



STATE OF ILLINOIS  
 HEALTH FACILITIES AND SERVICES REVIEW BOARD

525 WEST JEFFERSON ST. • SPRINGFIELD, ILLINOIS 62761 • (217) 782-3516 FAX: (217) 785-4111

<b>DOCKET ITEM NUMBER:</b> E-01	<b>BOARD MEETING:</b> October 25, 2016	<b>PROJECT NUMBER:</b> #04-027
<b>BUSINESS ITEM:</b> Declaratory Ruling Request		
<b>REQUESTING ENTITY(IES):</b> Chicago Prostate Surgery Center, Chicago		

**STATE BOARD STAFF REPORT**  
**DECLARATORY RULING REQUEST**

**I. Request for Declaratory Ruling**

On August 30, 2016, Chicago Prostate Cancer Surgery Center (“permit holder”) submitted a request for a declaratory ruling to the State Board.

**II. Background**

On February 3, 2005, the State Board approved the Chicago Prostate Surgery Center located at 815 Pasquinelli Drive, Westmont, Illinois to establish a limited specialty ASTC with two (2) operating rooms and eight (8) recovery stations that was “*limited to urological procedures dealing specifically with prostate cancer.*” [See Permit Letter at the end of this report]

At the February 2005 State Board Meeting, the permit holder discussed two (2) procedures brachytherapy a treatment for prostate cancer by the insertion of radioactive implants directly into the tissue and cryosurgical ablation which involves inserting cryoprobes [i.e. needle puncture to the skin] into the prostate gland to rapidly freeze and thaw tissue causing necrosis [i.e. the death of cells]. The cold is usually produced by use of liquid nitrogen. [<https://www.cancer.gov/>]

Prior to the February 2005 approval, the permit holder had submitted an application for permit **Project #97-031**. This application was withdrawn based upon the determination by the Department of Public Health that the services provided by Chicago Prostate Center were not considered surgery, and the facility is therefore not eligible for an ambulatory surgical treatment center license. Consequently, a certificate of need was not required and the application **#97-031** was void.

In 1999 the Department of Public Health determined the procedure (brachytherapy) performed by the permit holder does meet the definition of a surgical procedure. The Department determined that the procedure is an invasive procedure done by urological surgeons, and cystoscopy is an essential part of that procedure. Once that determination was made the permit holder could apply for a permit and if approved by the State Board would be licensed as an ambulatory surgical treatment center.

The permit holder filed an application for permit to establish a limited specialty ASTC as **Project #01-015**. At the August 2001 State Board Meeting the permit holder stated that it was important for IDPH to determine that the procedure was a surgical procedure because that would allow reimbursement by insurance providers. The project was approved with twelve (12) affirmative votes and one (1) dissenting vote. The dissenting Board member expressed concern with the inefficiency of one (1) and two (2) room surgical facilities. However, project #01-015 was never licensed due to problems retrofitting an existing building to meet all applicable licensure standards.

Subsequently, the permit holder submitted a third application for permit, **Project #04-027**. This project was submitted to the State Board for approval at the December 15, 2004 State Board Meeting. At that meeting, the permit holder requested a deferral to address concerns of the Board Members. The Board Members questioned the excess surgical capacity in the proposed GSA, no empirical evidence provided on the quality outcomes of the procedure, no cost benefit analysis provided with the application for permit, and concerns with the financial ratios presented by the permit holder. The applicants submitted the requested information and **Project #04-027** was approved at the February 2005 State Board Meeting by a vote of 3-0.

Over the past five (5) years the permit holder has averaged eight hundred thirty six (836) cases and hours per year [one (1) hour per case]. The permit holder has seen a drop in the number of surgical cases of eight percent (8%) compounded annually over the past five (5) years. Over this same five (5) year period the permit holder payor mix has averaged approximately 33% Medicaid, 63% Private Insurance and approximately 4% Private Pay. The permit holder explained the decline is primarily the result of a shift in referral patterns from one of CPCSC's historical referral sources

<b>TABLE ONE</b>							
<b>Chicago Prostate Surgery Center, Chicago</b>							
	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>Ave</b>	<b>Payor Source %</b>
Cases	1,048	942	848	713	629	836	
Hours	1,048	942	848	713	629	836	
Medicare	\$538,352	\$1,357,138	\$1,007,532	\$1,014,911	\$657,136	\$915,014	32.67%
Medicaid	\$0	\$0	\$0	\$0	\$0	\$0	0.00%
Other Public	\$0	\$1,529	\$16,978	\$29,205	\$4,724	\$10,487	0.37%
Private Insurance	\$3,229,640	\$1,254,849	\$1,121,204	\$1,692,671	\$1,507,464	\$1,761,166	62.88%
Private Pay	\$98,913	\$119,728	\$131,051	\$98,847	\$122,738	\$114,255	4.08%
Total Revenue	\$3,866,905	\$2,733,244	\$2,276,765	\$2,835,634	\$2,292,062	\$2,800,922	100.00%

In additional information provided by the permit holder, the permit holder expects to perform the following urological surgical procedures at the Center should the State Board approve the permit holder's request. Board Staff considers these procedures urological procedures.

