Physician plaintiffs have been and continue to be harmed by enforcement of Iowa’s certificate-of-need program.

**FOURTH CLAIM FOR RELIEF
On Behalf of Patient Plaintiffs
(Substantive Due Process Violation)**

252. Plaintiffs reallege and incorporate by reference each and every allegation set forth in ¶¶ 1 through 251 above.

253. The Due Process Clause of the Fourteenth Amendment protects certain unenumerated fundamental rights that are deeply rooted in this Nation’s history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.

254. This Nation has long entrusted in individuals those fundamentally personal medical decisions that lie at the core of personal autonomy, self-determination, and self-

defense.

255. A right of control over one's body has deep roots in the common law and American constitutional law.

256. The right to personal autonomy includes a person's legal and uninterrupted enjoyment of his or her life, limbs, body, and health, as well as the preservation of his or her health from such practices as may prejudice or annoy it.

257. Certificate-of-need requirements like Iowa's did not exist before 1964.

258. The Due Process Clause of the Fourteenth Amendment protects a fundamental individual right to, without arbitrary or irrational restrictions, voluntarily seek approved medical treatment from a willing and licensed provider.

259. Iowa does not have a compelling government interest in denying patient plaintiffs their right to access approved medical procedures from licensed physician plaintiffs.

260. Even if the state were to have a compelling interest, the certificate-of-need program is not narrowly tailored to achieve that goal.

261. In fact, Iowa does not even have a legitimate government interest in denying patient plaintiffs their right to access routine, safe, affordable, and licensed medical procedures from physician plaintiffs.

262. The only purpose behind Iowa's certificate-of-need scheme is to protect existing medical providers from economic competition. Iowa is denying patient plaintiffs the right to receive their preferred, safe, and affordable medical care solely to ensure that patient plaintiffs' healthcare spending flows to businesses of Iowa's choice instead of to the physicians of the patients' choice.

263. Economic protectionism is not a legitimate government interest.

264. Even if Iowa has a legitimate interest in denying patients their right to access approved medical procedures from the licensed physician plaintiffs, Iowa's certificate-of-need scheme irrationally forces patient plaintiffs and other Iowans to pay more, receive lower quality care, and risk higher rates of infection by undergoing treatments at local hospitals, which are exempt from certain certificate-of-need requirements when they add new outpatient facilities.

265. Patient plaintiffs Jensen and Driesen have been and continue to be harmed by enforcement of Iowa's certificate-of-need program because it unconstitutionally inhibits their right to voluntarily seek approved medical treatment from a willing and licensed provider.

266. Therefore, Iowa's prohibition against opening an institutional health facility and offering surgery services without prior government approval, on its face and as applied, violates that right.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. For an entry of judgment declaring that Iowa's certificate-of-need requirement for outpatient surgical facilities (Iowa Code §§ 135.61 *et seq.*; Iowa Admin. Code §§ 641—202.1(135) *et seq.* and 641—203.1(135) *et seq.*) 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;
2. For an entry of judgment declaring that Iowa's certificate-of-need requirement for outpatient surgery facilities 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;
3. For an entry of judgment declaring that Iowa's certificate-of-need requirement 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;

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

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

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

Dated this 1st day of September, 2017.

Respectfully submitted,

/s/ Joshua A. House

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of September, 2017, a true and correct copy of the foregoing Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief was filed with the Clerk of the Court and served on the following counsel of record using the CM/ECF system:

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