

MINUTES
STATE HEALTH FACILITIES COUNCIL
Tuesday, November 7, 2017
Room 310 W
Ola Babcock Miller Building
1112 East Grand Avenue
Des Moines, Iowa

9:00 AM Roll Call

MEMBERS PRESENT: H.W. Miller, M.D., Chairperson; Roberta Chambers; Brenda Perrin; Connie Schmett; and Roger Thomas

STAFF PRESENT: Becky Swift and Heather Adams, Counsel for the State

I. PROJECT RE-HEARING

1. Fox Eye Surgery Center, Cedar Rapids, Linn County: Establish an ambulatory surgery center
\$88,220

Staff Report by Becky Swift. The applicant was represented by Dr. Lee Birchansky and Michael Dodd, Fox Eye Surgery Center; Doug Wells and Tim Messenger, Wells + Associates Architecture; and Doug Fulton, Brick Gentry Law. The applicant made a presentation and answered questions posed by the Council.

Affected party in support of the application was John Vander Zee, M.D.

Affected parties in opposition included Doug Gross, Brown Winick Law representing St. Luke's and Surgery Center Cedar Rapids; Scott Kallemeyn, Surgery Center Cedar Rapids; Mike Broshar, Invision Architecture/St. Luke's; Ed McIntosh, Dorsey and Whitney, representing Mercy Medical Center; Molly Newhouse, Mercy Medical Center; Nathan Van Gendersen, Mercy Medical Center. Affected parties in opposition made a presentation and answered questions posed by the Council. A motion by Chambers, seconded by Schmett to enter exhibits presented by the opposition in support of oral testimony into the record carried unanimously by voice vote.

A motion by Schmett, seconded by Chambers, to enter additional exhibits presented by the opposition in support of oral testimony into the record carried unanimously by voice vote.

The applicant, represented by Doug Fulton, Brick Gentry; Doug Wells, Well + Associates Architecture and Dr. Lee Birchansky and Michael Dodd, Fox Eye Surgery Center, provided rebuttal and closing remarks. A motion by Schmett, seconded by Perrin, to enter exhibits presented by the applicant in support of oral testimony into the record carried unanimously by voice vote.

A motion by Thomas, seconded by Miller, to Grant a Certificate of Need carried 3-2. Perrin and Schmett voted no.

Chairperson Miller reminded the Council that the next face-to-face meeting would be held on February 21 and 22, 2018, at the Lab Facility on the DMACC Campus in Ankeny. He also noted that an electronic meeting would need to be held in December 2017.

A motion by Schmett seconded by Thomas, to adjourn carried unanimously by voice vote.

The meeting adjourned at 1:20 p.m.

FINDINGS OF FACT

1. Fox Eye Surgery is owned by Dr. Lee Birchansky, its medical director.
2. Fox Eye Surgery is proposing re-opening an abandoned ambulatory surgery center ("ASC"), which is adjacent to and within the same building as the applicant's ophthalmological practice, Fox Eye Laser and Cosmetic Institute (FELCI). The applicant states that the dormant ASC is fully equipped and ready to perform laser cataract surgery. The proposal calls for one operating room.
3. The proposed facility fee is \$1,950, which, according to the applicant, is a much lower charge that will open access to many patients who have been postponing cataract surgery due to costs.
4. The proposed facility will help provide additional access to those uninsured and indigent Iowans who can't afford the charges of alternate facilities. Financially struggling persons and persons without medical insurance will receive care at a reduced charge or free.
5. The applicant states that most cataract patients are elderly and many are disabled and that the facility is unique as it is the only single story, ADA compliant facility that was specifically designed to cater to elderly cataract patients many of whom are handicapped, ambulate with difficulty and have poor hearing and eyesight.
6. Fox Eye Surgery will accept patients of all ages, economic status, race, creed, color and national origins.
7. The breakdown of patient pay by source will be 6.8% private pay, 69.8% Medicare, 4.7% Medicaid, 13.9% Wellmark, and 4.8% other private insurance.
8. Fox Eye Surgery's uninsured and indigent cataract patients reside in 14 counties and Dr. Birchansky has clinics in three rural towns and provides surgery in the rural towns of Manchester, DeWitt, Anamosa, Maquoketa and Marengo. Dr. Birchansky will continue to regularly see patients and perform surgeries at these rural hospitals helping those patients who live in or nearby these rural communities.
9. Fox Eye was denied a CON in May 1996 to construct an ASC at a cost of \$1,173,000. Dr. Birchansky, through his limited liability company, Birchansky Real Estate LLC., constructed the surgery center in 1998 and leased it to St. Luke's Hospital. From 1998 until December 7, 2004, there were two operating suites in use at the proposed location. Fox Eye Laser & Cosmetic Institute, P.C. (FELCI) accounted for approximately 10,000 of the surgeries at this site over that time period.
10. FELCI is an ophthalmology group which employs Dr. Birchansky and Dr. Richard Stangler, two Cedar Rapids ophthalmologists whose medical office building is adjacent to the surgical

suites previously leased by the hospital. In addition, FELCI employs optometrist Dr. Brandon Stalzer.