- Cystoscopy with irrigation
- TUIP (Transurethral incision of the prostate)
- TURBT (Transurethral resection of bladder tumor)
- Bladder sling
- Bladder incision
- Circumcision
- Biopsy of testes
- Biopsy of penis
- Biopsy of bladder
- Orchiectomy
- Stent placement
- Urethroscopy (x-ray imaging or C-arm)

Additionally the applicants stated *“the facility has continued to improve its technique over the years which has, in turn, reduced the average procedure time. Additionally, the increased use of stranded seed products has reduced the need for cystoscopy after the implant. While there are some urologists that still perform a cystoscopy after the implant, most do not. Cases that do require the performance of a cystoscopy after an implant require much less time to complete. Accordingly, as compared to over a decade ago when this project was approved, there is no longer a need to account for long cystoscopy times. Finally, the facility does not use fluoroscopy anymore, which shaves even more time off of the procedure.”*

### **III. Applicable Statute and Rules**

The following sections of the Illinois Health Facilities Planning Act Administrative Rules are applicable to this declaratory ruling request.

#### **Section 1130.810 - Declaratory Rulings**

HFSRB shall render determinations on various matters relating to permits and the applicability of the statute and regulations. Requests for determination shall be made in writing. Pursuant to Section 5-150 of the Illinois Administrative Procedure Act, these determinations are declaratory rulings and are not subject to appeal. The following matters shall be subject to declaratory rulings by HFSRB, including, but are not limited to:

- a) whether a proposed project requires a permit or exemption;
- b) corrections to the facility inventories utilized by HFSRB;
- c) recognition that a particular service was in existence prior to permit requirements;
- d) amount of fees required;
- e) project classification as substantive or non-substantive; and
- f) applicability of rules.

## **Section 1130.660 - Approval of an Application**

- a) The number of affirmative votes required for approval of an application and issuance of a permit by HFSRB is specified in the Act. HFSRB shall consider the application and any additional information or modification submitted by the applicant, HFSRB staff reports, the public hearing testimony and written comments, if any, and other information coming before it in making its determination whether to approve the project. Applications are reviewed to determine compliance with review criteria contained in 77 Ill. Adm. Code 1110 and 1120. The failure of a project to meet one or more of the applicable review criteria shall not prohibit the issuance of a permit. A permit is effective on the date of HFSRB authorization.
- b) HFSRB may propose conditions to be placed upon any application for permit. Projects that are approved with conditions or stipulations shall contain the following:
  - 1) Specified conditions that are expressly agreed to by the applicant;
  - 2) Establishment of time frames for compliance with conditions;
  - 3) Establishment of reporting requirements; and
  - 4) Assurance that any change to the application for permit does not constitute a Type A modification as delineated in Section 1130.650(a) that would require a public hearing.
- c) Following issuance of a permit, HFSRB shall send a permit acceptance agreement to the permit holder, specifying and consolidating all post-permit requirements necessary to maintain compliance with the permit.
- d) Failure to comply with any conditions within the prescribed time frames shall provide a basis to invalidate the permit, or issue conditions, fines or other penalties or sanctions mandated in the Act and Section 1130.790.

### **IV. State Board Staff Comments:**

1. At the time of the approval of Permit #04-027 the State Board did not have rules in place regarding conditions or stipulations placed on permits. Those rules [77 IAC 1130-660] were not effective until June 1, 2013. Therefore none of the assurances referenced in 77 IAC 1130-660 above were not in place when the permit holder's project was approved.
2. The State Board's Surgical Categories are currently listed at Part 1110 Appendix A and include the following categories:

Cardiovascular	Oral/Maxillofacial Surgery
Colon and Rectal Surgery	Orthopaedic Surgery
Dermatology	Otolaryngology
General Dentistry	Pain Management

General Surgery	Physical Medicine & Rehab.
Gastroenterology	Plastic Surgery
Neurological Surgery	Podiatric Surgery
Nuclear Medicine	Radiology
Obstetrics/Gynecology	Thoracic Surgery
Ophthalmology	Urology

3. The State Board Staff's review of the transcripts of the August 2001, December 2014, and February 2005, State Board Meetings did not find any evidence that the intent of the State Board was to limit the permit holder to performing prostate brachytherapy and cryosurgical ablation. While these procedures were the only two (2) procedures discussed; these procedures fall under the urology surgical category. It is the opinion of the State Board Staff that the permit holder should be allowed to perform other procedures that fall under the urology surgical category. If other surgical categories are to be added the permit holder would need a permit to do so.

