



STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

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

DOCKET NO: H-04	BOARD MEETING: January 15, 2019	PROJECT NO: 18-040	PROJECT COST:
FACILITY NAME: OSF Saint Francis Medical Center		CITY: Peoria	Original: \$0
TYPE OF PROJECT: Substantive			HSA: II

PROJECT DESCRIPTION: The Applicant (OSF Healthcare System) proposes to establish a heart transplant program. There is no cost to this project and the completion date is upon State Board approval.

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicant (OSF Healthcare System) proposes to establish a heart transplant program. There is no cost to this project and the completion date is upon State Board approval.
- The State Board does not have a need methodology for this service. The Applicants have provided a methodology estimating the number of open heart transplants that will be performed at OSF Saint Francis Medical Center that is discussed at pages 51-59 of the Application for Permit. The State Board does not have a utilization standard for this service.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

- The proposed project is before the State Board because it establishes a category of service as defined at 20/ILCS 3960/3.

PURPOSE OF THE PROJECT:

- The Applicants stated that *“Through re-establishing the Heart Transplant Category of Service at OSF Saint Francis Medical Center, the System will be able to provide a full continuum of care for the cardiovascular disease.”*

PUBLIC HEARING/COMMENT:

- There was no request for a public hearing. No letters of opposition were received by State Board Staff.
- A Letter of support was included in the Application for Permit from Dr. William Cotts, Clinical Director Heart Failure and Transplantation Program at Advocate Christ Medical Center that stated in part *“Re-establishing the heart transplantation program at OSF Saint Francis Medical Center will ensure advanced cardiovascular care accessible in downstate Illinois. In addition, the reestablishment will assist in ensuring population health in the region.”* Other support letters were received from:
 - Jim Ardis, Mayor of Peoria
 - Deborah R. Simon, Regional CEO UnityPoint Health
 - Sara L. Rusch, MD Regional Dean The University of Illinois College of Medicine
 - State Senator David Koehler
 - US Congressman Darin LaHood
 - State Representative Michael Unes
 - State Senator Chuck Weaver
- Becky Crossman (patient) stated in part *“In 2010, the process to get on the heart transplant list began. Thus began trips to University of Chicago Medical Center. I was able to have many of the pre-heart plant tests in Peoria under Dr. Best’s guidance. On April 4, 2014, I received the call that there was a heart available just for me. My new heart was ‘transplanted’ shortly after midnight at Chicago, where I stayed for several weeks so I would not have to make the long trips back to Chicago for the required biopsies & tests to follow. After three months, I was permitted to have the procedures at OSF with Dr. Best and his team at Heartcare Midwest monitoring my progress and anti-rejection medicines. Currently, most of my follow ups are in Peoria with an annual day or two in Chicago. Anything that can be done in Peoria is such a blessing to me and my family. We are a little over an hour from Peoria and about four hours from Chicago. Chicago sometimes requires overnight stays. Having heart transplant services in Peoria/OSF would be such a asset to our area eliminating much of the stress on the patient and their families.”*

SUMMARY:

- The State Board Staff has reviewed the Application for Permit and the materials submitted in support of this project.
- The Applicant discontinued the heart transplant program in October of 2006 by stating “*due to the marked drop in volume of such services and the consideration of quality care for our patients, the Medical Center decided to discontinue this service.*”

Historical Heart Transplants OSF Saint Francis Medical Center Prior to Discontinuation

Year	2000	2001	2002	2003	2004	2005	2006
# Heart Transplants	13	13	10	7	7	10	3

1. Source: IDPH Hospital Profiles

Estimated Number of Heart Transplants based upon Applicant’s Methodology

Year	2017	2018	2019	2020	2021	2022
Patients	5-8	6-9	7-10	8-11	9-12	10-13

Source: Application for Permit

- The Applicant is asking the State Board to approve the establishment of the heart transplant program for the following reasons:
 1. Heart surgeons, cardiologists and collaborative staff currently in place;
 2. Sufficient resources (surgery rooms, recovery stations, ICU beds) in place in which no additional capital costs would be incurred;
 3. Ability to provide a continuum of care to heart patients in Illinois;
 4. Underserved population in the State of Illinois; and
 5. Major teaching hospital affiliated with the University of Illinois College of Medicine.
- The Applicant has met all of the requirements of the State Board.

STATE BOARD STAFF REPORT
Project #18-040
OSF Saint Francis Medical Center

APPLICATION/ CHRONOLOGY/SUMMARY	
Applicants(s)	OSF HealthCare System
Facility Name	OSF Saint Francis Medical Center
Location	530 NE Glen Oak Avenue, Peoria
Permit Holder	OSF HealthCare System OSF HealthCare System d/b/a OSF Saint Francis Medical Center
Operating Entity/Licensee	OSF HealthCare System d/b/a OSF Saint Francis Medical Center
Owner of Site	OSF HealthCare System
Application Received	October 19, 2018
Application Deemed Complete	October 19, 2018
Financial Commitment Date	January 15, 2019
Anticipated Completion Date	January 15, 2019
Review Period Ends	December 18, 2018
Review Period Extended by the State Board Staff?	No
Can the Applicants request a deferral?	Yes

I. Project Description

The Applicant (OSF Healthcare System) proposes to establish a heart transplant program. There is no cost to this project and the completion date is upon State Board approval.

II. Summary of Findings

- A. State Board Staff finds the proposed project is in conformance with all relevant provisions of Part 1110.
- B. Part 1120 is not applicable to this project.

III. General Information

The Applicant is OSF Healthcare System. OSF Healthcare System is an Illinois not-for-profit corporation incorporated in 1880 as The Sisters of the Third Order of St. Francis. OSF Healthcare System d/b/a OSF Saint Francis Hospital is a 609-bed acute care hospital in Peoria, Illinois.

OSF Healthcare System currently owns and operates the following acute care hospitals and free standing emergency center.

