

BAKER DONELSON

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February 3, 2017

VIA HAND DELIVERY AND EMAIL

Kevin McDonald, Chief
Certificate of Need Division
Maryland Health Care Commission
4160 Paterson Avenue
Baltimore, Maryland 21215

**Re: Columbia Surgical Institute, LLC
Certificate of Need Application**

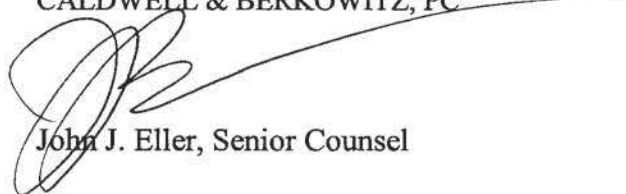
Dear Mr. McDonald:

Enclosed please find six copies of a Certificate of Need Application being filed on behalf of Columbia Surgical Institute, LLC ("CSI") regarding a project at CSI to add a second operating room ("OR"). A full copy of the application will also be emailed to you in searchable PDF and Word forms.

I hereby certify that a copy of the CON application has been provided to the local health department, as required by regulations.

If any further information is needed, please let us know.

Sincerely,
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC



John J. Eller, Senior Counsel

JJE/tjr

Enclosures

cc: Maura Rossman, MD, Health Officer - Howard County
Ms. Ruby Potter - Health Facilities Coordination Office
Scott LaBorwit, MD
Penelope Williams, Director, RN, MS/MHA
Howard L. Sollins, Esquire

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PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: Columbia Surgical Institute

Address: 6020 Meadowridge Center Drive, Suite H Elkridge, MD 21075 Howard County

2. NAME OF OWNERS

| | | |
|--------------------|---------------|---------------|
| Scott LaBorwit, MD | Ophthalmology | 73% ownership |
| Allan Rutzen, MD | Ophthalmology | % ownership |

3. APPLICANT

Legal Name of Project Applicant (Licensee or Proposed Licensee): Columbia Surgical Institute, LLC

Address: 6020 Meadowridge Center Drive, Suite H Elkridge, MD 21075 Howard County

Telephone: (410) 821-6400

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from the applicant:

No difference

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

- A. Governmental
- B. Corporation State & Date of Incorporation
(1) Non-profit
(2) For-profit
(3) Close
- C. Partnership
General
Limited
Limited Liability Partnership
Limited Liability Limited Partnership
Other (Specify): _____
- D. Limited Liability Company
- E. Other (Specify): _____
- To be formed:
Existing:

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary Contact:

Name and Title: Penelope L. Williams

Company Name: Penelope L Williams

Mailing Address: 4217 Dresden Street Kensington, MD 20895

Telephone: 240-691-9311

E-mail Address (required): pwilli759@icloud.com

Fax:

If company name is CON Consultant to CSI

different than applicant

briefly describe the

relationship.

B. Additional or Alternate Contact:

Name and Title: Scott LaBorwit, MD

Company Name: Columbia Surgical Institute

Mailing Address: 602 Meadowridge Center Drive, Suite H Elkridge, MD 21075

Telephone: 443-275-7800

E-mail Address (required): sel104@me.com

Fax: 410-796-0700

If company name is No Difference

different than applicant

briefly describe the

relationship.

7. TYPE OF PROJECT

The following list includes all project categories that require a CON pursuant to COMAR 10.24.01.02(A). Please mark all that apply in the list below.

If approved, this CON would result in (check as many as apply):

- (1) A new health care facility built, developed, or established
- (2) An existing health care facility moved to another site
- (3) A change in the bed capacity of a health care facility
- (4) A change in the type or scope of any health care service offered by a health care facility
- (5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at:
http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: *The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is, why you need to do it, and what it will cost. A one-page response will suffice. Please include:*

- (1) Brief Description of the project – what the applicant proposes to do*
- (2) Rationale for the project – the need and/or business case for the proposed project*
- (3) Cost – the total cost of implementing the proposed project*

Executive Summary

Columbia Surgical Institute (CSI) proposes to expand its current facility capacity by converting one existing procedure room to an outpatient operating room. The overall footprint and square footage of CSI will not change nor will the anesthesia type provided at the facility change.

Ophthalmologists at CSI are regional leaders in the delivery of diagnostic and treatment services to patients with a wide range of ophthalmic conditions. Demand for services has grown steadily each year, the first surgery in 2013, and there is no longer the availability of sufficient space to accommodate the current case volume and case type. Currently, CSI is the only facility (ASF or hospital) in Howard County providing surgical services for retinal conditions. Without the additional operating room, CSI will not be positioned to expand the treatment availability for these more complex cases and other surgical services required to meet the existing demand and projected growth. The service area projections indicate a continuing rise in CSI's patient target, (persons 65 years of age and older) and new patients who are part of the 20 million (and rising) people who now have access to health care coverage through health care exchange programs. Other driving factors for expansion include advanced technology that keeps CSI on the cutting-edge and attracts ophthalmology associates to the center.

CSI seeks approval for a project total budget of \$192,192 for plans, working drawings, renovation, and equipment, to be funded through a secured loan, paid over 5 years. The construction would be completed within 3 months and the project proposes to be utilized at optimal capacity or higher level within 3 years of the completed renovations.

B. Comprehensive Project Description: The description should include details regarding:

- (1) Construction, renovation, and demolition plans
- (2) Changes in square footage of departments and units
- (3) Physical plant or location changes
- (4) Changes to affected services following completion of the project
- (5) Outline the project schedule.

Project Description

The facility was built and received Determination for Coverage in July of 2012, compliant with 2010 FGI, NFPA - Life Safety Code, and other required guidelines. In 2014, FGI published revised guidelines and renamed Class A, B and C operating rooms. The project floor plan and project narrative reflect the revisions as noted below.

| FGI 2010 | FGI 2014 |
|-------------|----------------------------|
| Class A | Procedure Room |
| Class B & C | Outpatient Operating Rooms |

Highlights of key project features are noted below. The original floor plan (Appendix A) and proposed project floor plan (Appendix B) are provided as reference.

Renovation Summary (in square feet)

| Existing ASF | Existing ASF Unaltered | Renovated ASF | Total Space Following Project |
|--------------|------------------------|---------------|-------------------------------|
| 3,719 | 3,444 | 275 | 3,719 |

Corridor

Project

- Remove door that currently divides the existing OR from the project OR and OR Adjunct Procedure Room LenSx® and install cased metal frame.
- Repair flooring as needed at new frame.
- Rename corridor to 2014 FGI Guidelines, "Semi-Restricted".
- Apply labeling to doorway and floor to designate restricted areas.

Unchanged in Corridor

- Semi-Restricted area clearly marked with specific signage indicating authorized access only and appropriate attire required. Doors to restricted areas serve as physical barriers. Traffic in the semi-restricted area is limited to authorized personnel and patients when accompanied on stretchers by authorized personnel. Authorized

personnel are required to wear clean surgical attire, cover head and facial hair, and wear shoe covers.

- Authorized personnel access area through Pre-Op and Post-Op. Authorized personnel also access through one of two doors from “Staff Change”.

Outpatient Operating Room #2

Project

- Expose existing framed opening between Clean Assembly and OR #2.
- Furnish and install new prefinished doorframe, door, and hardware.
- Cut and cap plumbing supply and sanitary lines at sink.
- Remove sink and dispose of countertops with sink cut outs.
- Replace countertops.
- Paint hollow metal frames and walls as needed.
- Repair flooring at threshold location.
- Apply labeling to floor and signage to wall to designate restricted area around OR #2.
- Install TV Monitor.
- Install movable workstations and equipment.

Unchanged

- Firewall exists.
- HVAC ductwork and air handling system exists.
- Sprinkler system exists.
- Natural and overhead lighting exist.
- Flooring and other surfaces are appropriate for outpatient operating room.

Infrastructure Upgrades

No infrastructural upgrades are required. All utilities exist.

Project Schedule

The project will be completed in two phases and will not interrupt existing outpatient services, as the renovation work will be performed after hours and on weekends. While the renovation is anticipated to take less than 2 weeks, the project timeline from Certificate of Need approval to renovation and full utilization is 3 months, to allow for unanticipated permit, construction or equipment installation delays. Phase one will involve renovation. Phase two will include installation of equipment (i.e. microscope, phacoemulsification, other movable work stations and equipment and instruments).

9. CURRENT CAPACITY AND PROPOSED CHANGES

| Service | Unit Description | Currently Licensed/ Certified | Units to be Added or Reduced | Total Units if Project is Approved |
|-----------------------|------------------|----------------------------------|------------------------------|------------------------------------|
| ICF-MR | Beds | ___/___ | | |
| ICF-C/D | Beds | ___/___ | | |
| Residential Treatment | Beds | ___/___ | | |
| Ambulatory Surgery | Operating Rooms | 1 | +1 | 2 |
| | *Procedure Rooms | 3 | (1) | 2 |
| Home Health Agency | Counties | ___/___ | | |
| Hospice Program | Counties | ___/___ | | |
| Other (Specify) | | | | |
| TOTAL | | 4 | +1; (1) | 4 |

* While the YAG Laser Room was included on the original floor plan and approved with initial Determination it was not, at that time, recorded as a procedure room. Preparing the CON application lead CSI to consider usage of this space as a procedure room, consistent with a conversation between Penelope Williams, Consultant to CSI with MHCC's Kevin McDonald, on January 20, 2017.

This CON application entails continued use of the YAG Laser room, and conversion of an existing procedure room, presently used for storage, to use as an OR. The CON application also entails continued use of a procedure room, to use as an OR Adjunct Procedure Room for LenSx® procedures only, as part of the cataract surgery process.

10. COMMUNITY BASED SERVICES (IDENTIFY ANY COMMUNITY BASED SERVICES THAT ARE OR WILL BE OFFERED AT THE FACILITY AND EXPLAIN HOW EACH ONE WILL BE AFFECTED BY THE PROJECT.)

CSI offers a 15% discount on LenSx® laser and premium intraocular lenses for people in the military, police, firefighters, and veterans having cataract surgery. This will not change. CSI provides discounted rates and will continue to provide services at no cost or on a sliding fee scale for eligible people demonstrating financial hardship. Dr. LaBorwit provides lectures and conferences to local optometrists on various ophthalmic topics. The range of topics will expanded to reflect expanded services provided at CSI (i.e. retina and charity care).

11. REQUIRED APPROVALS AND SITE CONTROL

- A. Site size: 3,719 square feet
- B. Have all necessary State and local land use and environmental approvals, including zoning and site plan, for the project as proposed been obtained? YES X NO _____ (If NO, describe below the current status and timetable for receiving each of the necessary approvals.)

- C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

(1) Owned by: _____

(2) Options to purchase held by: _____
Please provide a copy of the purchase option as an attachment.

(3) Land Lease held by: Columbia Surgical Institute, LLC
Please provide a copy of the land lease as an attachment.

CSI's Lease Agreement is 106 pages. For the purposes of this project proposal, it will be made available in its entirety, upon request. Pages 1-4, are attached to demonstrate property address, lease period, and rental fee, and pages 25 and 26 for signature verification and date of execution (see Appendix C).

(4) Option to lease held by: _____
Please provide a copy of the option to lease as an attachment.

(5) Other: _____
Explain and provide legal documents as an attachment.

12. PROJECT

(INSTRUCTION: IN COMPLETING THE APPLICABLE OF ITEMS 10, 11 or 12, PLEASE CONSULT THE PERFORMANCE REQUIREMENT TARGET DATES SET FORTH IN COMMISSION REGULATIONS, COMAR 10.24.01.12)

For new construction or renovation projects.

Project Implementation Target Dates

- A. Obligation of Capital Expenditure 1 month from approval date
- B. Beginning Construction 1 month from capital obligation.
- C. Pre-Licensure/First Use 2 months from capital obligation.
- D. Full Utilization 3 months from first use.

For projects not involving construction or renovations.

Project Implementation Target Dates

- A. Obligation or expenditure of 51% of Capital Expenditure _____ months from CON approval date.
- B. Pre-Licensure/First Use _____ months from capital obligation.
- C. Full Utilization _____ months from first use.