**V. Other Information**

Appended to this report are the following:

1. Request for Declaratory Ruling
2. Permit #04-027 Letter
3. August 2001 State Board Transcripts
4. December 2004 State Board Transcripts
5. February 2005 State Board Transcripts



STATE OF ILLINOIS

**HEALTH FACILITIES PLANNING BOARD**

525 WEST JEFFERSON STREET • SPRINGFIELD, ILLINOIS 62761 • (217)782-3516

February 17, 2005

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Brian J. Moran, M.D., Manager  
Chicago Prostate Cancer Center  
One Oak Hill Center, Suite 100  
Westmont, IL 60559

RE: **PERMIT:** Illinois Health Facilities Planning Act 20 ILCS 3960  
**PROJECT:** #04-027, Chicago Prostate Cancer Surgery Center; Westmont (HSA VII)  
**PERMIT HOLDER(S):** Chicago Prostate Cancer Surgery Center, LLC and  
Moran and Associate, LLC **PERMIT AMOUNT:** \$2,081,169

Dear Dr. Moran:

On February 3, 2005, the Illinois Health Facilities Planning Board approved the application for permit for the referenced project based upon the project's substantial conformance with the applicable standards and criteria of Part 1110 and 1120. In arriving at a decision, the State Board considered the findings contained in the State Agency Report, the application material, and any testimony made before the State Board.

The permit is issued to Moran and Associate, LLC and Chicago Prostate Cancer Surgery Center, LLC, One Oak Hill Center, Suite 100, Westmont, IL 60559.

The project is to establish a limited-specialty ambulatory surgical treatment center with two operating rooms and eight recovery stations limited to urological procedures dealing specifically with prostate cancer to be known as Chicago Prostate Cancer Surgery Center located at 815 Pasquinelli Drive, Westmont, IL 60559.

This permit is valid only for the defined construction or modification, site, amount and the named permit holder and is not transferable or assignable.

In accordance with the Planning Act, the permit is valid until such time as the project has been completed, provided that (1) obligation of the project occurs prior to August 3, 2006 or before the project completion date, whichever comes first; and (2) the project commences and proceeds to completion with due diligence.

Pursuant to the requirements of 77 Ill. Adm. Code 1130, the permit holder is responsible for complying with the following requirements in order to maintain a

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OFFICE OF THE EXECUTIVE SECRETARY

**PERMIT LETTER**

Brian J. Moran – Project #04-027

February 17, 2005

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**valid permit. Failure to comply with the requirements may result in expiration of the permit or in State Board action to revoke the permit.**

1. OBLIGATION-PART 1130.720

The project must be obligated **prior to August 3, 2006, or before the project completion date, whichever comes first**, unless the permit holder obtains an "Extension of the Obligation Period" as provided in 77 Ill. Adm. Code 1130.730. Obligation means **receipt** by the Executive Secretary of a **notarized certification by two authorized representatives** (in the case of a corporation, one must be a member of the permit holder's board of directors) of the permit holder that attests that the project has been initiated on a given date and that the financial resources to fund the project are available or committed and that the project's cost, scope, design, square footage, number of beds or stations (as applicable) are in accord with what the State Board approved.

2. ALTERATION OF A PROJECT-PART 1130.750

**Any change** to a project subsequent to permit issuance constitutes an alteration to the project. **All alterations are to be reported** to the State Board prior to being incurred. Alterations that require action and approval from the State Board must be received at least 45 days in advance of the next scheduled State Board meeting.

3. ANNUAL PROGRESS REPORT-PART 1130.760

An annual progress report must be submitted to the Agency for every 12-month period from the date of permit issuance until such time as the project is completed. The annual progress report is due between 30 days prior or 30 days after the anniversary date of permit issuance and must contain the information required by Section 1130.760.

4. PROJECT COMPLETION REQUIREMENTS-PART 1130.770

The permit holder must submit a written notice of project completion as defined in Section 1130.140. **The project must be complete by November 30, 2006**, the date specified in the permit application, unless a permit renewal has been obtained in accordance with the provisions of Section 1130.740. Permit renewal requests must be in writing and submitted at least 45 days but not more than 90 days prior to the project's scheduled completion date. For projects having a cost, the certification of project completion must contain a report of final realized costs as specified by Section 1130.770.