TABLE ONE
Hospitals owned by OSF Healthcare System in Illinois

Hospital	City	Number of Beds ⁽¹⁾
OSF St. Francis Medical Center	Peoria	609
OSF St. Anthony Medical Center	Rockford	254
OSF Healthcare Heart of Mary Medical Center	Urbana	210
OSF Healthcare Sacred Heart Medical Center	Danville	174
OSF Saint Anthony Health Center	Alton	170
OSF St. Joseph Medical Center	Bloomington	149
Ottawa Regional Hospital & Healthcare Center d/b/a St Elizabeth Hospital	Ottawa	97
OSF St. Mary Medical Center	Galesburg	81
OSF St. James - John W. Albrecht Medical Center	Pontiac	42
OSF Saint Luke Medical Center (CAH) ⁽²⁾	Kewanee	25
OSF St. Paul Medical Center (CAH)	Mendota	25
OSF Holy Family Medical Center (CAH)	Monmouth	23
OSF Saint Elizabeth Medical Center FSEC	Streator	

1. Number of beds as of 12/31/2017
2. CAH = Critical Access Hospital

Financial commitment and completion will occur at the time of project approval. The project is a substantive project subject to a 60-day review. Non-Substantive projects are **all** projects not considered substantive or emergency projects. Substantive projects shall include no more than the following:

1. *Projects to construct a new or replacement facility located on a new site; or a replacement facility located on the same site as the original facility and the costs of the replacement facility exceed the capital expenditure minimum.*
2. *Projects proposing a new service or discontinuation of a service, which shall be reviewed by the Board within 60 days.*
3. *Projects proposing a change in the bed capacity of a health care facility by an increase in the total number of beds or by a redistribution of beds among various categories of service or by a relocation of beds from one facility to another by more than 20 beds or more than 10% of total bed capacity, as defined by the State Board in the Inventory, whichever is less, over a 2-year period. [20 ILCS 3960/12]*

Emergency Projects are projects that are emergent in nature and must be undertaken immediately to prevent or correct structural deficiencies or hazardous conditions that may harm or injure persons using the facility, as defined at 77 Ill. Adm. Code 1110.40(a). [20 ILCS 3960/12(9)]

IV. Project Details

The Applicant proposes to reestablish a heart transplantation program. The Applicant performed its first heart transplantation in April of 1987. From April of 1987 until 2006 the Applicant performed 197 heart transplants. In 2006 the heart transplant program was discontinued. According to the Applicant now has a transplantation surgeon on staff and this specialist has the surgical capability for the program to be established.

V. Project Uses and Sources of Funds

There is no cost for this project.

VI. Health Service Area

The health service area for organ transplantation is the State of Illinois. There are five hospitals providing heart transplantation in Illinois.

- Advocate Christ Medical Center – Oak Lawn
- Ann & Robert Lurie Children’s Hospital – Chicago (pediatric heart transplant)
- Loyola University Medical Center – Maywood
- Northwestern Memorial Hospital – Chicago
- University of Chicago Medical Center – Chicago

No formula need has been developed for this category of service. Per 77 ILAC 1100.720, it is the responsibility of the applicant to document the need for the service by complying with all applicable Review Criteria contained in 77 Ill. Adm. Code 1110.

VII. Background of the Applicants, Purpose of the Project, Safety Net Impact, Alternatives

A) Criterion 1110.110(a) - Background of the Applicant

To address this criterion the applicants must provide a list of all facilities currently owned in the State of Illinois and an attestation documenting that no adverse actions¹ have been taken against any applicant’s facility by either Medicare or Medicaid, or any State or Federal regulatory authority during the 3 years prior to the filing of the Application with the Illinois Health Facilities and Services Review Board or a certified listing of adverse action taken against any applicant’s facility; and authorization to the State Board and Agency access to information in order to verify any documentation or information submitted in response to the requirements of the application for permit.

1. The Applicants provided the necessary attestation that no adverse action has been taken against any facility owned or operated by the Applicants and authorization allowing the State Board and IDPH access to all information to verify information in the application for permit. [Application for Permit page 36]

¹ “Adverse action is defined as a disciplinary action taken by IDPH, CMMS, or any other State or federal agency against a person or entity that owns or operates or owns and operates a licensed or Medicare or Medicaid certified healthcare facility in the State of Illinois. These actions include, but are not limited to, all Type "A" and Type "AA" violations.” (77 IAC 1130.140)

2. Licensure and Joint Commission Accreditation has been provided as required at pages 35A and 35B of the Application for Permit.
3. Evidence of ownership of the site has been provided as required at page 21 of the Application for Permit. Organizational relationships can be found at pages 23 of the Application for Permit.
4. Certificates of Good Standing for OSF Healthcare System has been provided as required. An Illinois Certificate of Good Standing is evidence that an Illinois business franchise (i.e. Illinois Corporation, LLC or LP) is in existence, is authorized to transact business in the state of Illinois, and complies with all state of Illinois business requirements and therefore is in "Good Standing" in the State of Illinois. [Application for Permit page 30-32]
5. Compliance with Executive Order #2006-05 is not required for a project with no construction. Executive Order #2006-05 requires *all State Agencies responsible for regulating or permitting development within Special Flood Hazard Areas shall take all steps within their authority to ensure that such development meets the requirements of this Order. State Agencies engaged in planning programs or programs for the promotion of development shall inform participants in their programs of the existence and location of Special Flood Hazard Areas and of any State or local floodplain requirements in effect in such areas. Such State Agencies shall ensure that proposed development within Special Flood Hazard Areas would meet the requirements of this Order.*
6. Compliance with the Illinois State Agency Historic Resources Preservation Act is not required for projects with no construction. Illinois State Agency Historic Resources Preservation Act requires *all State Agencies in consultation with the Director of Historic Preservation, institute procedures to ensure that State projects consider the preservation and enhancement of both State owned and non-State owned historic resources* (20 ILCS 3420/1).