For projects not involving capital expenditures.

Project Implementation Target Dates

- A. Obligation or expenditure of 51% Project Budget _____ months from CON approval date.
- B. Pre-Licensure/First Use _____ months from CON approval.
- C. Full Utilization _____ months from first use.

13. PROJECT DRAWINGS

Projects involving new construction and/or renovations should include scalable schematic drawings of the facility at least a 1/16" scale. Drawings should be completely legible and include dates.

These drawings should include the following before (existing) and after (proposed), as applicable:

- A. *Floor plans for each floor affected with all rooms labeled by purpose or function, number of beds, location of bath rooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as "shell space".*
- B. *For projects involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.*
- C. *Specify dimensions and square footage of patient rooms.*

The Original Floor Plan is noted in (Appendix A) and the Proposed Floor Plan in (Appendix B). Highlights of the project are referenced in Project Description.

14. FEATURES OF PROJECT CONSTRUCTION

- A. If the project involves new construction or renovation, complete **Tables C and D of the Hospital CON Application Package**.
See Tables C and D
- B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project and identify the provider of each utility. Specify the steps that will be necessary to obtain utilities.

All utilities currently exist.

MHCC Table C Construction Characteristics

| INSTRUCTION: If project includes non-hospital space structures (e.g., parking garages, medical office buildings, or energy plants), complete an additional Table C for each structure. | | |
|--|--|------------|
| | New Construction | Renovation |
| BASE BUILDING CHARACTERISTICS | Check if applicable | |
| Class of Construction (For renovations the class of the building being renovated)* | | |
| Class A | | ✓ |
| Class B | | |
| Class C | | |
| Class D | | |
| Type of Construction/Renovation | | |
| Low | | |
| Average | | |
| Good | | ✓ |
| Excellent | | |
| Number of Stories | | 1 |
| *As defined by Marshall Valuation Service | | |
| PROJECT SPACE | List Number of Feet, if applicable | |
| Total Square Footage | Total Square Feet | |
| First Floor | | 3,719 |
| Second Floor | | |
| Average Square Feet | | |
| Perimeter in Linear Feet | 63 feet | |
| First Floor | | |
| Second Floor | | |
| Total Linear Feet | | |
| Average Linear Feet | | |
| Wall Height (floor to eaves) | Feet | |
| First Floor | | 10 feet |
| Second Floor | | |
| Average Wall Height | | |
| OTHER COMPONENTS | | |
| Elevators | List Number | |
| Passenger | | |
| Freight | | |
| Sprinklers | Square Feet Covered | |
| Wet System | | ✓ |
| Dry System | | |
| Other | Describe Type | |
| Type of HVAC System for proposed project | Heating and supply, return and exhaust ventilation supplied by the electrical system | |
| Type of Exterior walls for proposed project | | |

MHCC Table D
Onsite and Offsite Costs Included and Excluded in Marshall Valuation Costs

Table D costs are not applicable for proposed project.

| INSTRUCTION: If project includes non-hospital space structures (e.g., parking garages, medical office buildings, or energy plants), complete an additional Table D for each structure. | | |
|---|------------------------|------------------|
| | New Construction Costs | Renovation Costs |
| SITE PREPARATION COSTS | | |
| Normal Site Preparation | | |
| Utilities from Structure to Lot Line | | |
| Subtotal included in Marshall Valuation Costs | | |
| Site Demolition Costs | | |
| Storm Drains | | |
| Rough Grading | | |
| Hillside Foundation | | |
| Paving | | |
| Exterior Signs | | |
| Landscaping | | |
| Walls | | |
| Yard Lighting | | |
| Other (<i>Specify/add rows if needed</i>) | | |
| Subtotal On-Site excluded from Marshall Valuation Costs | | |
| OFFSITE COSTS | | |
| Roads | | |
| Utilities | | |
| Jurisdictional Hook-up Fees | | |
| Other (<i>Specify/add rows if needed</i>) | | |
| Subtotal Off-Site excluded from Marshall Valuation Costs | | |
| TOTAL Estimated On-Site and Off-Site Costs <u>not</u> included in Marshall Valuation Costs | | |
| TOTAL Site and Off-Site Costs included and excluded from Marshall Valuation Service* | | |
| *The combined total site and offsite cost included and excluded from Marshall Valuation Service should typically equal the estimated site preparation cost reported in Application Part II, Project Budget (see Table E. Project Budget). If these numbers are not equal, please reconcile the numbers in an explanation in an attachment to the application. | | |

PART II - PROJECT BUDGET

TABLE E. PROJECT BUDGET

INSTRUCTION: Estimates for Capital Costs (1.a-e), Financing Costs and Other Cash Requirements (2.a-g), and Working Capital Startup Costs (3) must reflect current costs as of the date of application and include all costs for construction and renovation. Explain the basis for construction cost estimates, renovation cost estimates, contingencies, interest during construction period, and inflation in an attachment to the application. See additional instruction in the column to the right of the table.

NOTE: Inflation should only be included in the Inflation allowance line A.1.e. The value of donated land for the project should be included on Line A.1.a as a use of funds and on line B.8 as a source of funds

| | Other Structure | Total |
|--|------------------|------------------|
| A. USE OF FUNDS | | |
| 1. CAPITAL COSTS | | |
| a. Land Purchase | | \$0 |
| b. New Construction | | |
| (1) Building | | \$0 |
| (2) Fixed Equipment | | \$0 |
| (3) Site and Infrastructure | | \$0 |
| (4) Architect/Engineering Fees | | \$0 |
| (5) Permits (Building, Utilities, Etc.) | | \$0 |
| SUBTOTAL | \$0 | \$0 |
| c. Renovations | | |
| (1) Building | \$8,092 | \$8,092 |
| (2) Fixed Equipment (not included in construction) | \$3,000 | \$3,000 |
| (3) Architect/Engineering Fees | \$3,000 | \$3,000 |
| (4) Permits (Building, Utilities, Etc.) | \$100 | \$100 |
| SUBTOTAL | \$14,192 | \$14,192 |
| d. Other Capital Costs | | |
| (1) Movable Equipment | | |
| Phaco machine (Centurion) | \$60,000 | \$60,000 |
| Microscope | \$70,000 | \$70,000 |
| Additional stretcher | \$14,000 | \$14,000 |
| Other items | \$16,000 | \$16,000 |
| (2) Contingency Allowance | | |
| (3) Gross interest during construction period | | |
| (4) Other (Specify/add rows if needed) | | |
| SUBTOTAL | \$160,000 | \$160,000 |
| TOTAL CURRENT CAPITAL COSTS | \$174,192 | \$174,192 |
| e. Inflation Allowance | | \$0 |
| TOTAL CAPITAL COSTS | \$174,192 | \$174,192 |

| | | | |
|---|---|------------------|------------------|
| 2. Financing Cost and Other Cash Requirements | | | |
| a. | Loan Placement Fees | \$1,000 | \$1,000 |
| b. | Bond Discount | | \$0 |
| c. | Legal Fees | \$10,000 | \$10,000 |
| d. | Non-Legal Consultant Fees | \$7,000 | \$7,000 |
| e. | Liquidation of Existing Debt | | \$0 |
| f. | Debt Service Reserve Fund | | \$0 |
| g. | Other (Specify/add rows if needed) | | \$0 |
| SUBTOTAL | | \$18,000 | \$18,000 |
| 3. | Working Capital Startup Costs | | \$0 |
| TOTAL USES OF FUNDS | | \$192,192 | \$192,192 |
| B. Sources of Funds | | | |
| 1. | Cash | | \$0 |
| 2. | Philanthropy (to date and expected) | | \$0 |
| 3. | Authorized Bonds | | \$0 |
| 4. | Interest Income from bond proceeds listed in #3 | | \$0 |
| 5. | Mortgage | | \$0 |
| 6. | Working Capital Loans | \$192,192 | \$192,192 |
| 7. | Grants or Appropriations | | |
| a. | Federal | | \$0 |
| b. | State | | \$0 |
| c. | Local | | \$0 |
| 8. | Other (Specify/add rows if needed) | | \$0 |
| TOTAL SOURCES OF FUNDS | | \$192,192 | \$192,192 |
| Annual Lease Costs (if applicable) | | | |
| 1. | Land | | \$0 |
| 2. | Building | | \$0 |
| 3. | Major Movable Equipment | | \$0 |
| 4. | Minor Movable Equipment | | \$0 |
| 5. | Other (Specify/add rows if needed) | | \$0 |
| Describe the terms of the lease(s) below, including information on the fair market value of the item(s), and the number of years, annual cost, and the interest rate for the lease. | | | |

Note: Applicant should include a list of all assumptions and specify what is included in each budget line, as well as the source of cost estimates and the manner in which all cost estimates are derived. Explain how the budgeted amount for contingencies was determined and why the amount budgeted is adequate for the project given the nature of the project and the current stage of design (i.e., schematic, working drawings, etc.).

Renovation estimates were secured from contractor, KasCon. (Appendix D). Movable equipment (Phacoemulsification, Microscope, surgical instruments, stretchers, TV monitor,

anesthesia cabinets and other operating room supplies based on current market value.) Since the proposed project will replicate the existing OR, costs for equipment have been reviewed and negotiated with current vendors. Loan fees based on a \$192,192 loan at 4% interest over 5 years, with Howard Bank, of which CSI has a line of credit in the amount of \$250,000. (See Appendix L) The project budget is below the line of credit, which provides for contingency allowance.

PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. List names and addresses of all owners and individuals responsible for the proposed project and its implementation.

Scott LaBorwit MD, Allan Rutzen, MD

2. Are the applicant, owners, or the responsible persons listed in response to Part 1, questions 2, 3, 4, 7, and 9 above now involved, or have they ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of these facilities, including facility name, address, and dates of involvement.

Scott LaBorwit:

Baltimore Eye Surgical Center - 2007-Present
6231 North Charles Street
Baltimore, MD 21212

Dulaney Eye Institute - 2002-2007
901 Dulaney Valley Rd # 220,
Towson, MD 21204

3. Has the Maryland license or certification of the applicant facility, or any of the facilities listed in response to Question 2, above, been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant, owners or individuals responsible for implementation of the Project were not involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.

No

4. Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) received inquiries in last from 10 years from any federal or state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with any state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.


No

5. Have the applicant, owners or responsible individuals listed in response to Part 1, questions 2, 3, 4, 7, and 9, above, ever pled guilty to or been convicted of a criminal offense in any way connected with the ownership, development or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).

No

One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project that is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the proposed or existing facility.

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information and belief.



Signature of Owner or Board-designated
Official
Principal Partner

Position/Title
Scott LaBorwit, MD

Printed Name

Date: January 20, 2017

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR

10.24.01.08G(3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G(3), listed below.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards and other review criteria.

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and to the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G(3)(a). The State Health Plan.

Every applicant must address each applicable standard in the chapter of the State Health Plan for Facilities and Services¹. Commission staff can help guide applicants to the chapter(s) that applies to a particular proposal. Please provide a direct, concise response explaining the project's consistency with each standard. Some standards require specific documentation (e.g., policies, certifications) which should be included within the application as an exhibit.

SURGERY Standards

10.24.11.05 A. General Standards.

The following general standards encompass Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health General §19-114 (d). Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application.

Standard .05(A)(1) Information Regarding Charges.

Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

CSI provides upon inquiry or as required information concerning charges for the full range of surgical services provided. See Appendix E for CSI's facility fee.

Standard .05(A)(2) Charity Care Policy.

a) Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons

¹ [1] Copies of all applicable State Health Plan chapters are available from the Commission and are available on the Commission's web site here: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp

consistent with this policy. The policy shall have the following provisions

(i) *Determination of Eligibility for Charity Care.* Within two business days following a patient's request for charity care services, application for medical assistance, or both, the facility shall make a determination of probable eligibility.

(ii) *Notice of Charity Care Policy.* Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the surgical facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, facilities should address any financial concerns of patients, and individual notice regarding the facility's charity care policy shall be provided.