11. The applicant applied for a CON three additional times. These applications were denied at meetings held in January 2005, January 2008 and October 2008. In August 2007, the Iowa Supreme Court issued a decision affirming the denial of the second application. In the fall of 2008, Dr. Birchansky filed an appeal of the Council's decision to deny the fourth application. The Council's denial was upheld by the Iowa Court of Appeals in August of 2010.
12. Fox Eye Surgery applied for a CON for a fifth time in May of 2017. On July 19, 2017, Fox Eye received a Certificate of Need for a freestanding outpatient surgical facility.
13. On September 18, 2017, a re-hearing request was filed by affected parties in opposition. The re-hearing request was granted at a hearing held on October 6, 2017.
14. This is the applicant's sixth attempt to attempt to receive a certificate of need for a freestanding outpatient surgical facility.
15. Fox Eye Surgery will offer safe, convenient, comfortable, non-intimidating, less costly and more efficient eye surgery in the most appropriate environment for its patients. The proposed facility will offer patients the most desirable and flexible daily scheduling times including Saturday mornings. The applicant notes that Dr. Birchansky can use his own equipment, own staff and will be in his own environment at Fox Eye, which makes him proficient at what he does.
16. Fox Eye noted in testimony provided at the hearing that 90% of cataract surgeries performed today are being done at office-based ASC's, which have a lower rate of infections and complications.
17. Fox Eye Surgery considers the service area to be Cedar Rapids, Iowa. Many of FELCI's cataract patients live in Cedar Rapids, Linn County. The applicant notes that other cataract patients come from Benton, Blackhawk, Bremer, Buchanan, Cedar, Clayton, Clinton, Delaware, Dubuque, Iowa, Jackson, Jones, and Muscatine Counties.
18. Affected parties in opposition to the proposal state that the operating room capacity at the two hospitals along with the seven operating rooms at the Surgery Center Cedar Rapids (SCCR), an ambulatory surgery center, can accommodate the procedures that are proposed to be performed at the Fox Eye location.
19. Fox Eye Surgery notes that the surgery times (mornings and Saturdays) which are most beneficial to its patients are not available at the hospitals or the SCCR.
20. Fox Eye Surgery engaged an architect and engineer who provided a cost breakdown and who reached out to the Department of Inspections and Appeals and the State Fire Marshal's office to discuss compliance with current life safety codes and the costs associated with retrofitting the current space to meet these codes. Fox Eye Surgery noted that upon CON approval, it

will have the life and safety inspection performed by an accreditation agency with Medicare deemed status. If additional modifications are indicated then the surgery center will be brought into compliance and compliance will be verified before opening to the public.

21. Included in Fox Eye's supplemental submission of November 1, 2017, was correspondence with both the Fire Marshal's Office and the Department of Inspections and Appeals.
22. The Fire Marshal's office is considering Fox Eye a new ambulatory surgery center as it was never licensed by the DIA nor inspected by the Fire Marshal's Office.
23. The correspondence with the Fire Marshal's office indicates that Fox Eye must either submit "as built" construction plans and documents or a report from an architect or engineer, licensed in the state of Iowa, which verifies the facility meets codes and standards that pertain to ambulatory care occupancies.
24. According to the architect retained by Fox Eye after the original hearing in July, Wells + Associates PC, the facility would need some construction updates (\$9,900), and modifications of the HVAC (\$33,220), plumbing and electrical systems (\$9,300) to bring it up to current code. Additionally, there would be architecture and engineering fees as well as construction management and commissioning fees (\$4,160), and a project contingency of \$20,000, for a total projected cost of \$ 88,220.
25. The applicant provided a pro forma which indicates the proposal to be financially feasible. The pro forma assumes 645 surgeries the first year of operation growing to 711 by year three. Net profit before taxes the first year is \$131,228 growing to \$161,239 by year three. Also included in the pro forma is the Fox Eye rent payment of \$36,000 per year.
26. Projected data includes the assumption that utilization will grow by 5 percent yearly as baby boomers turn 65 and older. Fox Eye Surgery expects that one third of its patients will choose to have their surgeries at SCCR and that two-thirds will choose to have their surgeries at the Fox Eye Surgery facility.