B) Criterion 1110.110(b) – Purpose of the Project

To demonstrate compliance with this criterion the Applicants must document that the project will provide health services that improve the health care or well-being of the market area population to be served. The Applicants shall define the planning area or market area, or other area, per the applicant's definition. The Applicants shall address the purpose of the project, i.e., identify the issues or problems that the project is proposing to address or solve. Information to be provided shall include, but is not limited to, identification of existing problems or issues that need to be addressed, as applicable and appropriate for the project.

The Applicant stated: *“OSF HealthCare and its affiliated medical centers, in particular OSF Saint Francis Medical Center, along with their medical staffs, provides a full range of cardiovascular diagnostic and treatment services, excepting heart transplants. Through re-establishing the Heart Transplant Category of Service at OSF Saint Francis Medical Center, the System will be able to provide a full continuum of care for the cardiovascular disease.” Per the Applicant the planning area for this service would be the area served by the 12 medical centers.*” [See Application for Permit page 38]

C) Criterion 1110.110 (c) Safety Net Impact

All health care facilities, with the exception of skilled and intermediate long term care facilities licensed under the Nursing Home Care Act, shall provide a safety net impact statement, which shall be filed with an application for a substantive project (see Section 1110.40). Safety net services are the services provided by health care providers or organizations that deliver health care services to persons with barriers to mainstream health care due to lack of insurance, inability to pay, special needs, ethnic or cultural characteristics, or geographic isolation. [20 ILCS 3960/5.4]

This is a substantive project. The Applicant stated the following in regards the impact the proposed project will have on Safety Net Services.

“By re-establishing the Heart Transplantation Category of Service at OSF Saint Francis Medical Center, safety net services will be enhanced due to providing local access. There will be no changes in OSF HealthCare System nor OSF Saint Francis Medical Center financial policies. Hence, safety net services will not be impacted.”

**TABLE TWO
OSF Healthcare System
Charity Care**

Year	2017	2016	2015
Net Patient Revenue	\$2,057,383,657	\$1,970,497,496	\$1,917,020,581
Charity Care (Charges)	\$123,255,304	\$121,815,596	\$123,694,713
Charity Care (Cost)	\$26,127,456	\$25,170,596	\$24,351,000

**Charity Care
OSF Saint Francis Medical Center**

Year	2017	2016	2015
Net Patient Revenue	\$1,082,355,144	\$1,021,803,803	\$1,014,273,408
Charity Care (Charges)	\$65,319,955	\$65,695,605	\$62,261,622
Charity Care (Cost)	\$13,218,733	\$13,322,866	\$13,031,517
# of Patients	5,199	4,411	3,473

**Medicaid
OSF Saint Francis Medical Center**

Year	2017	2016	2015
Total Medicaid Rev.	\$204,319,838	\$168,834,136	\$156,456,867
Total # of Patients	147,890	137,808	134,107

D) Criterion 1110.110 (d) - Alternatives to the Proposed Project

To demonstrate compliance with this criterion the Applicants must document that the proposed project is the most effective or least costly alternative for meeting the health care needs of the population to be served by the project.

No alternative was considered for this project.

VIII. Project Scope and Size, Utilization and Unfinished/Shell Space

A) Criterion 1110. 120 (a) - Size of Project

To demonstrate compliance with this criterion the Applicants must document that that the physical space proposed for the project is necessary and appropriate. The proposed square footage cannot deviate from the square footage range indicated in Appendix B, or exceed the square footage standard in Appendix B if the standard is a single number, unless square footage can be justified by documenting, as described in subsection (a)(2).

No new construction or modernization is being proposed for this project.

B) Criterion 1110.120(b) - Project Services Utilization

To demonstrate compliance with this criterion the Applicants must document that, by the end of the second year of operation, the annual utilization of the clinical service areas or equipment shall meet or exceed the utilization standards specified in Appendix B. The number of years projected shall not exceed the number of historical years documented. All Diagnostic and Treatment utilization numbers are the minimums per unit for establishing more than one unit, except where noted in 77 Ill. Adm. Code 1100. [Part 1110 Appendix B]

The State Board has not developed a utilization standard for heart transplantation.

C) Criterion 1110.120 (e) - Assurances

To document compliance with this criterion the Applicants representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that, by the end of the second year of operation after project completion, the Applicants will meet or exceed the utilization standards specified in Appendix B.

Assurance is not required because the State Board has not developed a utilization standard for heart transplantation.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT TO BE IN CONFORMANCE WITH CRITERION SIZE OF THE PROJECT, PROJECTED UTILIZATION, ASSURANCES (77 ILAC 1110.120(a), (b) & (e))

IX. Selected Organ Transplant

A) Criterion 1110.240(b)(1) to (4) - Planning Area Need

The applicant shall document at the proposed category of service is necessary to serve the planning area's population, based on the following:

- 1) 77 Ill. Adm. Code 1100 (Formula Calculation)
- 2) Service to Planning Area Residents
Applicants proposing to establish this category of service shall document that the primary purpose of the project will be to provide necessary health care to the residents of the area in which the proposed project will be physically located (i.e., the planning or geographical service area, as applicable) for each category of service included in the project.
- 3) Service Demand – Establishment of Category of Service
The establishment of this category of service is necessary to accommodate the service demand experienced annually by the existing applicant facility over the latest 2-year period, as evidenced by historical and projected referrals, or, if the applicant proposes to establish a new hospital, the applicant shall submit projected referrals.
- 4) Service Accessibility
The establishment of this category of service is necessary to improve access for planning area residents. The applicant shall document the following:
 - A) Service Restrictions
The applicant shall document that at least one of the following factors exists in the planning area:
 - i) The absence of the proposed service within the planning area;
 - ii) Access limitations due to payor status of patients, including, but not limited to, individuals with health care coverage through Medicare, Medicaid, managed care or charity care;
 - iii) Restrictive admission policies of existing providers;
 - iv) The area population and existing care system exhibit indicators of medical care problems, such as an average family income level below the State average poverty level, high infant mortality, or designation

by the Secretary of Health and Human Services as a Health Professional Shortage Area, a Medically Underserved Area, or a Medically Underserved Population;

- v) For purposes of this subsection (b)(4) only, all services within the 3-hour normal travel time meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100.