(iii) *Criteria for Eligibility.* Hospitals shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. ASFs, at a minimum, must include the following eligibility criteria in charity care policies. Persons with family income below 100 percent of the current federal poverty guideline who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge. At a minimum, persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ASFs described in these regulations.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

(c) A proposal to establish or expand an ASF for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:

(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and

(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.

(iii) If an existing ASF has not met the expected level of charity care for the two most recent years reported to MHCC, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the service area population.

(d) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project,

shall commit to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:

- (i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and
- (ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.
- (iii) If the health maintenance organization's track record is not consistent with the expected level for the population in the proposed service area, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the population in the proposed service area.

Charity Care

Historically, CSI demonstrates a commitment to providing surgical and non-surgical services at reduced fees or bill forgiveness to people with financial hardship. For the most recent two years reported, CSI estimates charitable services provided exceed the amount of commitment required for determination of coverage by Certificate of Need. CSI estimates \$21,225 in charity services provided in 2015 and \$38,035 in 2016. According to MHCC staff, during the pre-application meeting, and confirmed by email (Kevin McDonald to Penelope Williams, 11/21/16), the statewide charity care benchmark for ASFs is 0.52%. CSI's charity contributions exceeded the statewide commitment as follows:

| | | |
|-----------|-------------------------------------|-------------------|
| Year 2015 | $\$1,689,370 \times 0.52 = \$8,785$ | Provided \$21,225 |
| Year 2016 | $\$1,905,098 \times 0.52 = \$9,907$ | Provided \$38,035 |

CSI commits to not only meeting but also exceeding the minimum requirement. Charity care contributions for projected years, as noted below, translate to approximately 20 cataract cases per year.

| | 2017 | 2018 | 2019 | 2020 |
|------------------------------------|-----------|-----------|-----------|-----------|
| Projected Expense | 2,758,013 | 3,230,600 | 3,492,683 | 3,788,513 |
| Minimum Charity Care Commitment | 0.52% | 0.52% | 0.52% | 0.52% |
| Minimum Charity Care Amount | 14,342 | 16,799 | 18,162 | 19,700 |
| CSI Target Charity Care Commitment | 1.11% | 0.95% | 0.88% | 0.81% |
| Target Charity Care Amount | 30,600 | 30,600 | 30,600 | 30,600 |

While not under MHCC’s definition of “charity care”, or included in the estimate above, it is worth noting other CSI advocacy efforts, on behalf of all people, to ensure reasonable and cost effective treatment.

1. Dr. LaBorwit routinely administers medications directly in the eye, intra-operatively, (during surgery). This practice of medication administration eliminates or in some cases minimizes the need for prescribed post-operative eye drops used routinely by many ophthalmologists. The positive impact on patient care is an eight-fold reduction in risk for infection and a patient cost savings of \$200-300/per eye for cataract surgery. Having performed 787 cases in 2016, this translates to a savings of \$157,400 - \$236,100.
2. CSI provides a 15% discount on intraocular premium lenses and LenSx® (for cataract surgery) to people in the military, firefighters, veterans, and police.
3. CSI works with suppliers to secure discounted or in-kind (donated) lenses, surgical supply kits, or devices for persons who demonstrate financial hardship.
4. CSI’s anesthesia providers discount or provide at no charge for anesthesia services to persons who demonstrate financial hardship.
5. CSI reduces the cataract facility rate \$1,500 to \$900 for people electing self-pay.

CSI has a written Financial Assistance policy and program. The policy ensures persons that demonstrate financial hardship receive information about the program and offered assistance with completing the application. At minimum, persons with family income below 100% of the current

federal poverty level with no health insurance coverage and are not eligible for public programs providing coverage for medical expenses receive services free of charge. Persons above 100% of the poverty level but less than 200% will receive discounted services based on a sliding fee scale. Persons above 200%, that demonstrated financial hardship will be considered on a case by case basis.

To promote the program, CSI builds relationships with community agencies and organizations in Howard and Anne Arundel Counties, where slightly more than 70% of the patient population resides. Personal contact and follow up correspondence is provided to Howard County Community Partnership Services, Housing Commission and social services. The next available publication for including CSI in the *Howard County Resource - Guide For Aging Adults, Persons with Disabilities and Caregivers*, is October 2017. Therefore, CSI connected with key staff to distribute information about the program to county case managers and social workers who have direct contact with the target population. For Anne Arundel County, information about the program is shared with public health nursing program personnel. Outreach is also directed toward faith-based organizations. For other service area outreach, associates physicians with CSI have their practices around the service area. This casts a wide net for reaching persons living in areas with higher poverty levels. In December 2016, optometry practices that refer persons to CSI ophthalmologists received correspondence, promoting the program and informing them on how to access more information. Outreach effort through mailings and presentations is ongoing. Public notice and information regarding CSI's financial assistance program is provided on the CSI website (<http://www.columbia-surgical.com>) and also displayed at the reception desk.

The assessment for financial need is facilitated prior to a patient's arrival for surgery and in many cases identified at the physician's office during a routine eye exam. Assessment for need might also be identified by staff, in the associate's offices, since this is where the patient first learns about the need for surgery and anticipated costs. Whether received prior to surgery or identified at time of surgery, CSI makes a determination of probable eligibility within 2 business days following the patient's request for charity care services.

Standard .05(A)(3) Quality of Care.

A facility providing surgical services shall provide high quality care.

- (a) *An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health and Mental Hygiene.*

CSI is in good standing with Maryland Department of Health and Mental Hygiene. The current certification is represented as Appendix G.

(b) *A hospital shall document that it is accredited by the Joint Commission.*

(c) *An existing ambulatory surgical facility shall document that it is:*

(i) *In compliance with the conditions of participation of the Medicare and Medicaid programs; and*

CSI is in good standing with Centers for Medicare and secured a provider number July 1, 2013.

(ii) *Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification.*

CSI is in good standing with AAAASF. The current certification is represented as Appendix H.

(d) *A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will:*

(i) *Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment.*

(ii) *Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.*

Standard .05(A)(4) Transfer Agreements.

(a) *Each ASF and hospital shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital.*

(b) *Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene regulations implementing the requirements of Health-General Article §19-308.2.*

CSI has a written transfer agreement, compliant with DHMH regulations, with Howard County Hospital. A copy of the transfer agreement is attached at Appendix I.

(c) *Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.*

CSI has a written emergency transfer policy compliant with DHMH regulations, with Howard County Hospital. In an emergency the 911 call center is contacted and medical staff care for the

patient until rescue responders arrive..

10.24.11.05B. Project Review Standards.

The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards.

Standard .05B(1) Service Area.

An applicant proposing to establish a new hospital providing surgical services or a new ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.

The service area for CSI is within Baltimore and suburban Washington regions; Anne Arundel County, Baltimore City, Baltimore County, Frederick County, Howard County, Montgomery County, Prince George’s County, with 70% of patients located in Howard and Anne Arundel Counties. A list of zip codes representing the service area by county is noted in Exhibit A and a comprehensive list of service area zip codes is included as Appendix J. CSI anticipates the projected service area to remain reasonably consistent.

Exhibit A
CSI Service Area

| County | Service Area Zip Codes |
|------------------------|--|
| Anne Arundel | 21122, 21061, 21146, 21060, 21144, 21012, 21108, 21225, 21076, 21401, 21090, 21113, 20724, 21037, 21403, 21114 |
| Baltimore City | 21229, 21230, 21212, 21214 |
| Baltimore County | 21228, 21227, 21208, 21234, 21117, 21093, 21163, 21222, 21236, 21133, 21136 |
| Frederick | 217,69, 21701, 21702, 21773, 21776, 21771, 21787 |
| Howard County | 20723, 21042, 21043, 21044, 21045, 21046, 21075, 21029, 20759, 21794, 20777, 21738, 20794, 21041 |
| Montgomery County | 20832, 20853, 20866, 20905, 20872, 20906, 20904 |
| Prince George’s County | 20705, 20707, 20708 |

Source: CSI patient database

Standard .05B(2) Need - Minimum Utilization for Establishment of a New or Replacement Facility.

This standard does not apply. See .05B(3) below.

Standard .05B(3) Need - Minimum Utilization for Expansion of An Existing Facility.

An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall:

- (a) Demonstrate the need for each proposed additional operating room, utilizing the operating room capacity assumptions and other guidance included at Regulation .06 of this Chapter;
- (b) Demonstrate that its existing operating rooms were utilized at optimal capacity in the most recent 12-month period for which data has been reported to the Health Services Cost Review Commission or to the Maryland Health Care Commission; and
- (c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity. The needs assessment shall include the following:
 - (i) Historic trends in the use of surgical facilities at the existing facility;
 - (ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and
 - (iii) Projected cases to be performed in each proposed additional operating room.

Historic utilization patterns (Exhibit B) continue to trend upwards as a result of organic growth and strategic planning efforts described further in the project response to 10.24.01.08G(3)(b). In 2016 OR case volume total was 1,663. The average OR time was 28 minutes with an average turn around time of 26 minutes. This calculates the need for .92 ORs. Utilizing the operating room capacity assumptions as outlined in COMAR 10.24.11.06A, CSI assumes “any fractional need for operating room will be rounded up to the nearest whole number” thus putting CSI at optimal capacity, (80% of full capacity or 1,632 per OR per year), as in Exhibit C.

Exhibit B
Historic OR Trends By Surgeon

| | Specialty | 2013 | 2014 | 2015 | 2016 |
|-------------|-------------------|-------------|-------------|-------------|-------------|
| Kalyani | Cataracts | 35 | 14 | 0 | 0 |
| LaBorwit | Cataract/Glaucoma | 363 | 817 | 825 | 830 |
| Lima | Oculoplastics | 2 | 42 | 16 | 65 |
| Rutzen | Cataract/Cornea | 103 | 327 | 361 | 329 |
| Lui | Cataract | | 50 | 151 | 234 |
| Schor | Glaucoma | | 1 | 28 | 18 |
| Bernfeld | Cataract/Cornea | | | 27 | 40 |
| Wray | Cataract | | | 22 | 37 |
| Hanna | Cataract | | | | 57 |
| Heffez | Retina | | | | 30 |
| Ali | Cataract/Glaucoma | | | | 21 |
| Salvo | Cataract | | | | 2 |
| Chan | Cataract/Glaucoma | | | | |
| Goel | Cataract | | | | |
| Syed | Retina | | | | |
| Swamy | Cataract/Glaucoma | | | | |
| Total Cases | | 503 | 1,251 | 1,430 | 1,663 |

Exhibit C
Current Operating Room Time Required

| | |
|---|--------|
| Total Cases 2016 | 1,663 |
| Average Surgery Minutes | 28 |
| Total Surgery Minutes | 46,564 |
| Average Turn Around Time in minutes per case | 26 |
| Total Turn Around Time in Minutes | 43,238 |
| Total Operating Room and Turn Around Time minutes | 89,802 |
| *Optimal Operating Room Capacity (80%) | 97,920 |
| Needed Operating Rooms (Utilization = .92, rounded to nearest whole number Source: COMAR 10.24.11 .06 (2)(d)) | 1.0 |

Source: CSI Case and Procedure Records

CSI acknowledges COMAR 10.24.11.06D *Operating Room Inventory Assumptions*, specifically paragraph (3), and requests review and consideration for the impact LenSx® technology has on cataract surgery and overall OR utilization. LenSx®, is not an independent procedure (as described in further detail in .08G(3)(b) Need), and is the first step taken during the cataract procedure when the surgery is scheduled as laser assisted. In 2016, 58% of all CSI cataract cases were laser assisted using LenSx® technology. This has significant impact on OR utilization since the OR is held open and unavailable, until the laser portion of the procedure is performed and the patient is transferred directly to the OR to complete the remaining steps. The average 10 minutes to perform LenSx® increases the total OR time required for each laser assisted cataract case. Since cataracts make up approximately 87% of all OR cases by type, the 2016 utilization, adjusted for LenSx® is 1.26 and projected 1.95 by 2019. See details in Exhibit D below.