Projected Surgical Utilization

<u>Year</u>	<u>Utilization</u>
1	645
2	677
3	711

27. There are two hospitals, Mercy Medical Center and St. Luke's in Cedar Rapids, and there are three ophthalmology groups in Cedar Rapids, FELCI, Wolfe Eye Clinic and Iowa Eye Center. Cataract surgeries are currently performed at the Surgery Center of Cedar Rapids (SCCR). Mercy Medical Center previously performed cataract surgery onsite.

28. Beginning June 2017, Mercy Medical Center moved its cataract surgery services to a new medical park in Hiawatha, Iowa, which is roughly two miles from the Fox Eye Surgery location. Wolfe Eye Clinic, a competitor of Fox Eye Surgery, is a partner with Mercy in the new medical park, which, according to Fox Eye Surgery, makes it more difficult for Dr. Birchansky to obtain the surgical times he desires. Additionally, while Mercy indicates that independent providers like Dr. Birchansky may use the new outpatient surgery site, the signage at the new location and the set-up of the facility will make it appear to patients as if they are being treated at a Wolfe Eye Clinic facility.
29. The SCCR is owned by Iowa Eye Center, St. Luke's Hospital, and other partners. The SCCR has undergone significant expansion within the past four years.
30. Significant changes in the existing health care system, and specifically in the outpatient surgery health care market, have occurred in Cedar Rapids in the decade since the Council denied Dr. Birchansky's former applications. At the time of the prior denials, the facilities which provided outpatient surgery offered independent providers like Dr. Birchansky the opportunity to perform cataract surgeries at their locations on equal footing with physicians aligned with ophthalmology groups in Cedar Rapids. Currently, the existing facilities offering outpatient cataract surgery have more closely aligned with competitors to Dr. Birchansky. Specifically, Mercy has partnered with the Wolfe Eye Clinic in the development of the Hiawatha ASC and patients receiving cataract surgery at that location could clearly infer that they are being treated by Wolfe Eye-affiliated physicians. Additionally, both existing outpatient cataract surgery providers have made substantial investments in and undertaken expansions of their outpatient surgical facilities since the dates of the prior denials of Dr. Birchansky's applications.
31. Fox Eye Surgery provided one letter of support from 2016, and nine letters of support from 2007 in the application. These letters are from patients who expressed satisfaction with Dr. Birchansky, the desire to have their surgery at the same location as FELCI, and less wait time as reasons for their support.
32. Noted by an affected party who testified in support of the project was that block scheduling at current facilities causes operating rooms to be unavailable to other surgeons, such as Dr. Birchansky, until 24 hours in advance, and that the premier morning times are also not available.
33. Six letters of opposition were received for the July meeting from hospitals and providers in the area and six affected parties appeared at the hearings in opposition to the proposal. Cited as reasons for opposition were excess surgical capacity at existing facilities, no delays in scheduling ophthalmologic surgeries or other outpatient surgeries, the distance of the drive to Cedar Rapids for surgery, no cost savings to patients, outdated equipment at Fox Eye Surgery, and the ability of Fox Eye Surgery to expand to include additional operating rooms or provide an unlimited range of services without further CON review.
34. Additional letters of opposition were submitted on October 24 and November 2 in response to the re-hearing. These letters cite similar issues as the letters submitted for the July 19

hearing. The affected parties further raised questions about the costs cited by the applicant and indicated their belief that the costs for the project will be substantially higher than those estimated by Fox Eye Surgery.

35. Fox Eye Surgery, in a letter submitted November 3, responded to a letter dated November 2 from Brown Winick writing on behalf of St. Luke's and SCCR by noting, that in his opinion, there were many inaccuracies in the information provided.
36. Fox Eye Surgery, in a letter dated November 2, provided information from the VP and General Manager of Bausch and Lomb that the equipment he uses is still in use today by ophthalmic surgeons here in the US and around the world. Bausch and Lomb indicates that the equipment used by Dr. Birchansky when maintained properly "can provide very safe and effective service" and has proven to "be a very reliable system throughout the years and has been used confidently and safely in millions of procedures globally."
37. Fox Eye Surgery anticipates minimal service volume impact to SCCR assuming that roughly one third of FELCI's patients will continue to choose SCCR for their cataract surgery. The applicant notes that Mercy and SCCR are being used in an appropriate, efficient, and profitable manner providing over 47,500 surgeries per year.
38. The applicant specifies 5.0 FTEs, including one nurse manager, 1.5 RN's, one certified scrub tech and one secretary/medical billing clerk will be needed to staff the ASC. Dr. Birchansky will serve at the 0.5 FTE medical director for the ASC.
39. Costs for the project are anticipated to be \$66,220, with a contingency of \$20,000 for a total cost of \$88,220. These costs, unlike those offered by the applicant at the July hearing, are based upon input from an experienced and registered architect and actual bids for the various component costs. The project will be paid with savings from Birchansky Real Estate LLC.
40. If the costs increase by 15%, the applicant will need to come back before the Council to request a cost overrun, and Council approval would be required prior to proceeding with an increase in the cost of the project.