1. 77 Ill. Adm. Code 1100 (Formula Calculation)

The State Board has not established a need calculation for this service. Per 77 ILAC 1100.720 it is the responsibility of the applicant to document the need for the service by complying with all applicable Review Criteria contained in 77 Ill. Adm. Code 1110.

2. Service to Planning Area Residents

The Planning Area for this service is the State of Illinois. The Applicant describes its service area as the area served by the 12 acute care hospitals identified above (Table One). The Primary Market Area is a 23-county geographic area in north and western Illinois stretching from Alton to Rockford. The Secondary Market Area is a 7-county area which includes the cities of Champaign / Urbana and Danville. These two market areas are based on OSF HealthCare Medical Center locations within these areas and their respective adult (15+) 2016 M/S admissions which is the latest published AHQ data for analysis purposes. OSF HealthCare derived service population in the primary geographic market area is 558,278 adults and 88,597 adults in the defined secondary geographic area for a total adult population served / service population of 646,875 adults (15+). This is approximately 6.2 percent of Illinois adult population in 2016.

3. Service Demand

Historically the Applicant has referred a total of eight patients over the past three years for heart transplants.

Historical Referrals from OSF Saint Francis Medical Center to				
	CY 2015	CY 2016	CY 2017	Total
Northwestern Medical Center	1	3	2	6
University of Chicago Medical Center		1	1	2

In lieu of projected referrals the Applicant provided the following attestation:

“My name is Stephen E. Hippler, M.D. as Chief Clinical Officer for OSF HealthCare System, I attest to the fact patients and their families receiving care throughout the OSF HealthCare System, prefer to remain therein for their heart transplantation based on the System's ability to provide complex and robust comprehensive care, pre- and post-transplantation, including care provided by various other OSF specialty providers. Those physicians associated with our integrated system and, in particular, OSF Saint Francis Medical Center, prefer to refer their cardiovascular and heart failure patients within the System to ensure a continuum of care, while clearly allowing for patient and family preference. OSF HealthCare System has a physician organization employing over 700

physicians as well as having independent physicians on our affiliated hospital medical staffs. As such, to request individual physician patient referral letters for the Heart Transplant Program Category of Service re-establishment is an over-whelming task. Thus, this attestation letter is provided to meet Illinois Health Facility Board Criterion 1110.240 (b)(3)(B). We fully expect to meet the conservative heart transplants, as projected herein, through associated referrals into the re-established Program.”

The Applicant provided a methodology to estimate the number of heart transplants that will be performed should the State Board approve this project. To estimate the need for this service the Applicant provided the following methodology:

- 1) Establish Illinois and OSF's geographic service areas;
- 2) Derive the total adult population to be served (service population);
- 3) Assume there will be no in- or out-migration from either Illinois or from OSF's adult derived service population for the heart transplantation program;
- 4) Establish/ determine the prevalence rate for adult heart failure in the marketplace;
- 5) Derive the estimated adult population with heart failure within either Illinois or OSF's geographic service areas or markets;
- 6) Establish the percent of adult heart failure patients eligible for a heart transplant;
- 7) Establish the percent of those eligible for a heart transplant to be placed on the transplant waiting list;
- 8) Establish the percent of adults on the heart transplant list who will become recipients;
- 9) Derive/ estimate the number of adults within Illinois, and the OSF HealthCare System, who will receive a transplant heart;
- 10) Provide for follow-up care post-transplantation (OSF Healthcare System).

Based upon this methodology the Applicant has calculated a current estimated utilization of approximately 5 to 8 heart transplants annually based on its current geographic markets and market share, assuming no change in demographics or demand factors. For a complete discussion of this methodology refer to pages 48-55 of the Application for Permit.

Estimated Number of Heart Transplants based upon the methodology above						
Year	2017	2018	2019	2020	2021	2022
Patients	5-8	6-9	7-10	8-11	9-12	10-13

Source: Application for Permit

Sg2 Analytics², in a separate forecast for OSF Saint Francis Medical Center, indicated that by 2022 there would be 22 heart transplant discharges from its Primary Service Area.

4. Service Accessibility

As stated above the planning area for this service is the State of Illinois. There is no evidence of access limitations due to payor status of patients, or restrictive admission policies at existing providers. All of the existing providers of heart transplant service are approximately 3 or more hours from the proposed project. There are five hospitals that

² Sg2 is a Vizient company that provides demand forecasting, clinical and strategic intelligence and consulting to provide a look into national, regional and local trends across the full inpatient and outpatient healthcare continuum. Sg2 identifies, in a specific geography: patient volumes, primary referring physicians driving that volume, and the focus of market participants and more.

provided heart transplant services in 2017 all located in the Chicago area (one is a pediatric heart transplant program - Anne and Robert Lurie Children’s Memorial Hospital).

The Applicant also provided responses to the following:

- **Waiting Time for Heart Transplant**

The patient must meet rigorous clinical criteria to be placed on a transplant waiting list and the process to procure a donor heart and match it to a recipient is complex. Thus, the waiting time criteria is more relevant to organ availability and subsequent transplantation than waiting time related to "access" to a facility or program such as an emergency room.

- **Admission Restrictions for Heart Transplant**

Any potential restrictions are patient specific (clinical status), and not facility related, due to the clinical evaluations and protocols in place for a heart transplant recipient.

- **Population Characteristics**

The need / demand for heart transplants in Illinois is based on several factors. The actual number of transplants varies yearly based on potential donor organ availability and recipient compatibility. There does not appear to be an access problem, (based on this criteria), excepting geographic access and state-wide program mal-distribution (clustering in the Chicago area).