It is important to note that the LenSx® procedure room functions exclusively as an adjunct to the OR in which cataract procedures are performed. The proposed floor plan is labeled “adjunct” because the procedure is not performed independently and the procedure room is not used separately, for other procedures. While performed in the procedure room as a clean procedure with sterile single use supplies, it is possible to perform LenSx® in a sterile environment. Regardless of environment, strict infection control standards are maintained knowing the patient will transfer directly to the operating room. Also, the semi-restricted corridor through which patients pass from the LenSx® room to the OR is not, nor required to be sterile. The LenSx® room will continue to be

used exclusively for LenSx® procedures, and will not be used separately, for other procedures, for which fees are billed.

Exhibit D
Utilization Adjusted for LenSx®

| | OR Utilization 2016 | Adjusted to include 2016 LenSx® | Projected OR Utilization 2019 | Adjusted to include LenSx® 2019 |
|---|------------------------|---|-------------------------------------|---|
| Total Cases 2016 | 1,663 | 831 | 3,175 | 1,960 |
| Average Surgery Minutes | 28 | 10 | 31 | 10 |
| Total Surgery Minutes | 46,564 | 8,310 | 98,423 | 19,600 |
| Average Turn Around Time in minutes per case | 26 | Inclusive with Average Surgery Minutes | 23 | Inclusive with Average Surgery Minutes |
| Total Turn Around Time in Minutes | 43,238 | | 73,024 | |
| Total Operating Room and Turn Around Time minutes | 89,802 | 98,112 | 171,447 | 191,047 |
| *Optimal Operating Room Capacity (80%) | 97,920 | | 97,920 | |
| Needed Operating Rooms (Utilization = .92, rounded to nearest whole number Source: COMAR 10.24.11 .06 (2)(d)) | 1.0 | 1.26 | 1.75 | 1.95 |

CSI ophthalmologists have their physician practice in a number of locations throughout the service area. Practices include:

- Kalyani Eye
- Select Eye Care
- Medical Eye Center
- Rutzen Eye Center
- Annapolis Eye Consultants
- Retina Consultants
- Maryland Glaucoma and Eye Care
- Maryland Retina
- University of Maryland Medical Center

Since the first surgery in 2013, CSI's volume has steadily increased along with the number of associates. With two original partners and two associates in 2013, eight associates joined the facility by 2015 and an additional four joined at the end of 2016. CSI's original two partners and one original associate (LaBorwit, Rutzen and Lima) anticipate increased case volumes. Kalyani, who performed 49 cases between 2013 and 2016, remains credentialed, however, chose to move his volume to a different facility. Bernfeld and Schor will not remain credentialed. Bernfeld shifted his case volume to a facility closer to their practice and Schor, a consulting physician, returned to his

practice in Bethesda. While many associates will retain credentialing with other ASF's to support their growing practices and serve patients where they reside, each has reviewed and affirmed their projected volume. Exhibit E illustrates projected case volume by 2021. Growth rates of 46%, 20%, 9%, 9% and 7% are projected for years 2017-2021.

Exhibit E
Projected Case Volume by Associate, 2017-2021

| | 2017 | 2018 | 2019 | 2020 | 2021 |
|-------------|-------|-------|-------|-------|-------|
| Kalyani | 0 | 0 | 0 | 0 | 0 |
| LaBorwit | 872 | 915 | 961 | 1009 | 1059 |
| Lima | 130 | 137 | 143 | 150 | 158 |
| Rutzen | 362 | 398 | 438 | 482 | 530 |
| Lui | 281 | 309 | 340 | 374 | 411 |
| Schor | | | | | |
| Bernfeld | | | | | |
| Wray | 60 | 66 | 73 | 80 | 84 |
| Hanna | 114 | 137 | 150 | 166 | 174 |
| Heffez | 36 | 60 | 84 | 108 | 132 |
| Ali | 144 | 288 | 317 | 348 | 366 |
| Chan | 144 | 158 | 174 | 192 | 201 |
| Goel | 156 | 192 | 211 | 232 | 244 |
| Syed | 60 | 120 | 132 | 145 | 152 |
| Swamy | 24 | 42 | 46 | 51 | 53 |
| Salvo | 48 | 96 | 106 | 116 | 122 |
| Total Cases | 2,431 | 2,918 | 3,175 | 3,453 | 3,686 |

Assumed growth rates are based on compound annual growth rate.

Standard .05B(4) Design Requirements.

Floor plans submitted by an applicant must be consistent with the current FGI Guidelines.

(b) An ASF shall meet the requirements in Section 3.7 of the FGI Guidelines.

CSI meets the requirements noted in Section 3.7 of the 2014 FGI Guidelines found in Appendix K.

(c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.

Design features are not at variance.

Standard .05B(5) Support Services.

Each applicant shall agree to provide as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services.

CSI maintains current Clinical Laboratory Improvement Amendments (CLIA) waiver for eligible tests that can be performed in a facility, (i.e. pregnancy tests). All other laboratory testing performed on tissue samples are provided by qualified laboratory facilities (LabQuest and LabCorp). Radiology procedures are not performed at CSI.

Standard .05B(6) Patient Safety.

The design of surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:

- (a) Document the manner in which the planning of the project took patient safety into account; and*
- (b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities;*

The CSI facility was built in 2012 to ensure provision of safe patient care, to comply with local and state building codes, and to comply with NFPA 101-Life Safety Code. The facility met all local, state and federal requirements for State licensure, Medicare certification and AAAASF accreditation. The same attention to detail applies to the project renovation to ensure compliance with all requirements for life and fire safety, infection control, quality assessment and improvement, patient transfer, credentialing, and medical record keeping. Surgeons, anesthesiologists, OR nurses and technologists with knowledge and experience with the facility and procedures were consulted regarding a list of fixed and mobile equipment. While the full listing of safety features related to the project would be extensive, many included in the design are as follows:

Environment

- Room size meet requirements to allow for the presence of all equipment and personnel necessary for the performance of the surgical procedure. A minimum required 4 feet (48 inches) of clear space on each side of the operating room table to accommodate emergency personnel and equipment in case of emergency.
- Wall plugs are sufficient to prevent overloading and with ground fault interrupters are used to prevent an electric shock.
- Ventilation and filtration system to restrict air movement in and between the various departments and reduce airborne micro-organisms and cross contamination. HVAC includes dedicated thermostat in the room to monitor adequate temperature and humidity of the room to accommodate for patient comfort and provide accurate control of environmental conditions. Heating and supply, return and exhaust ventilation in the OR supplied by the electrical system has back up generator available within 30 seconds.

- Pre-existing hand washing sink is located in the semi-restricted corridor, near the operating room and alcohol rub (hand sanitizer) dispenser is located inside the operating room and immediately outside of the operating room door, compliant with Centers for Disease Control guidelines for hand hygiene.
- Natural lighting exists in the operating room exists. Additional and adequate lighting is installed in the ceiling for optimal visibility.
- Unauthorized individuals are deterred from entering the operating room suite by signs, locks or facility personnel. Signage includes indication for proper protective attire.

Storage

- Sterile supplies are stored in wall mounted cabinets and drawers away from heavy traffic areas and potential contamination.

Surfaces

- Surfaces are constructed from material that can easily be cleaned and decontaminated.
- Operating room ceiling surface is smooth and washable to free particulate matter that could contaminate the operating room.
- Operating floor and sterile corridor are seamless and free from obstacles and fall risks.

Sterilization and Instrument Processing

- There is strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.
- The instrument preparation and assembly area (clean utility area) is separated by walls from the instrument cleaning area (dirty utility area) Dirty instruments are removed from the operating suite and clean instruments are returned through separate doors to prevent risk of contamination.
- Source oxygen and suction is present for routine and emergency needs.

Emergency Power

- Emergency power source generator is available with ample power to operate essential electrical equipment used in the operating room within 30 seconds of a power failure.

Medical Hazardous Waste

- Hazardous material waste is stored in Occupational Safety and Health Act (OSHA) acceptable container and separated from general refuse.
- Puncture resistant sharps containers are located close to the area in which they are used by the circulating nurse and anesthesiologist ensuring safe disposal.

Standard .05B(7) Construction Costs.

The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

Part (a) of this standard is not applicable to CSI. See part (b).

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors.

The project building cost information is compared to the benchmark cost of good quality Class A construction using the current Marshall & Swift/Boeckh (formerly Marshall & Swift) Valuation (see Exhibit F). The valuation was calculated using an online service, CoreLogic® provider of Marshall & Swift cost estimating for commercial property. The calculation considered updated multipliers (auto-calculated by the program) based on site terrain, building levels, and geographic locality. Other relevant components were factored such as type of occupancy (ASF) and systems (HVAC and sprinklers). Analysis of the project construction cost per square foot compared with the Marshall & Swift Valuation demonstrates the projected cost per square foot is conservative and does not exceed the reasonableness of construction cost as referenced in State Health Plan.

Source: www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=9446426

Source: www.corelogic.com/products/marshall-swift-valuation-service.aspx

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.

Exhibit F
Marshall & Swift Valuation

| | |
|---|----------------------------|
| Section I - Area | |
| Area | 3,719 |
| Building Stories | 1 |
| Shape | Rectangular |
| Perimeter | CoreLogic® calculated |
| Multiplier | CoreLogic® calculated |
| Section II - Occupancy and Systems | |
| Occupancy | Outpatient Surgical Center |
| Class | A |
| Ceiling Height | 10 Feet |
| Quality | Good |
| HVAC | Electric |
| Sprinkler | Wet Sprinkler |
| Section III - Calculation All Sections | |
| Basic Structure | |
| Base Cost | \$302.62 |
| Exterior Walls | \$33.10 |
| Heating & Cooling | \$6.95 |
| Sprinklers | \$5.03 |
| Basic Structure Cost | \$347.70 |

Project Renovation Cost

| Base Calculation | Actual | Per Square Foot |
|-----------------------------------|----------|-----------------|
| Building | \$8,092 | \$29.42 |
| Fixed Equipment | \$3000 | \$10.90 |
| Site Preparation | \$0 | \$0.00 |
| Architectural Fees | \$3,000 | \$10.90 |
| Capitalized Construction Interest | \$0 | \$0.00 |
| Permits | \$100 | \$0.36 |
| Subtotal | \$14,192 | \$51.61 |

Comparison (in Square Feet)

| | |
|--------------------------------------|----------|
| Project | \$ 51.61 |
| Marshall & Swift Valuation Benchmark | \$347.70 |

CSI's project costs are below the Marshall & Swift Benchmark.

Standard .05B(8) Financial Feasibility.

A surgical facility project shall be financially feasible. Financial projections filed as part of an application that includes the establishment or expansion of surgical facilities and services shall be accompanied by a statement containing each assumption used to develop the projections.

(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the likely service area population of the facility;

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant facility or, if a new facility, the recent experience of similar facilities;

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities; and

(iv) The facility will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

(b) A project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project may be approved upon demonstration that overall facility financial performance will be positive and that the services will benefit the facility's primary service area population.

Utilization projections are consistent with historic trends in use of the applicable service by the likely service area population of the facility. Revenue estimates are consistent with utilization projections and based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity provision. Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels are experienced by CSI. MHCC Table 1 projects that volumes will continue to grow and projected revenues over total expenses demonstrate profitability.

Standard .05B(9) Preference in Comparative Reviews.

In the case of a comparative review of CON applications to establish an ambulatory surgical facility or provide surgical services, preference will be given to a project that commits to serve a larger proportion of charity care and Medicaid patients. Applicants' commitment to provide charity care will be evaluated based on their past record of providing such care and their proposed outreach strategies for meeting their projected levels of charity care.

This standard is not applicable.

10.24.01.08G(3)(b). Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

INSTRUCTIONS: Please discuss the need of the population served or to be served by the Project.

Responses should include a quantitative analysis that, at a minimum, describes the Project's expected service area, population size, characteristics, and projected growth. If the relevant chapter of the State Health Plan includes a need standard or need projection methodology, please reference/address it in your response. For applications proposing to address the need of special population groups, please specifically identify those populations that are underserved and describe how this Project will address their needs.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. List all assumptions made in the need analysis regarding demand for services, utilization rate(s), and the relevant population, and provide information supporting the validity of the assumptions.