CONCLUSIONS OF LAW

In determining whether to issue a certificate of need, the Council considers the eighteen criteria listed in Iowa Code § 135.64(1)(a)-(r). In addition, the legislature has provided that the Council may grant a certificate of need only if it finds the following four factors exist:

- a. Less costly, more efficient or more appropriate alternatives to the proposed institutional health service are not available and the development of such alternatives is not practicable;
- b. Any existing facilities providing institutional health services similar to those proposed are being used in an appropriate and efficient manner;

- c. In the case of new construction, alternatives including but not limited to modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable;
- d. Patients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service or changed institutional health service, in the absence of that proposed new service.

1. The Council concludes that less costly, more efficient or more appropriate alternatives to the proposed health service are not available and the development of such alternatives is not practicable. Dr. Birchansky has experienced difficulties in scheduling his patients for cataract surgeries at the alternative facilities in the service area, and those difficulties will be exacerbated with the opening of Mercy Medical Center's new outpatient surgical facility. Additionally, to require that Dr. Birchansky continue to perform surgeries at a facility which is so publicly affiliated with another ophthalmology group is not an appropriate alternative, especially in light of his existing, but currently dormant, ASC. Iowa Code Sections 135.64(1) and 135.64(2)a.

2. The Council concludes that existing facilities providing health services similar to those proposed are and will continue to be used in an appropriate and efficient manner and will not be impacted by this project. The Council takes note that collectively Mercy and SCCR perform 47,500 surgeries per year; the small percentage of these surgeries which originate from Fox Eye will have minimal impact on these facilities. Additionally, the Council notes that a portion of Fox Eye Surgery patients will continue to choose SCCR for their cataract surgery which will further minimize the impact on that facility. The Council further finds that both Mercy and SCCR have undergone significant expansions within the past several years which indicate their facilities are being utilized at an efficient level, and their continued investment in and expansion of outpatient surgery rooms indicates past and expected future rates of high utilization. Finally, Dr. Birchansky will continue to see patients and perform surgeries in the rural locations he currently services, further minimizing the impact on those facilities. Iowa Code Sections 135.64(1) and 135.64(2)b.

3. The Council concludes that the proposed project does not involve new construction. Iowa Code Sections 135.64(1) and 135.4(2)c.

4. The Council concludes that patients will experience serious problems in obtaining care of the type which will be furnished by the proposed new institutional health service, in the absence of that proposed service. The Council finds that the applicant has had difficulties in scheduling times for surgeries for his patients at existing facilities and that those difficulties will increase given the ownership structure of existing facilities. The Council concludes that cataract surgery patients are primarily the elderly -- many of whom are handicapped, ambulate with difficulty and have poor hearing and eyesight. The Council concludes that these patients would benefit from having surgery done in a single story facility in the same location as FELCI and that they would also benefit from having the option of morning and Saturday surgery times, which may not be available at other locations. Iowa Code Sections 135.64(1) and 135.64(2)d.

The facts, considered in light of the criteria contained in Iowa Code Section 135.64 (1 and 2) (2017), led the Council to find that a Certificate of Need should be awarded.

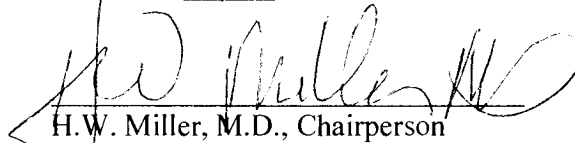
The decision of the Council may be appealed pursuant to Iowa Code Section 135.70 (2017).

It is required in accordance with 641 Iowa Administrative Code 202.12 that a progress report shall be submitted to the Iowa Department of Public Health six (6) months after approval. This report shall fully identify the project in descriptive terms. The report shall also reflect an amended project schedule if necessary.

The Certificate of Need is valid for a twelve (12) month period from the date of these findings. This is subject to the meeting of all requirements of the Iowa Department of Public Health. Requests for extension of a Certificate of Need must be filed in writing to the Iowa Department of Public Health from the applicant no later than forty-five (45) days prior to the expiration of the Certificate. These requests shall fully identify the project and indicate the current status of the project in descriptive terms.

No changes that vary from or alter the terms of the approved application including a change in the approved dollar cost shall be made unless requested in writing to the department and approved. Failure to notify and receive permission of the department to change the project as originally approved may result in the imposition of sanctions provided in Iowa Code section 135.73 (641 Iowa Administrative Code 202.14).

Dated this 19 day of December 2017



H.W. Miller, M.D., Chairperson
State Health Facilities Council
Iowa Department of Public Health

cc: State Health Facilities Council
Iowa Department of Inspections and Appeals:
Health Facilities Division