**TABLE THREE
Existing Heart Transplant Programs**

Facility	City	Distance Hours ⁽²⁾	Historical Utilization by Facility ⁽¹⁾				
			CY 2013	CY 2014	CY 2015	CY 2016	CY 2017
Advocate Christ Medical Center	Oak Lawn	3.5	19	14	16	26	23
Loyola University Medical Center	Maywood	3.5	14	12	18	36	27
Northwestern Memorial Hospital	Chicago	3.3	21	32	24	31	39
University of Chicago Medical Center	Chicago	3.2	26	35	33	31	33
Total			80	93	91	124	122

1. Source: IDPH Hospital Profile Information (2013-2017)
2. The travel times between OSF Saint Francis Medical Center and Chicago based transplant centers, approximately 160 to 180 miles away, can be several hours based on the travel mode ... automobile, ambulance, or air transport, notwithstanding traffic conditions, construction, and weather. Once a donor heart is procured, and a candidate match is made, there is a short window of time, which is less than 6 hours, from procurement to transplantation. Hence, these two travel times are relevant for a successful heart transplantation. First, transporting the procured organ to the transplant center, and second, transporting the recipient to the respective center. Travel time presented in the table is approximate based upon MapQuest.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION PLANNING AREA NEED (77 ILAC 1110.240(b)(1) to (4))

B) Criterion 1110.240 - Unnecessary Duplication/Mal-distribution

1. Unnecessary Duplication

The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information:

- A) A list of all zip code areas that are located, in total or in part, within 3 hours normal travel time of the project's site;

- B) The total population of the identified zip code areas (based upon the most recent population numbers available for the State of Illinois population); and
- C) The names and locations of all existing or approved health care facilities located within 3 hours normal travel time from the project site that provide this category of service.

The Applicant stated *“that Illinois has 102 counties with 1,569 distinct zip codes. The 3-hour normal travel time boundaries, from Peoria, contain 82 counties; only 20 counties in southernmost Illinois are not included in this geographic area. Based on IDPH/IHFSRB population data, this 82-county geographic area has an approximate 2016 population of 12,601,085 individuals or 97.1 percent of the Illinois population. The 82 counties within the 3-hour normal travel time from OSF Saint Francis Medical Center contain approximately 1,421 zip codes in that the zip code and county boundaries are not co-terminus.”*

As shown above there are four adult heart transplant programs in the State of Illinois all clustered in the Chicago area and over 3 hours from the proposed project.

2. Mal-distribution of Service

The applicant shall document that the project will not result in mal-distribution of services. Mal-distribution exists when the identified area (within the planning area) has an excess supply of facilities, beds and services characterized by such factors as, but not limited to:

- A) Historical utilization (for the latest 12-month period prior to submission of the application) for existing facilities and services that is below the occupancy standard established pursuant to 77 Ill. Adm. Code 1100; or
- B) Insufficient population to provide the volume or caseload necessary to utilize the services proposed by the project at or above occupancy standards.

The Applicant states *“that downstate Illinois is deficient in having this Category of Service locally available. Within the designed state-wide planning area for a heart transplantation program, there are four centers, all clustered in the Chicago area. Thus, by definition, there is a mal-distribution within the state. Geographic access to this highly specialized program is compromised. As well, patient safety and quality care is jeopardized by fostering potentially excessive travel for those fragile heart failure patients requiring a time sensitive transplantation once a donor/ recipient match is made.”*

3. Impact on Other Area Providers

The applicant shall document that, within 24 months after project completion, the proposed project:

- A) Will not lower the utilization of other area providers below the occupancy standards specified in 77 Ill. Adm. Code 1100; and
- B) Will not lower, to a further extent, the utilization of other area hospitals that are currently (during the latest 12-month period) operating below the occupancy standards.

The State Board does not have an occupancy standard for heart transplant.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION UNNECESSARY DUPLICATION/MALDISTRIBUTION (77 ILAC 1110.240 (c)(1) to (3))

C) Criterion 1110.240(e) - Staffing Availability

The applicant shall document that relevant clinical and professional staffing needs for the proposed project were considered and that licensure and The Joint Commission staffing requirements can be

met. In addition, the applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.

OSF Saint Francis Medical Center is a designated transplantation center. The professional and non-professional nursing staff that will be caring for the patient pre and post-transplant will be from the present staff. The Applicant has a team of VAD/transplant nurses³ already on staff. These staff fulfill annual competencies and educational requirements which include but are limited to, CPR certification, advanced cardiac life support certification, care of postoperative open heart patients, operation of monitoring technology and pharmacological testing.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION STAFFING AVAILABILITY (77 ILAC 1110.240(e))

D) Criterion 1110.240(f) - Surgical Staff

The applicant shall document that the facility has at least one transplant surgeon certified in the applicable specialty on staff and that each has had a minimum of one year of training and experience in transplant surgery, post-operative care, long term management of organ recipients and the immunosuppressive management of transplant patients. Documentation shall consist of curricula vitae of transplant surgeons on staff and certification by an authorized representative that the personnel with the appropriate certification and experience are on the hospital staff.

OSF Saint Francis Medical Center has added a qualified heart transplantation surgeon to its medical staff. Resumes for this individual as well as existing cardiovascular surgeons are included in the Application for Permit at pages 80-161.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION SURGICAL STAFF (77 ILAC 1110.240(f))

E) Criterion 1110.240(g) - Collaborative Support

The applicant shall document collaboration with experts in the fields of hepatology, cardiology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine. Documentation of collaborate involvement shall include, but not be limited to, a plan of operation detailing the interaction of the transplant program and the stated specialty areas.

OSF Saint Francis Medical Center is a designated organ transplant center for kidney and pancreas transplantation, the support services are currently available and existing protocols/operational policies and procedures will be utilized as appropriate, for the re-established heart transplantation program.