Project Drivers

Operational Challenges. Ocular surgery (eye surgery) is unique in that immediate post-operative (the first 24-36 hours following surgery) it is imperative for a patient to be seen by the surgeon and assessed for any number of infections or complications such as ocular hypertension (increased eye pressure) and assure the position of implants (intraocular lens following cataract, shunt following glaucoma; or cornea in transplant) are in place and have not dislocated as a direct or indirect result of patient compliance. This immediate post-operative care meets the standards of practice recommended by professional ophthalmology associations such as American Academy of Ophthalmology, American Optometric Association, and Outpatient Ophthalmic Surgery Society. Immediate follow-up is especially important when the patient has co-existing medical conditions that make them more vulnerable to complications. With patient safety at the forefront, ophthalmologists typically do not schedule surgery on Fridays or when the immediate post-operative day falls on a holiday. This constraint challenges surgeons to find available operating room time Monday through Thursday. With this schedule, it is not uncommon for CSI to extend daily business hours to accommodate the case volume.

Source: American Optometric Association, Care of the Adult Patient with Cataract, www.aoa.org/documents/optometrists/CPG-8.pdf

Gap in Retina Providers. Retina surgery is performed to treat conditions and diseases that affect the back of the eye and CSI’s position as the sole provider (ASF or Hospital) in Howard County is invaluable to those requiring treatment. The project would provide for current and projected case volume and create the opportunity to fill a gap in Howard County in which capacity and competency to perform retina surgery is available.

One of several types of retina surgery performed at CSI is repair for retinal detachment. While most retinal detachments do not require emergency surgery, there are circumstances that present as urgent. When this is the case, surgery should not be delayed to prevent risk of permanent vision loss. Some urgent cases occur immediately following a routine doctors appointment or following complex cataract surgery. The project provides the opportunity to add urgent retina cases to the schedule.

Retinal surgery was historically a 1-2 hours procedure performed in a hospital, requiring a specialist, complex instruments and general anesthesia. Advanced technology has dramatically changed the way retinal surgery is done and surgeons are moving their cases away from hospitals that are challenged to keep pace with advancing technology and retaining specialists. CSI has the latest technology available for retina surgery in the Constellation® Vision System. While other ophthalmologists identified in CSI’s service area (Exhibit G) have similar technology, most facilities are an average 31 miles from CSI.

Exhibit G
Constellation® Vision System Distribution

| Maryland Counties Served | Facility |
|--------------------------|---|
| Anne Arundel | Anne Arundel Medical Center |
| Baltimore City | Wilmer Eye Institute, Sinai Hospital, University of Maryland Midtown, VA Baltimore |
| Baltimore County | Greater Baltimore Medical Center, Dulaney Eye Institute, Timonium Surgery Center, Kaiser Baltimore |
| Howard County | Columbia Surgical Institute |
| Montgomery County | Friendship ASC, Palisades Eye Surgery Center, Montgomery Surgery Center, Suburban Hospital, Kaiser Kensington, National Naval Medical Center, National Institutes of Health |

Source: CSI partners, associates, and supply vendors assisted to generate this list.

In addition to advanced technology, pricing has shifted where retina procedures are performed. While accessing retina procedure cost estimates for service area facilities was difficult to locate, the 2014 Medicare national average reimbursement rate for retina macular pucker performed at an ASC is \$1,663.54, and the national average reimbursement in a hospital outpatient department is \$3,060.33. Medicare reimbursement for a macular pucker performed at CSI is \$962.75, below the

current hospital rate. As Medicare reimbursement rates continue to fall and reimbursement reform continues on local and national levels, surgeons will continue to shift retina cases to the ASF.

Source: ophthalmologymanagement.com/supplements/2014/august-2014/the-ophthalmic-asc/adding-retina-to-an-asc

The limitations with one operating room prevent CSI from maximizing the potential for surgical case mix. Before performing retinal surgery, technicians must first clean and disinfect all surfaces, remove equipment and instruments specific to other ophthalmic procedure types and re-set the room with equipment and instruments specific to retina surgery. These include install and set up of Constellation® Vision System, adjust of the microscope to new procedure specifications; prepare case appropriate medication treatments; and align the surgical support team. Room turn around time from other ophthalmic procedure types to retinal ranges from 40 – 60 minutes. Changing equipment means the continuous movement of sensitive and precisely calibrated machinery, risking its ability to perform optimally. Damage to the equipment could pose serious and unnecessary delays in delivering quality patient care and incur repair costs. Unanticipated case cancellations result in lost time and missed income.

Dr. Hefez joined CSI as a retinal specialist in 2016, performing 30 procedures and blocking approximately 3,000 OR minutes, (including turn around time). Dr. Hefez anticipates performing an additional 288 cases minimum, by 2020. A second retinal specialist, Dr. Syed, joined CSI in late 2016 and is projected to perform minimum 123 cases by 2020. Considering CSI's current level of capacity, there would not be sufficient OR time for Drs. Hefez and Syed to provide needed retinal services or expand their practices. The project would provide the opportunity to permanently locate Constellation® Vision System and other retina related supplies and equipment in the new OR, permit scheduling the more lengthy and complicated retina cases without loss of OR time for other cases, permit more timely response to urgent retina cases and prevent treatment delays and unnecessary travel frustration for many patients.

Advanced Technology. As discussed previously in Standard .05B(3), LenSx® is groundbreaking femtosecond laser technology specifically for and used in conjunction with cataract surgery. This technology is approved by the U.S. Food and Drug Administration (FDA) for corneal incisions, capsulotomy and lens fragmentation in cataract surgery. Essentially, this procedure makes the perfect opening in the eye lens, without the need for surgical blades. Another feature is the ability to make laser incisions to correct astigmatism. LenSx®, a component of cataract surgery, is performed in the procedure room, as a clean procedure with sterile single use supplies. However, it is possible to perform LenSx® in a sterile environment. Regardless of environment, strict infection control

standards are maintained knowing the patient will transfer directly to the operating room. In terms of quality patient care, locating LenSx® in close proximity to the OR provides for continuous patient monitoring thereby optimizing their level of comfort during the process.

Laser assisted surgery is optional for patients and is currently not reimbursed by insurance payers or Medicare. Surgeons recommend LenSx® because they believe the incision precision and increased recovery time improve the safety of the surgery, critical for the delivery of quality patient care.

To CSI’s knowledge, nine providers in the service area use LenSx® technology. None of the providers include hospitals.

Exhibit H
LenSx® Distribution

| Maryland Counties Served | Facility |
|--------------------------|---|
| Anne Arundel | Chesapeake Eye Surgery Center, Baltimore Washington Eye |
| Baltimore City | Wilmer Eye Institute |
| Baltimore County | Baltimore Eye Surgical Center, Dulaney Eye Institute |
| Howard County | Snowden Surgery Center, Columbia Surgical Institute |
| Montgomery County | The Eye Surgery Center, Friendship ASC |

Source: CSI partners, associates, and supply vendors assisted to generate this list.

Using LenSx® technology impacts OR utilization since the OR is held open and unavailable, until the laser portion of the procedure is performed and the patient is transferred directly from the Adjunct OR Procedure Room LenSx® to the OR to complete the remaining steps of the cataract procedure. The average 10 minutes to perform LenSx® increases the total OR time required for each cataract laser assisted case. Since cataracts make up approximately 87% of all OR cases by type, the 2016 utilization, adjusted for LenSx® is 1.26 and projected 1.95 by 2019. Refer to Exhibit D, in Standard .05B(3). CSI’s LenSx® case volume projections are expected to double between 2016 and 2019.

Demand for Ophthalmologists with Aging Population. By 2030, more than 72 million people will be over 65 years of age and the population growth of those older than 85 years is a fast-growing segment.¹ In 2014, *An Aging Nation*, released by the U.S. Census Bureau, indicated Americans are living longer. While many are living healthier lives, advanced age is associated with an increased risk for a number of medical conditions, related to the eye, that include; cataract, glaucoma, macular degeneration, and retinopathy. All of these conditions rank as leading causes of loss of vision or blindness. Exhibit I illustrates population growth of people ages 65 years and over between the years 2010 and 2015, in CSI’s primary and secondary service area.

Exhibit I
Percent of Population Ages 65 and Over

| Maryland Counties Served | 2010 | 2015 | Percent Change |
|--------------------------|------|------|----------------|
| Anne Arundel | 11.8 | 13.7 | 16.1 |
| Baltimore City | 11.7 | 12.5 | 6.8 |
| Baltimore County | 14.6 | 16.1 | 10.3 |
| Carroll County | 13.0 | 15.8 | 21.5 |
| Frederick County | 11.1 | 13.3 | 19.8 |
| Hartford County | 14.6 | 15.9 | 8.9 |
| Howard County | 10.1 | 12.7 | 25.7 |
| Montgomery County | 12.3 | 14.1 | 14.6 |
| Prince George's County | 9.4 | 11.7 | 24.5 |
| Queen Anne's County | 14.9 | 17.8 | 19.5 |

Source: U.S. Census Bureau at census.gov

Strategic Objectives. CSI has developed strategic objectives for meeting patient needs within the region. Strategies for achieving these objectives include advancing clinical excellence and achieving accelerated growth in ophthalmology and surgery in both capacity and capability. CSI will add a minimum four associates by the end of 2016, with active case volume available as early as January 1, 2017. With a minimum thirteen associates credentialed, case volume projections as noted previously are anticipated to increase by more than 100% from 2016 to 2020.

Finally, expansion of CSI is vital to the implementation of their strategic objectives in the following ways:

- Responding to the health care needs of the aging population in their service area.
- Having the capacity and capability to accept new patients.
- Filling a gap in Howard County by being the only provider, ASF or hospital, with capacity to perform retina surgery.
- Having a direct impact on the nations public health goals for Healthy People 2020 Vision for diabetic retinopathy, glaucoma, cataract, and age-related macular degeneration (AMD).
- Welcoming uninsured and underinsured patients.
- Maintaining cutting edge technology and innovative approaches to eye surgery.
- Providing cost effective methods and treatments for optimizing quality patient care for those with compromised vision or vision loss.

Complete Tables 1 and/or 2 below, as applies.

[(INSTRUCTION: Complete Table 1 for the Entire Facility, including the proposed project, and Table 2 for the proposed project only using the space provided on the following pages. Only existing facility applicants should complete Table 1. All Applicants should complete Table 2. Please indicate on the Table if the reporting period is Calendar Year (CY) or Fiscal Year (FY)]

TABLE 1: STATISTICAL PROJECTIONS - ENTIRE FACILITY

| CY or FY (Circle) | Two Most Actual Ended Recent Years | | Current Year Projected | Projected Years (ending with first full year at full utilization) | | | |
|---------------------------------------|------------------------------------|--------|------------------------|---|--------|--------|---------|
| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
| Ambulatory Surgical Facilities | | | | | | | |
| a. Number of operating rooms (ORs) | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
| • Total Procedures in ORs | 1,262 | 1,441 | 1,739 | 2,648 | 3,181 | 3,460 | 3,763 |
| • Total Cases in ORs | 1,251 | 1,430 | 1,663 | 2,430 | 2,919 | 3,175 | 3,453 |
| • Total Surgical Minutes in ORs** | 32,526 | 37,180 | 46,564 | 75,336 | 90,450 | 98,423 | 107,038 |
| b. Number of Procedure Rooms (PRs) | 2 | 2 | 2 | 1 | 1 | 1 | 1 |
| • Total Procedures in PRs (LenSx) *** | 711 | 820 | 831 | 1580 | 1817 | 1960 | 2111 |
| • Total Cases in PRs | 711 | 820 | 831 | 1580 | 1817 | 1960 | 2111 |
| • Total Minutes in PRs** | 7110 | 8,200 | 8,310 | 15,800 | 18,170 | 19,600 | 21,110 |

*Number of beds and occupancy percentage should be reported on the basis of licensed beds.

