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April 21, 2019

Via E-Mail
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Mr. Richard H. Sewell
Interim Chair
Illinois Health Facilities and Services Review
Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

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APR 19 2019

HEALTH FACILITIES &
SERVICES REVIEW BOARD

**Re: River North Center for Reproductive Health (Proj. No. 19-003)
Response to Board Report**

Dear Mr. Sewell:

Polsinelli PC represents the applicants in the River North Center for Reproductive Health application for permit to establish a reproductive health care ("family building") ambulatory surgical treatment center in Chicago (the "IVF Center"). In this capacity, we are writing in response to the Illinois Health Facilities and Services Review Board's ("Board") findings pursuant to Section 6(c-5) of the Illinois Health Facilities Planning Act (the "Planning Act").

This planned IVF Center is associated with the long-established Fertility Centers of Illinois ("FCI") family building clinic with a sole focus of helping people become parents when infertility has blocked their path. FCI must aggregate the surgical operations of its two IVF clinics within an Illinois Department of Public Health ("IDPH") licensed surgery center due to:

- (1) multiple physical plant constraints at its two primary locations and
- (2) an inability to provide urological surgery, which is also an essential fertility service, for males with reproductive challenges,

As the Board knows, a CON permit is a prerequisite to IDPH licensure. This is the basis for the pending CON request for the IVF Center.

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1. Board Findings

As previously submitted, the IVF Center will create a seamless care system to surgically treat the full spectrum of female and male infertility problems with Assisted Reproductive Technology ("ART"). In addition to limitations at its current locations based on IDPH rules and space constraints, existing surgical providers are not options because a human embryology and andrology laboratory must be located in a low traffic area and physically isolated from other laboratory activities and proximately located to the patient treatment room to allow for direct communication between the physician performing the procedure and the lab technicians and specialized transportation of human genetic material (oocytes and embryos). The lab personnel required for this service are highly specialized in micromanipulation, egg retrieval, intracytoplasmic sperm injection (ICSI), embryo biopsy, and embryo vitrification (freezing). They are dedicated to this subspecialty and cannot be replaced by other lab technicians.

Also, FCI is a large infertility treatment group and there are many physicians who will utilize the IVF Center so volumes are very high with a specialized cyclical treatment protocol (based on ovulation cycles) and they need a dedicated center. There is no other alternative among the existing surgical facilities.

a. Project Utilization/Service Demand

FCI currently performs ART procedures, including IVF, at its River North and Highland Park medical offices which collectively have three procedure rooms. IVF is a complex series of procedures used to treat fertility or genetic problems to assist with the conception of a child. The various phases must be precisely timed to increase the chance of pregnancy. FCI has outgrown its current locations, and scheduling is problematic at its medical offices as FCI physicians cannot schedule adequate procedure time for their patients. FCI analyzed other nearby surgical providers, but none can manage FCI's IVF volume or meet the lab requirements for the IVF Clinic. As discussed in greater detail below, in order to ensure high pregnancy success rates and patient care, these procedures can only be performed in the planned IVF Clinic which will have the state-of-the-art requirements for IVF services including proper air handling and a dedicated embryology/andrology laboratory.

Further, due to IDPH restrictions, FCI cannot provide the full spectrum of surgical fertility services at its medical offices. As noted in the application for permit, FCI is the primary intake point for couples struggling with infertility. As standard procedure, both females and males undergo extensive infertility screening. Currently, FCI refers males with potential fertility issues to urologists outside of the practice for follow up. In order to have better continuity of

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care, these urological procedures should be performed adjacent to the andrology lab; however, the urologists are not employed by FCI and therefore cannot do surgical procedures at the FCI medical offices. The planned IVF Center's receipt of a license is necessary to comply with the requirements of the Ambulatory Surgical Treatment Act, which dictate that a medical practice is only exempt from the requirement to obtain a license if the use of its surgical suites is restricted to physicians who are legally affiliated with the medical practice as owners or employees and less than 50% of the activities conducted in its office are surgical in nature.¹ Without the license, IVF services cannot be transferred from the doctors' offices and the urologists cannot provide services there.

b. Geographic Service Area

FCI is the third largest fertility center in the country and achieved its reputation and size due to its high success rates and ability to treat the most complex infertility cases. FCI's singleton pregnancy rates driven by its careful adherence to e-SET transfer practices² and pregnancy outcomes are the best in the Midwest given the volume of patients FCI sees every year.³ As noted throughout the application for permit, the IVF Center will not only serve patients in Chicago, but patients throughout Illinois, the Midwest, the United States, and in some cases throughout the world. Due to its high pregnancy success rate and reputation as a leader in the field of reproductive endocrinology and infertility, patients come from throughout the United States for infertility treatment to receive the specialized care FCI provides. Illinois has been a leader in ART due to the legislature's mandate to cover ART as an insurance benefit for families who are otherwise unable to have children. While FCI's large service area was cited as a negative in the Board Staff report, its excellent reputation has broadened its service area, and we do not believe this should "count against it" in any way. People are willing to travel to get the services they require to get pregnant and have children.

c. Treatment Room Need

As noted above, FCI has outgrown its current location. Due to the specialized care and to provide the full spectrum of reproductive health services, which cannot be in FCI's medical offices, an ASTC license is necessary. Based upon the number of referrals projected in the physician referral letters, there is sufficient need to justify the proposed number of procedure

¹ 77 Ill. Admin. Code § 205.110.

² Single embryo transfers are preferred for purposes of reducing high cost pregnancies and neonatal care.

³ This is based on publicly available Society for Assisted Reproductive Technology.



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rooms. As we have noted previously, these services are only reimbursed under private insurance policies not government benefit programs and the applicants have no reasonable expectation that the reimbursement rates will change for the new site given the high level of sophistication of the primary insurers in Illinois. The caseload volume is certainly high enough to justify the number of rooms needed. The applicants have no incentive to over build.

d. Service Accessibility/Unnecessary Duplication of Services/
Maldistribution

Board staff notes the proposed procedures can be performed at existing facilities within the geographic service area with excess capacity. The area surgery centers approved to perform gynecological surgical procedures are not appropriate for this service. This care setting cannot be reproduced a multi-specialty surgery center due to the laboratory and lab staffing requirements, air handling requirements, and the specialized care provided.

Quality of air in the clinical embryology laboratory is considered critical for high IVF success rates, as the conditions must mimic those inside the uterus. The air filters, which must be located in the procedure rooms and embryology/andrology laboratory, need to filter a higher concentration of particles than required for a standard operating room. The embryology laboratory is the starting point of the design of any IVF clinic. Retrofitting an existing surgery center is costly and impractical. It would involve breaking into the ceiling to install new air filters and adding a specialized air handler, which would occupy an entire room. Further, the embryology laboratory needs to be adjacent to the procedure rooms. Carrying embryos even down the hall to the embryology laboratory could compromise pregnancy success and patient care.

e. Availability of Funds

The pro forma financial statements submitted with the application for permit were prepared by an independent certified public accountant based upon projected case volume and assumptions provided by management for the first two years of operation. As these financial statements project future performance, there are no accounts that can be audited to confirm the accuracy of the projections. However, management used good faith and best efforts to provide valid assumption data consistent with the project costs and the applicant believes that the pro forma financial statement is a valid prediction of future financial performance of the planned IVF Center.



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Thank you for your consideration of the Applicants' response to the Board's findings for the River North Center for Reproductive Health application for permit.

Sincerely,

A handwritten signature in blue ink that reads "Anne M. Cooper".

Anne M. Cooper

cc: Marcus Williamson