³ A ventricular assist device (VAD) — also known as a mechanical circulatory support device — is an implantable mechanical pump that helps pump blood from the lower chambers of your heart (the ventricles) to the rest of your body. A VAD is used in people who have weakened hearts or heart failure. Although a VAD can be placed in the left, right or both ventricles of your heart, it is most frequently used in the left ventricle. When placed in the left ventricle it is called a left ventricular assist device (LVAD). You may have a VAD implanted while you wait for a heart transplant or for your heart to become strong enough to effectively pump blood on its own. Your doctor may also recommend having a VAD implanted as a long-term treatment if you have heart failure and you're not a good candidate for a heart transplant. [Source: Mayo Clinic]

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION COLLABORATIVE SUPPORT (77 ILAC 1110.240(g))

F) Criterion 1110.240(h) - Support Services

An applicant shall submit a certification from an authorized representative that attests to each of the following:

- 1) Availability of on-site access to microbiology, clinical chemistry, radiology, blood bank and resources required to monitor use of immunosuppressive drugs;
- 2) Access to tissue typing services; and
- 3) Ability to provide psychiatric and social counseling for the transplant recipients and for their families.

As a designated organ transplant center for kidney and pancreas transplantation, the support services are currently available and existing protocols/ operational policies and procedures will be utilized as appropriate, for the re-established heart transplantation program.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION SUPPORT SERVICES (77 ILAC 1110.240(h))

G) Criterion 1110.240(i) - Performance Requirements

- 1) The applicant shall document that the proposed category of service will be provided at a teaching institution.
- 2) The applicant shall document that the proposed category of service will be performed in conjunction with graduate medical education.
- 3) The applicant shall provide proof of membership in the Organ Procurement and Transplantation Network (OPTN) and a federally designated organ procurement organization (OPO).

1. The Applicant attested that the heart transplant program will be provided at the University of Illinois College of Medicine at Peoria. (Application for Permit page 69)
2. The Applicant attested that the heart transplant program will be performed in conjunction with associated graduate medical education (G.M.E.) programs. (Application for Permit page 69)
3. The OSF Saint Francis Medical Center's kidney transplant program was approved for membership with UNOS on November 4, 1987, and remains a member in good standing. The United Network for Organ Sharing (UNOS) has a contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services, to administer the Organ Procurement and Transplantation (OPTN) Network. UNOS conducted a focused desk review of OSF Saint Francis Medical Center kidney transplant program March 16-17, 2017. That review have been provided at pages 70-73 of the Application for Permit. The focused desk audit had no findings.

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION PERFORMANCE REQUIREMENTS (77 ILAC 1110.240(i))

H) Criterion 1110.240(j) - Assurances

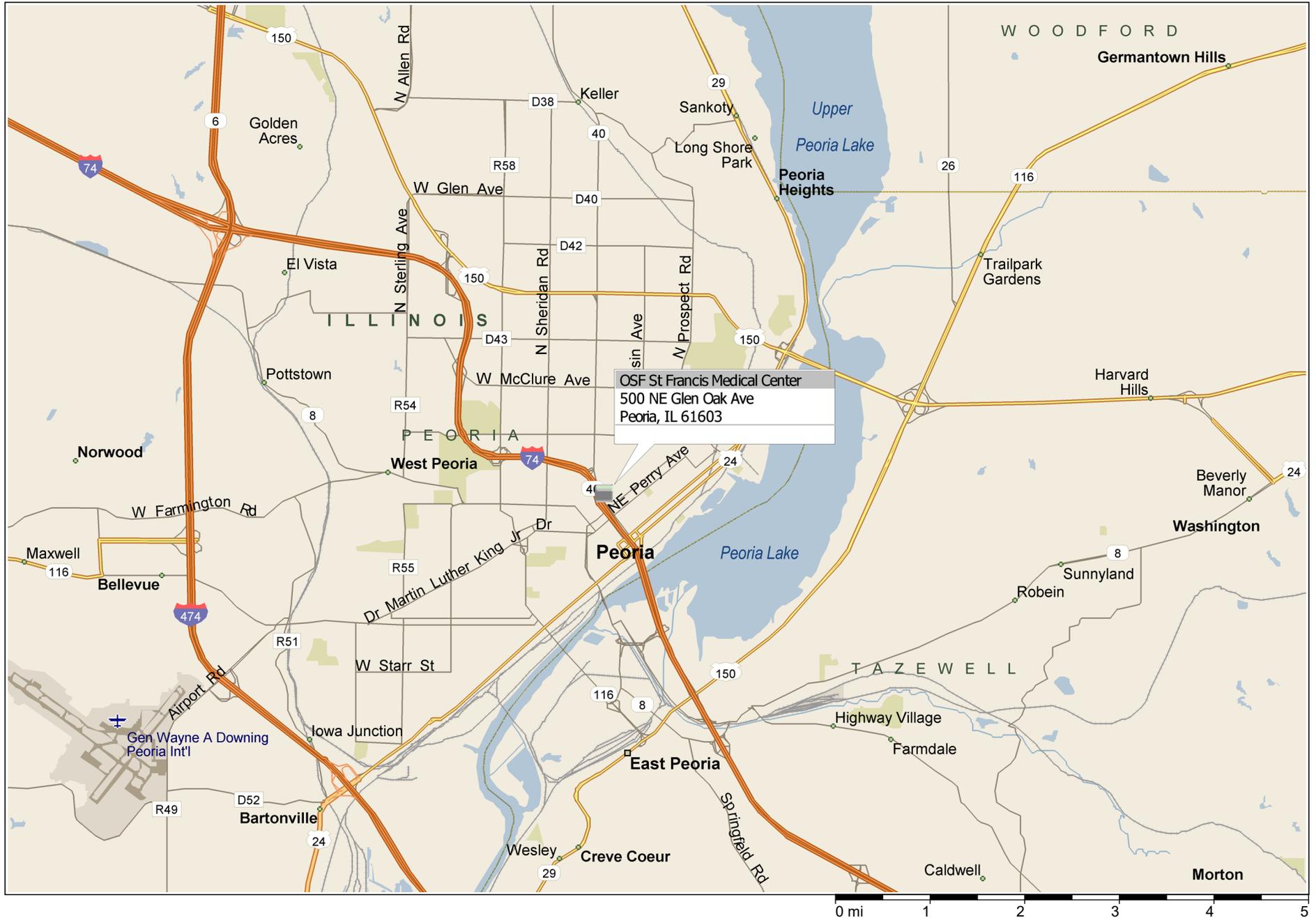
The applicant representative who signs the CON application shall submit a signed and dated statement attesting to the applicant's understanding that, by the second year of operation after the project completion, the applicant will achieve and maintain the occupancy standards specified in 77 Ill. Adm. Code 1100 for each category of service involved in the proposal.