**Do not include turnover time.

*** Preparing for the CON lead the applicant to consider usage of Procedure Rooms. The room labeled YAG Laser on both the original and project floor plans was not previously recorded as a procedure room and was approved as such in the original determination. Therefore, YAG lasers are not included in the Table 1. CSI reports the following procedures and cases for YAG procedures and projections. Each YAG takes an average 10 minutes.

| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---------------|-------|-------|-------|-------|-------|-------|-------|
| Procedures | 660 | 614 | 604 | 634 | 666 | 669 | 734 |
| Cases | 660 | 614 | 604 | 634 | 666 | 669 | 734 |
| Total Minutes | 6,600 | 6,140 | 6,040 | 6,340 | 6,660 | 6,690 | 7,340 |

**TABLE 2: STATISTICAL PROJECTIONS - PROPOSED PROJECT
(INSTRUCTION: All applicants should complete this table.)**

Data reflected in Table 1 represents the facility projections for both entire facility and proposed project. Per discussions with MHCC staff and an email confirmation (Kevin McDonald and Penelope Williams on 12/14/2016, it was determined that Table 2 is not applicable and the narrative serves to describe statistical projections of the proposed project.

| | Projected Years (Ending with first full year at full utilization) | | | |
|---------------------------------------|--|------|------|------|
| CY or FY (Circle) | 20__ | 20__ | 20__ | 20__ |
| Ambulatory Surgical Facilities | | | | |
| a. Number of operating rooms (ORs) | | | | |
| • Total Procedures in ORs | | | | |
| • Total Cases in ORs | | | | |
| • Total Surgical Minutes in ORs** | | | | |
| b. Number of Procedure Rooms (PRs) | | | | |
| • Total Procedures in PRs | | | | |
| • Total Cases in PRs | | | | |
| • Total Minutes in PRs** | | | | |

*Do not include turnover time

10.24.01.08G(3)(c). Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the project. It should also identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including the alternative of the services being provided by existing facilities.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and

the costs of each alternative. The cost analysis should go beyond development cost to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective goal and objective achievement or the most effective solution to the identified problem(s) for the level of cost required to implement the project, when compared to the effectiveness and cost of alternatives including the alternative of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

The planning process for the project started in 2012, with a vision to provide ophthalmology services to people in the Baltimore region. Anticipating expansion, CSI's initial design included one OR and two sizable procedures rooms to accommodate for a second OR at a future time. Implementation of the project included a YAG laser room tailored to the needs of the patient population and use, through the present time, of one of the two other spaces designed and approved as procedure room, presently used for storage and a procedure room for LenSx®, the first step in laser assisted cataract surgery. Since most of the capital investment occurred during the initial construction, project renovation costs are minimal.

CSI has evaluated several alternatives to the proposed project.

1. *Expansion of CSI's service hours to include evening hours and Fridays for all ophthalmic related procedures.* Option 1 was not feasible because 1) fasting requirements for patients makes extension of service hours unrealistic; 2) extending hours would require hiring additional staff at premium pay for evening and weekend hours, and overtime costing more to provide services; 3) patients are at greater risk for falls or other injury in the evening with compromised visual acuity and following moderate sedation; 4) immediate next-day post operative appointments on weekends is not ideal for patients and again presents additional challenges and cost related to adjusted staffing hours; 5) availability of physicians during later hours and on weekends is already challenging and resident hours are limited, by law.

2. *Referring retina patients from Howard County and the surrounding areas to continue to seek services from other ASFs and hospitals outside Howard County.* Option 2 would not be in the best interest of patients in the service area because 1) it would seem unreasonable to have patients travel outside the county for services that are readily available within a reasonable driving distance; 2) some retina procedures are urgent and delays in treatment could result in permanent vision loss; 3) retina services provided at surrounding service area hospitals would be more expensive for patients and may result in financial hardship; 4) ophthalmologists perform surgery

where they have and are able to maintain credentialing, which already presents geographic limitations for patients seeking care close to home; 5) shifting case volume to another facility would result in heavier case volumes, potentially placing referral facilities with the same capacity issues.

10.24.01.08G(3)(d). Viability of the Proposal.

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete Tables 3 and/or 4 below, as applicable. Attach additional pages as necessary detailing assumptions with respect to each revenue and expense line item.

TABLE 3: REVENUES AND EXPENSES - ENTIRE FACILITY (including proposed project)

(INSTRUCTION: ALL EXISTING FACILITY APPLICANTS MUST SUBMIT AUDITED FINANCIAL STATEMENTS)

It is important to note that while CSI has generously provided free and reduced cost non-surgical and non-surgical services to persons with financial hardship, itemized documentation for these services was not specifically recorded as “charity care” and therefore, difficult to extract exact dollar amounts. Estimates, based on State Health Plan charity care definition and criteria were made available for this proposal and included in the narrative previously stated, see Standard .05(A)(2) Charity Care Policy. To include such estimates in Table 3 would not reflect other figures accurately, offsetting actual net revenue. Policy and documentation practices are now in place to account for “charity care” contributions and be readily available for reporting purposes.

| | Two Most Actual Ended Recent Years | | Current Year Projected | Projected Years (ending with first full year at full utilization) | | | |
|--------------------------------------|------------------------------------|-----------|------------------------|---|-----------|-----------|-----------|
| CY or FY | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
| 1. Revenue | | | | | | | |
| a. Inpatient services | | | | | | | |
| b. Outpatient services | 1,862,604 | 2,185,171 | 2,292,276 | 3,497,950 | 4,038,857 | 4,388,502 | 4,820,714 |
| c. Gross patient service revenue | 1,862,604 | 2,185,171 | 2,292,276 | 3,497,950 | 4,038,857 | 4,388,502 | 4,820,714 |
| d. Allowance for bad debt | | | | | | | |
| e. Contractual allowance | | | | | | | |
| f. Charity Care | | | | | | | |
| g. Net patient services revenue | 1,862,604 | 2,185,171 | 2,292,276 | 3,497,950 | 4,038,857 | 4,388,502 | 4,820,714 |
| h. Other operating revenues: Refunds | -15,541 | -17,467 | -15,982 | -16,725 | -16,354 | -16,354 | -16,477 |
| j. Net operating revenue | 1,847,063 | 2,167,703 | 2,276,294 | 3,481,225 | 4,022,503 | 4,372,149 | 4,804,237 |

| Table 3 Cont'd | Two Most Actual Ended Recent Years | | Current Year Projected | Projected Years (ending with first full year at full utilization) | | | |
|----------------|------------------------------------|--|------------------------|---|--|--|--|
|----------------|------------------------------------|--|------------------------|---|--|--|--|

| CY or FY | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---------|---------|---------|---------|---------|---------|---------|
| 2. Expenses | | | | | | | |
| a. Salaries, wages, and professional fees, fringe | 385,528 | 385,163 | 537,437 | 687,177 | 789,321 | 858,177 | 932,409 |
| b. | 222,531 | 236,605 | 304,828 | 385,459 | 461,662 | 501,935 | 545,352 |

| | | | | | | | |
|-----------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Contractual services | | | | | | | |
| c. Interest on Current Debt | 23,369 | 25,968 | 20,134 | 23,157 | 23,086 | 22,126 | 22,790 |
| d. Interest on project debt | | | | 7,329 | 5,827 | 4,263 | 2,636 |
| e. Current Depreciation | 74,799 | 58,076 | 19,600 | 50,825 | 42,833 | 37,753 | 43,804 |
| f. Project Depreciation | | | | 23,142 | 23,142 | 23,142 | 23,142 |
| g. Current amortization | | | | | | | |
| h. Project amortization | | | | 44,200 | 44,200 | 44,200 | 44,200 |
| i. Supplies | 961,205 | 927,325 | 947,355 | 1,440,400 | 1,725,160 | 1,875,655 | 2,037,898 |
| j. Other Expenses | 58,961 | 56,233 | 75,743 | 96,326 | 115,369 | 125,433 | 136,283 |
| k. Total operating expenses | 1,726,392 | 1,689,370 | 1,905,098 | 2,758,013 | 3,230,600 | 3,492,683 | 3,788,513 |
| 3. Income | | | | | | | |
| a. Income from operation | 120,670 | 478,333 | 371,196 | 723,212 | 791,903 | 879,466 | 1,015,724 |
| b. Non-operating Income | | | | | | | |
| c. Subtotal | 120,670 | 478,333 | 371,196 | 723,212 | 791,903 | 879,466 | 1,015,724 |
| d. Income tax | | | | | | | |
| e. Net income (loss) | 120,670 | 478,333 | 371,196 | 723,212 | 791,903 | 879,466 | 1,015,724 |

| Table 3 Cont. CY or FY (Circle) | Two Most Actual Ended Recent Years | | Current Year Projected | Projected Years (ending with first full year at full utilization) | | | |
|---|--|------|------------------------------|---|------|------|------|
| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
| A. of Total Revenue | | | | | | | |
| 1. Medicare | 61% | 60% | 59% | 60% | 60% | 60% | 60% |
| 2. Medicaid | 1% | 1% | 2% | 1% | 1% | 1% | 1% |
| 3. Blue Cross | 22% | 23% | 22% | 23% | 23% | 23% | 23% |
| 4. Commercial Insurance | 15% | 15% | 16% | 15% | 15% | 15% | 15% |
| 5. Self-Pay | 1% | 1% | 1% | 1% | 1% | 1% | 1% |
| 6. Other (Specify) | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| 7. TOTAL | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| B. Percent of Patient Days/Visits/Procedures (as applicable) | | | | | | | |
| 1. Medicare | 60% | 58% | 58% | 58% | 58% | 58% | 58% |
| 2. Medicaid | 1% | 2% | 2% | 2% | 2% | 2% | 2% |
| 3. Blue Cross | 22% | 23% | 21% | 22% | 22% | 22% | 22% |
| 4. Commercial Insurance | 16% | 16% | 18% | 17% | 17% | 17% | 17% |
| 5. Self-Pay | 1% | 1% | 1% | 1% | 1% | 1% | 1% |
| 6. Other (Specify) | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| 7. TOTAL | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

TABLE 4: REVENUES AND EXPENSES - PROPOSED PROJECT

(INSTRUCTION: Each applicant should complete this table for the proposed project only)

Data reflected in Table 3 represents the facility revenue and expenses for both entire facility and proposed project. Per discussions with MHCC staff and an email confirmation (Kevin McDonald and Penelope Williams on 12/14/2016), it was determined that Table 4 is not applicable and the narrative serves to describe revenue and expenses of the proposed project.

| | Projected Years (Ending with first full year at full utilization) | | | |
|--|--|------|------|------|
| CY or FY (Circle) | 20__ | 20__ | 20__ | 20__ |
| 1. Revenues | | | | |
| a. Inpatient Services | | | | |
| b. Outpatient Services | | | | |
| c. Gross Patient Services Revenue | | | | |
| d. Allowance for Bad Debt | | | | |
| e. Contractual Allowance | | | | |
| f. Charity Care | | | | |
| g. Net Patient Care Service Revenues | | | | |
| h. Total Net Operating Revenue | | | | |
| 2. Expenses | | | | |
| a. Salaries, Wages, and Professional Fees, (including fringe benefits) | | | | |
| b. Contractual Services | | | | |
| c. Interest on Current Debt | | | | |
| d. Interest on Project Debt | | | | |
| e. Current Depreciation | | | | |
| f. Project Depreciation | | | | |
| g. Current Amortization | | | | |
| h. Project Amortization | | | | |
| i. Supplies | | | | |
| j. Other Expenses (Specify) | | | | |
| k. Total Operating Expenses | | | | |
| 3. Income | | | | |
| a. Income from Operation | | | | |
| Table 4 Cont. | | | | |
| | Projected Years (Ending with first full year at full utilization) | | | |
| CY or FY (Circle) | 20__ | 20__ | 20__ | 20__ |
| b. Non-Operating Income | | | | |

| | | | | |
|--|------|------|------|------|
| c. Subtotal | | | | |
| d. Income Taxes | | | | |
| e. Net Income (Loss) | | | | |
| 4. Patient Mix: | | | | |
| A. Percent of Total Revenue | | | | |
| 1. Medicare | | | | |
| 2. Medicaid | | | | |
| 3. Blue Cross | | | | |
| 4. Commercial Insurance | | | | |
| 5. Self-Pay | | | | |
| 6. Other (Specify) | | | | |
| 7. TOTAL | 100% | 100% | 100% | 100% |
| | | | | |
| B. Percent of Patient Days/Visits/Procedures (as applicable) | | | | |
| 1. Medicare | | | | |
| 2. Medicaid | | | | |
| 3. Blue Cross | | | | |
| 4. Commercial Insurance | | | | |
| 5. Self-Pay | | | | |
| 6. Other (Specify) | | | | |
| 7. TOTAL | 100% | 100% | 100% | 100% |

Complete Table L (Workforce) from the Hospital CON Application Table Package.