**PERMIT LETTER**

Brian J. Moran – Project #04-027

February 17, 2005

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This permit does not exempt the project or permit holder from licensing and certification requirements, including approval of applicable architectural plans and specifications prior to construction. Should you have any questions regarding the permit requirements, please contact Donald Jones.

Sincerely,



Jeffrey S. Mark  
Executive Secretary

Cc: Michael I. Copelin, Consultant  
Copelin Healthcare Consulting, Inc.  
2033 S. 4<sup>th</sup> Street  
Springfield, IL 62703

cc: Project-Temporary **Original**  
Project – **Certified** Original  
Project **Folder**  
ES-File

Division Staff  
Enrique Unanue (3 copies)  
Kathy Tibbs

NEW YORK  
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AUGUST 29, 2016

VIA EMAIL AND U.S. MAIL

**RECEIVED**

AUG 30 2016

Juan Morado Jr.  
General Counsel and Ethics Officer  
Health Facilities and Services Review Board  
69 West Washington Street Suite 3500  
Chicago, IL 60602

**HEALTH FACILITIES &  
SERVICES REVIEW BOARD**

**Re: Declaratory Ruling Request Submitted on behalf of Chicago Prostate Cancer  
Surgery Center, LLC, Project #04-027**

Dear Mr. Morado:

On behalf of Chicago Prostate Cancer Surgery Center, LLC (the "Permit Holder"), we are submitting this request for a declaratory ruling (the "Declaratory Ruling Request") in accordance with 77 Ill. Admin. Code §1130.810(f) and in accordance with the Health Facilities and Services Review Board (the "Board") practice identifying a declaratory ruling as the proper means for addressing the modification or removal of any reporting requirement or other condition placed upon a project. This Declaratory Ruling Request constitutes a distinct and discrete request for the Board to remove any limitation or perceived condition to which the Permit Holder may be subject in performing the full spectrum of urological procedures at Chicago Prostate Cancer Surgery Center (the "Center").

On February 3, 2005, the Board approved the establishment by the Permit Holder of a limited specialty ambulatory surgical treatment center (an "ASTC") with two operating rooms and eight recovery stations. The primary focus of that project was, and has remained, serving patients seeking treatment for prostate cancer. However, the Center is not currently operating at capacity and, as a result, a quality single-specialty ASTC licensed for urology is being underutilized. In the course of discussions with practitioners about the performance of additional urological procedures at the Center, a question arose as to whether the approval, as issued by the Board, could be perceived as a limitation on the spectrum of urological procedures appropriately performed at the Center. (See Exhibit A, February 17, 2005 Permit Letter.) A decision was reached, out of respect for the Board, its rules, and in an abundance of caution, to obtain Board

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approval prior to the performance of urological procedures at the Center beyond those related to the treatment of prostate cancer.

These circumstances present a unique opportunity to increase access to care by simply clarifying that the Center can properly provide urological procedures in addition to those related to the treatment of prostate cancer. Brachytherapy will remain a primary focus of the Center. There is no fundamental shift in the care to be provided or the commitment to serving individuals facing prostate cancer. The Permit Holder is not seeking the addition of another category of service or surgical specialty.

In the most recent reporting year, 2014, the Center performed 713 surgical procedures, with an average case time of one hour (equally split between surgical and prep/clean-up time). Open five days per week, 10 hours each day, the Center currently has hundreds of hours of unutilized surgical time. In keeping with the principles of the Certificate of Need program, the Permit Holder seeks to better utilize the Center by providing additional urological care.

Of the 713 surgical procedures performed in 2014, 100% of them were urological. If this Declaratory Ruling Request is granted, 100% of the procedures performed at the Center will still be urological. However, the performance of additional urological procedures would result in better utilization of the Center and enhanced access to urological care for patients.

The Center is served by an experienced staff, well-versed in the treatment of urological issues and dedicated to the delivery of high quality patient care. In 2014, approximately 45% of the Center's patients were Medicare beneficiaries. This clarification would increase access to high quality urological care for patients covered by government health care programs. This clarification would also enhance access to care for women, by allowing the Center to perform urological procedures required by female patients. A single-specialty ASTC dedicated to urological procedures would remain a single-specialty ASTC dedicated to urological procedures. The only change would be that additional patients in need of urological care would be able to access that care.

Accordingly, we respectfully request that the Board clarify that any limitation or condition placed upon the Permit Holder regarding the performance of urological procedures related to the treatment of prostate cancer be removed and that the Center be allowed to perform the full spectrum of urological procedures.

Should any additional information or clarification be needed, please let us know.

Respectfully submitted,



**Mark J. Silberman**

On behalf of: **Chicago Prostate Cancer Surgery Center, LLC**