The State Board does not have an occupancy standard for heart transplant. The Applicant did provide the following attestation from Robert G. Anderson, President, OSF Saint Francis Medical Center attested to the following:

- “1) The Medical Center medical staff has the appropriate heart transplantation certificates and experience.*
- 2) There is on-site access at the Medical Center to the defined support services noted in the criterion.*
- 3) The Medical Center is a teaching institution associated with the University of Illinois College of Medicine at Peoria which sponsors eleven (11) residency training programs and six (6) fellowship programs.*
- 4) The heart transplant program will be performed in conjunction with associated graduate medical education (G.M.E.) programs.*
- 5) The facility is a member of the Organ Procurement and Transplantation Network (OPTN) as documented by our current transplant programs.”*

STATE BOARD STAFF FINDS THE PROPOSED PROJECT IN CONFORMANCE WITH CRITERION ASSURANCE (77 ILAC 1110.240(j))

18-040 OSF St Francis Medical Center - Peoria



<u>Ownership, Management and General Information</u>		<u>Patients by Race</u>		<u>Patients by Ethnicity</u>	
ADMINISTRATOR NAME:	Robert Anderson	White	84.3%	Hispanic or Latino:	3.1%
ADMINSTRATOR PHONE	309-655-7796	Black	11.5%	Not Hispanic or Latino:	96.5%
OWNERSHIP:	OSF Healthcare System	American Indian	0.1%	Unknown:	0.5%
OPERATOR:	OSF Healthcare System	Asian	0.6%		
MANAGEMENT:	Church-Related	Hawaiian/ Pacific	0.0%	IDPH Number:	2394
CERTIFICATION:		Unknown	3.4%	HPA	C-01
FACILITY DESIGNATION:	General Hospital			HSA	2
ADDRESS	530 N.E. Glen Oak Ave.	CITY:	Peoria	COUNTY:	Peoria County

<u>Facility Utilization Data by Category of Service</u>										
<u>Clinical Service</u>	Authorized CON Beds 12/31/2017	Peak Beds Setup and Staffed	Peak Census	Admissions	Inpatient Days	Observation Days	Average Length of Stay	Average Daily Census	CON Occupancy Rate %	Staffed Bed Occupancy Rate %
Medical/Surgical	379	379	367	20,519	105,763	12,960	5.8	325.3	85.8	85.8
0-14 Years				104	147					
15-44 Years				3,755	17,886					
45-64 Years				6,576	34,713					
65-74 Years				4,551	23,675					
75 Years +				5,533	29,342					
Pediatric	40	40	40	2,381	9,983	1,765	4.9	32.2	80.5	80.5
Intensive Care	91	91	81	5,677	21,662	71	3.8	59.5	65.4	65.4
Direct Admission				4,326	15,800					
Transfers				1,351	5,862					
Obstetric/Gynecology	52	52	50	3,384	11,219	694	3.5	32.6	62.8	62.8
Maternity				3,238	10,850					
Clean Gynecology				146	369					
Neonatal	40	40	32	782	9,219	3	11.8	25.3	63.2	63.2
Long Term Care	0	0	0	0	0	0	0.0	0.0	0.0	0.0
Swing Beds			0	0	0		0.0	0.0		
Total AMI	0			0	0	0	0.0	0.0	0.0	
Adolescent AMI		0	0	0	0	0	0.0	0.0		0.0
Adult AMI		0	0	0	0	0	0.0	0.0		0.0
Rehabilitation	27	27	26	536	8,185	0	15.3	22.4	83.1	83.1
Long-Term Acute Care	0	0	0	0	0	0	0.0	0.0	0.0	0.0
Dedicated Observation	36					1917				
Facility Utilization	629			31,928	166,031	17,410	5.7	502.6	79.9	

(Includes ICU Direct Admissions Only)

<u>Inpatients and Outpatients Served by Payor Source</u>							
	Medicare	Medicaid	Other Public	Private Insurance	Private Pay	Charity Care	Totals
Inpatients	45.9%	24.1%	1.0%	27.0%	0.8%	1.3%	
	14647	7698	309	8628	244	402	31,928
Outpatients	36.0%	23.6%	0.6%	37.4%	1.6%	0.8%	
	213653	140192	3731	222193	9426	4797	593,992

<u>Financial Year Reported:</u>	10/1/2016 to	9/30/2017	<u>Inpatient and Outpatient Net Revenue by Payor Source</u>					<u>Charity Care Expense</u>	<u>Total Charity Care Expense</u>
	Medicare	Medicaid	Other Public	Private Insurance	Private Pay	Totals			
Inpatient Revenue (\$)	25.4%	22.5%	0.6%	50.9%	0.6%	100.0%		13,218,733	
	160,675,516	142,185,638	4,048,907	321,374,457	3,695,424	631,979,942	7,460,440		
Outpatient Revenue (\$)	12.9%	13.8%	0.8%	70.3%	2.2%	100.0%			
	58,059,354	62,134,200	3,605,559	316,570,255	10,005,834	450,375,202	5,758,293	Total Charity Care as % of Net Revenue 1.2%	