Salaries for Table L are averages of base pay rates and do not include fringe benefits or professional fee. Therefore, the current year total cost for Table L reflects differently than Table 3 in which wages, professional fee and fringe are included. Had those assumptions been included in Table L, the totals would reflect similarly.

TABLE L. WORK FORCE INFORMATION

INSTRUCTION: List the facility's existing staffing and changes required by this project. Include all major job categories under each heading provided in the table. The number of Full Time Equivalents (FTEs) should be calculated on the basis of 2,080 paid hours per year equals one FTE. In an attachment to the application, explain any factor used in converting paid hours to worked hours. Please ensure that the projections in this table are consistent with expenses provided in uninflated projections in Tables G and J. See additional instruction in the column to the right of the table.

| Job Category | CURRENT ENTIRE FACILITY | | | PROJECTED CHANGES AS A RESULT OF THE PROPOSED PROJECT THROUGH THE LAST YEAR OF PROJECTION (CURRENT) | | | OTHER EXPECTED CHANGES IN OPERATIONS THROUGH THE LAST YEAR OF PROJECTION (CURRENT DOLLARS) | | | PROJECTED ENTIRE FACILITY THROUGH THE LAST YEAR OF PROJECTION | |
|--|-------------------------|------------------------|-------------------------|---|------------------------|---|--|------------------------|------------|---|---|
| | Current Year FTEs | Average Salary per FTE | Current Year Total Cost | FTEs | Average Salary per FTE | Total Cost (should be consistent with projections in Table J) | FTEs | Average Salary per FTE | Total Cost | FTEs | Total Cost (should be consistent with projections in Table G) |
| 1. Regular Employees | | | | | | | | | | | |
| <i>Administration (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| Nurse Manager | 1.25 | \$75,150 | \$93,938 | 0.0 | | \$0 | 0.0 | | \$0 | 1.25 | \$93,938 |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| Total Administration | 1.25 | \$75,150 | \$93,938 | | | \$0 | | | \$0 | 1.25 | \$93,938 |
| <i>Direct Care Staff (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| Registered Nurse | 2.75 | \$59,300 | \$163,075 | 1.0 | \$59,300 | \$59,300 | 0.0 | | \$0 | 3.75 | \$222,375 |
| Surgical Techs | 2.0 | \$41,975 | \$83,950 | 1.0 | \$41,975 | \$41,975 | | | \$0 | 3.0 | \$125,925 |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| Total Direct Care | 4.75 | | \$247,025 | 2.0 | | \$101,275 | | | \$0 | 6.75 | \$348,300 |
| <i>Support Staff (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| Receptionist | 1 | \$39,390 | \$39,390 | 0.0 | | \$0 | 0.0 | | \$0 | 1.0 | \$39,390 |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| Total Support | 1.00 | | \$39,390 | | | \$0 | | | \$0 | 1.0 | \$39,390 |
| REGULAR EMPLOYEES TOTAL | 7.00 | | \$380,353 | | | \$101,275 | | | \$0 | 7.0 | \$481,628 |
| 2. Contractual Employees | | | | | | | | | | | |
| <i>Administration (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| Total Administration | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| <i>Direct Care Staff (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| Total Direct Care Staff | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| <i>Support Staff (List general categories, add rows if needed)</i> | | | | | | | | | | | |
| | - | - | | | | | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| Total Support Staff | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| CONTRACTUAL EMPLOYEES TOTAL | | | \$0 | | | \$0 | | | \$0 | 0.0 | \$0 |
| Benefits (State method of calculating benefits) | | | | | | | | | | | |
| | | | | | | | | | | | |
| TOTAL COST | 7.00 | | \$380,353 | 0.0 | | \$101,275 | 0.0 | | \$0 | | \$481,628 |

- Audited financial statements for the past two years should be provided by all applicant entities and parent companies to demonstrate the financial condition of the entities involved and the availability of the equity contribution. If audited financial statements are not available for the entity or individuals that will provide the equity contribution, submit documentation of the financial condition of the entities and/or individuals providing the funds and the availability of such funds. Acceptable documentation is a letter signed by an independent Certified Public Accountant. Such letter shall detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.

Financial Feasibility: As noted in Exhibit B and Table 3, CSI has a documented record demonstrating steady growth and financial performance. Revenue estimates are consistent with utilization projection. While audited financials are not available, CSI has a letter from Chris Marasco with Howard Bank, attesting CSI's established line of credit in the amount of \$250,000 (see Appendix L). The line of credit exceeds the project budgeted amount and is sufficient to cover additional and unforeseen project related expenses.

ASC's Value to Maryland: In 2014, Medicare saved \$25 million on cataract procedures in Maryland alone. While Medicare's current payment structure give ASC's approximately 55% of what it gives hospital outpatient department (HOPD), ASC's like CSI will "continue to provide Medicare beneficiaries essential surgical services".

Projected Levels of Utilization: Local support is demonstrated by the attestations of commitment from thirteen associates. A 42% growth in OR case volume is anticipated from 2017 thru 2020. This does not reflect projected growth for LenSx® and non-OR procedures. Also, CSI anticipates adding other associates in the upcoming three years.

Population Growth: Based on available census data for 2012-2015, the service area total population has a growth rate of 5.2% each year. Howard County, the service area with the largest 2016 weighted average case volume of 41.3% has an average growth rate of people ages 65 years and older of 19.8%. Anne Arundel County has a 2016 weighted average case volume of 27.5%, and an average growth rate of people ages 65 years and older of 12%. Therefore, Approximately 70% of case volume in the service area has an aging population (people 65 years and older) growth rate of approximately 16%. Based on the growth of the target demographic and projected population growth, there is need for the project.

Source: <https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=CF>

- If debt financing is required and/or grants or fund raising is proposed, detail the experience of the entities and/or individuals involved in obtaining such financing and grants and in raising funds for similar projects. If grant funding is proposed, identify the grant that has been or will be pursued and document the eligibility of the proposed project for the grant.

Not applicable to project.

- Describe and document relevant community support for the proposed project.

County social services recognize the need for persons to have access to quality and affordable eye care. Social services agencies and public health organizations circulate to their membership information about CSI charity services and publishes the facility in written resource materials circulated countywide.

CSI Physicians, patients and senators support the project. See Appendices M, Letters of Support, for letters from Dr. Lui, Letter from Dr. Heffez, and Letter and Senator James Robey.

- Identify the performance requirements applicable to the proposed project (see question 12, "Project Schedule") and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, obtaining State and local land use, environmental, and design approvals, contracting and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame(s).

Surgeons, anesthesiologists, OR nurses and technologists with knowledge and experience with the facility and procedures were consulted regarding a list of fixed and mobile equipment. Renovation estimates were secured from the facility's previous contractor, KasCon. Movable equipment (Phacoemulsification, Microscope, surgical instruments, stretchers, TV monitor, anesthesia cabinets and other operating room supplies based on current market value.) Since the proposed project will replicate the existing OR, costs for equipment have been reviewed and negotiated with current vendors. The floor plan was discussed with a consultant advising CSI during the initial build out. Loan fees based on a \$192,192 loan at 4% interest over 5 years, with Howard Bank, of which CSI has a line of credit in the amount of \$250,000. The project will be completed in two phases and will not interrupt existing outpatient services, as the renovation work will be performed after hours and on weekends. While the renovation is anticipated to take less than 2 weeks, the project timeline from Certificate of Need approval to renovation and full utilization is 3 months, to allow for unanticipated permit, construction or equipment installation delays. Phase one will involve renovation. Phase two will include installation of equipment (i.e. microscope, phacoemulsification, other movable work stations and equipment and instruments).

10.24.01.08G(3)(e). Compliance with Conditions of Previous Certificates of Need.

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

INSTRUCTIONS: List all of the Maryland Certificates of Need that have been issued to the project applicant, its parent, or its affiliates or subsidiaries over the prior 15 years, including their terms and conditions, and any changes to approved Certificates that needed to be obtained. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

None

10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System.

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project. Please assure that all sources of information used in the impact analysis are identified and identify all the assumptions made in the impact analysis with respect to demand for services, payer mix, access to service and cost to the health care delivery system including relevant populations considered in the analysis, and changes in market share, with information that supports the validity of these assumptions. Provide an analysis of the following impacts:

- a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project;

It is not uncommon for surgeons to maintain credentialing with more than one ASF and or hospital. For new surgeons, this provides options for securing operating room time since established, high case volume, and facility owners generally have preference for block operating room time. For established and new surgeons with multiple physician practices, this provides the opportunity to perform surgery at a facility within proximity to their practice and or patient population. Credentialing with more than one facility has both patient and physician benefit.

Patient Benefit

- Treatment by a preferred provider
- Treatment at a convenient geographic location
- Treatment at a facility with specialized team and equipment
- Wider offering of surgical appointments slots to select from

Physician Benefit

- Opportunity to expand practice within a desired geographic region
- Access to specific equipment and team
- Expanded OR time and or block scheduling
- Increased opportunity to schedule urgent cases
- Efficiency in time management with practice in close proximity to facility

Given the shift from hospital-based ophthalmology surgery to an ASF and the interest of surgeons to align with one or more facility suited to their patient need and practice specialty, it is not likely the proposed project will have an adverse impact on existing health care providers in the service area since the additional OR is proposed to meet the current and projected case volume that is consistent with population growth and demand for facilities with capacity to accommodate expanding physician practices and specialty services.

An assessment of associates with CSI indicates the majority is building their practice thus resulting in no shift in case volume from other facilities. MHCC Ambulatory Surgery Provider Directory data shows Baltimore Eye Surgery Center had 2,467 OR cases in 2014. At a projected and conservative growth rate of 8%, Baltimore Eye Surgery Center is estimated to have 2,877 OR cases in 2016 and projected 3,107 in 2017. LaBorwit will shift approximately 60 cases from Baltimore Eye Surgery Center in 2017, approximately 2% of Baltimore Eye Surgical Center's total case volume, and estimates not more than 3% in projected years. Some of these cases will accommodate people residing in Howard County and others generated by patient scheduling request. Rutzen and Hanna only operate at CSI. Heffez will continue to perform complex and emergency retina cases at Suburban while Syed is shifting his hospital cases and few from other ASFs for access to retina technology and capable team. Swamy will not shift cases from University of Maryland Medical Center and will utilize CSI for cases generated as a result of consulting with Select Eye Care.

Source: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_amsurg/documents/con_amsurg_directory_report_2015_20160209.pdf

b) On the payer mix of all other existing health care providers that are likely to experience some impact on payer mix as a result of this project. If an applicant for a new nursing home claims no impact on payer mix, the applicant must identify the likely source of any expected increase in patients by payer.

Adverse impact on the payer mix of all other existing health care providers as a result of the project is not likely. CSI is not intending a service rate increase to offset capital costs for the project nor change accessibility of services. Impact on payer mix is more likely influenced by external events, such as the age of patients with health insurance resulting from health care exchange

programs. An average 60% of cases are Medicare and projected to remain unchanged. Facility self pay fees are anticipate to remain consistent with Medicare reimbursement rates.

c) On access to health care services for the service area population that will be served by the project. (State and support the assumptions used in this analysis of the impact on access);

Access to health care services will improve in the service area with expanded availability of specialized providers, including retina specialists. The project will also provide a surgical home for several surgeons building or expanding their practice and projected volumes affirmed by associates as noted in Appendix N. The project will benefit people ages 65 years and older. The project will expand an existing and well-established facility with sincere interest in serving the community and people with limited resources to pay for quality eye care. Finally, the project will extend the capacity of a facility providing the highest standard care, with advanced technology, and while maintaining costs at a level that keeps the facility financially secure.