<u>Birthing Data</u>		<u>Newborn Nursery Utilization</u>			<u>Organ Transplantation</u>	
Number of Total Births:	2,894	Level I	Level II	Level II+	Kidney:	40
Number of Live Births:	2,860	Beds	91	20	Heart:	0
Birthing Rooms:	0	Patient Days	4,722	7,137	Lung:	0
Labor Rooms:	0	Total Newborn Patient Days		22,800	Heart/Lung:	0
Delivery Rooms:	0				Pancreas:	3
Labor-Delivery-Recovery Rooms:	9				Liver:	0
Labor-Delivery-Recovery-Postpartum Rooms:	0	<u>Laboratory Studies</u>			Total:	43
C-Section Rooms:	2	Inpatient Studies		1,493,428		
CSections Performed:	1,055	Outpatient Studies		2,017,412		
		Studies Performed Under Contract		180,704		

Surgery and Operating Room Utilization

Surgical Specialty	Operating Rooms				Surgical Cases		Surgical Hours			Hours per Case	
	Inpatient	Outpatient	Combined	Total	Inpatient	Outpatient	Inpatient	Outpatient	Total Hours	Inpatient	Outpatient
Cardiovascular	0	0	2	2	749	24	3585	38	3623	4.8	1.6
Dermatology	0	0	0	0	0	0	0	0	0	0.0	0.0
General	0	0	15	15	3162	3830	8969	7322	16291	2.8	1.9
Gastroenterology	0	0	0	0	20	34	30	39	69	1.5	1.1
Neurology	0	0	4	4	1582	678	6059	1362	7421	3.8	2.0
OB/Gynecology	0	0	0	0	300	1134	1116	2865	3981	3.7	2.5
Oral/Maxillofacial	0	0	0	0	106	63	282	147	429	2.7	2.3
Ophthalmology	0	0	0	0	8	67	13	129	142	1.6	1.9
Orthopedic	0	0	5	5	2754	2024	7844	3646	11490	2.8	1.8
Otolaryngology	0	0	0	0	99	736	208	1134	1342	2.1	1.5
Plastic Surgery	0	0	0	0	47	189	129	402	531	2.7	2.1
Podiatry	0	0	0	0	151	121	195	214	409	1.3	1.8
Thoracic	0	0	0	0	299	122	841	134	975	2.8	1.1
Urology	0	0	0	0	301	1466	1092	2201	3293	3.6	1.5
Totals	0	0	26	26	9578	10488	30363	19633	49996	3.2	1.9

SURGICAL RECOVERY STATIONS

Stage 1 Recovery Stations

50

Stage 2 Recovery Stations

Dedicated and Non-Dedicated Procedure Room Utilization

Procedure Type	Procedure Rooms				Surgical Cases		Surgical Hours			Hours per Case	
	Inpatient	Outpatient	Combined	Total	Inpatient	Outpatient	Inpatient	Outpatient	Total Hours	Inpatient	Outpatient
Gastrointestinal	0	0	5	5	1888	7376	2310	7654	9964	1.2	1.0
Laser Eye Procedures	0	0	0	0	0	0	0	0	0	0.0	0.0
Pain Management	0	0	0	0	0	0	0	0	0	0.0	0.0
Cystoscopy	0	0	1	1	253	1361	271	1455	1726	1.1	1.1

Multipurpose Non-Dedicated Rooms

Pediatric Dental, Ga					34	842	51	1066	1117	1.5	1.3
					0	0	0	0	0	0.0	0.0
	0	0	0	0	0	0	0	0	0	0.0	0.0

Emergency/Trauma Care

Certified Trauma Center	Yes
Level of Trauma Service	Level 1
	Adult & Child
Operating Rooms Dedicated for Trauma Care	1
Number of Trauma Visits:	1,630
Patients Admitted from Trauma	994
Emergency Service Type:	Comprehensive
Number of Emergency Room Stations	57
Persons Treated by Emergency Services:	75,291
Patients Admitted from Emergency:	13,305
Total ED Visits (Emergency+Trauma):	76,921

Free-Standing Emergency Center

Beds in Free-Standing Centers	0
Patient Visits in Free-Standing Centers	0
Hospital Admissions from Free-Standing Center	0

Outpatient Service Data

Total Outpatient Visits	593,992
Outpatient Visits at the Hospital/ Campus:	348,430
Outpatient Visits Offsite/off campus	245,562

Cardiac Catheterization Labs

Total Cath Labs (Dedicated+Nondedicated labs):	6
Cath Labs used for Angiography procedures	1
Dedicated Diagnostic Catheterization Lab	0
Dedicated Interventional Catheterization Labs	0
Dedicated EP Catheterization Labs	2

Cardiac Catheterization Utilization

Total Cardiac Cath Procedures:	4,326
Diagnostic Catheterizations (0-14)	30
Diagnostic Catheterizations (15+)	1,845
Interventional Catheterizations (0-14):	93
Interventional Catheterization (15+)	1,230
EP Catheterizations (15+)	1,128

Cardiac Surgery Data

Total Cardiac Surgery Cases:	591
Pediatric (0 - 14 Years):	163
Adult (15 Years and Older):	428
Coronary Artery Bypass Grafts (CABGs) performed of total Cardiac Cases :	190

Diagnostic/Interventional Equipment

	Owned Contract		Examinations		
	Owned	Contract	Inpatient	Outpt	Contract
General Radiography/Fluoroscopy	53	0	63,566	95,248	0
Nuclear Medicine	6	0	1,116	6,167	0
Mammography	7	0	15	31,631	0
Ultrasound	17	0	14,909	57,628	0
Angiography	4	0			
Diagnostic Angiography			2,093	2,598	0
Interventional Angiography			3,920	3,830	0
Positron Emission Tomography (PET)	1	0	201	1,134	0
Computerized Axial Tomography (CAT)	6	0	17,314	30,463	0
Magnetic Resonance Imaging	7	0	5,828	20,811	0

Therapeutic Equipment

	Owned Contract		Therapies/Treatments
	Owned	Contract	
Lithotripsy	0	1	84
Linear Accelerator	3	0	15,112
Image Guided Rad Therapy			5,511
Intensity Modulated Rad Thrpy			8,710
High Dose Brachytherapy	1	0	348
Proton Beam Therapy	0	0	0
Gamma Knife	0	1	71
Cyber knife	0	0	0