Maryland Health Services Cost Review Commission (HSCRC) Experience Report for 2016 shows same day surgery (coded SDS) for hospitals in the project service area as follows: Anne Arundel Hospital 17,599, Johns Hopkins 24,492, Sinai 12,640, UM Harford Memorial 1,167, Howard County General 8,981 and Suburban 5,630. Given this data, CSI believes impact on these facilities will have minimal to no adverse impact resulting from the project.

Source: http://www.hscrc.state.md.us/hsp_Data2.cfm

d) On costs to the health care delivery system.

If the applicant is an existing facility or program, provide a summary description of the impact of the proposed project on the applicant's costs and charges, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

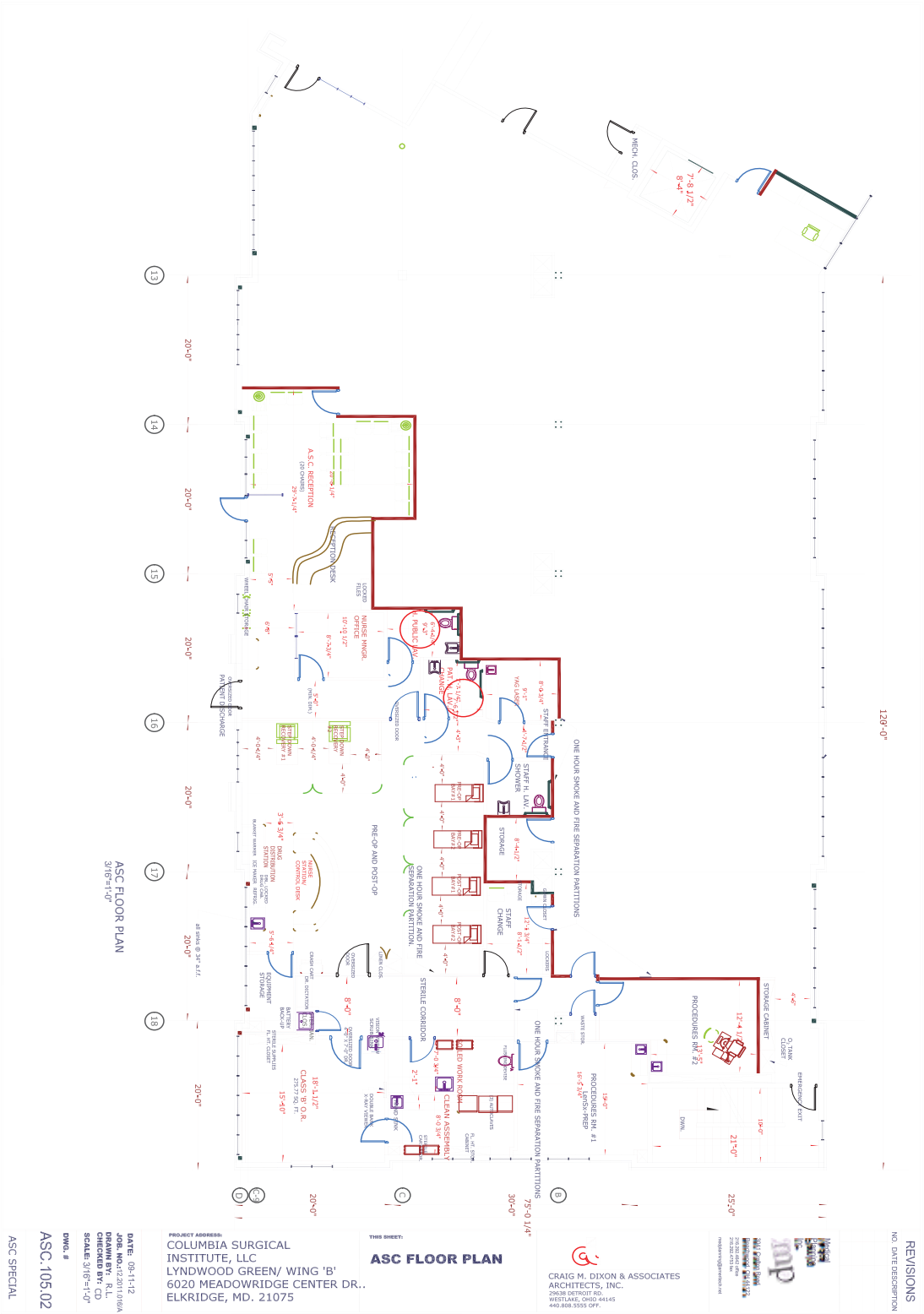
Utilization projections are consistent with historic trends in use of the applicable service by the likely service area population of the facility. Revenue estimates are consistent with utilization projections and based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity provision. Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels are experienced by CSI. MHCC Table 1 projects that volumes will continue to grow and projected revenues over total expenses demonstrate profitability.

CSI has low staff turn over. Clinical personnel include 1.25 FTE nurse managers, 2.75 FTE registered nurses, 2 FTE surgical scrub technicians, and 1 FTE receptionist. An additional 2 FTEs

(29% increase in staff FTE) are needed for the project and include 1 FTE registered nurse and 1 FTE scrub technician. Staff are cross trained and able to serve multiple clinical and surgical functions ensuring consistency and continuity of the clinical team during planned or unplanned staff absences. PRN or as needed staff are utilized and available when the surgical schedule demands more FTE support. Contract labor is minimal. CSI has an agreement with a local anesthesia group that bills separately for their services. The project will require an additional anesthesia provider at no direct expense to the project. Medications used by anesthesia providers are a direct expense to CSI and will increase proportionately with case volume.

Finally, billing services are outsourced. Any increased expense related to billing services will be proportionate with case volume.

Appendix A Original Project Floor Plan



ASC FLOOR PLAN

DATE: 08-11-12
 JOB NO.: 122011-086A
 DRAWN BY: R.L.
 CHECKED BY: CD
 SCALE: 3/16"=1'-0"
 DWG. #
ASC-105.02
 ASC SPECIAL

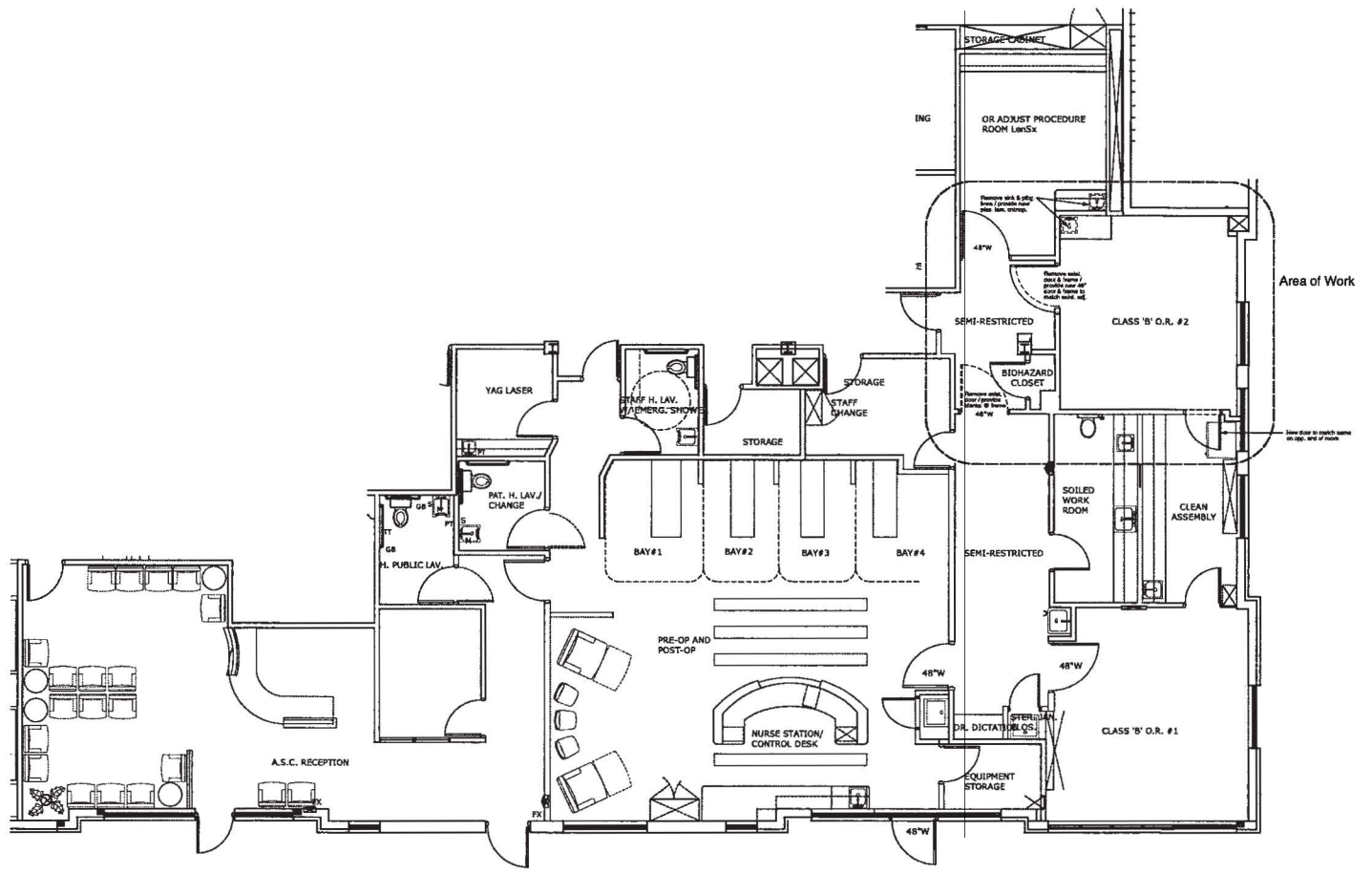
PROJECT ADDRESS:
 COLUMBIA SURGICAL
 INSTITUTE, LLC
 LYNWOOD GREEN/ WING 'B'
 6020 MEADOWRIDGE CENTER DR.,
 ELKCRIDGE, MD. 21075

ASC FLOOR PLAN

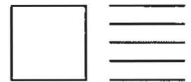
CRAIG M. DIXON & ASSOCIATES
 ARCHITECTS, INC.
 3535 CENTER RD.
 WESTLAKE, OHIO 44145
 440.488.2535 OFF.

REVISIONS
 NO. DATE DESCRIPTION

Appendix B
Proposed Project Floor Plan



Option 1



Floor Plan
1/4" = 1'-0"



Proposed New Operating Room
Columbia Surgical Institute
Meadowridge Professional Center
6050 Meadowridge Drive
Ellicott City, Maryland

10 Nov 16
29 Dec 16
30 Dec 16
30 Jan 17

SK100

Appendix C Lease Agreement

LEASE AGREEMENT

THIS LEASE AGREEMENT (this "Lease") made the 28th day of November, 2012 (the "Effective Date"), by and between **FRECKLED OSTRICH PROPERTIES, LLC**, a Maryland limited liability company, whose address is 5800 Laurel Leaves Lane, Clarksville, Maryland 21029 ("Landlord"), and **COLUMBIA SURGICAL INSTITUTE, LLC**, a Maryland limited liability company, having an address at 5800 Laurel Leaves Lane, Clarksville, Maryland 21029 ("Tenant").

WITNESSETH, that in consideration of the rents and covenants hereinafter set forth, Landlord hereby leases to the Tenant and Tenant hereby takes from Landlord the following described premises upon the following covenants and conditions:

SECTION 1. PREMISES.

A. Landlord hereby leases to Tenant and Tenant hereby leases from Landlord, that certain premises (the "Premises") containing approximately 4,169 rentable square feet as indicated on a drawing identified by the parties hereto as Exhibit A. The Premises constitute a portion of that certain condominium unit located at 6020-L Meadowridge Center Drive, Elkridge, Maryland 21075 and more particularly identified as "Unit 3" (the "Property") in the 100-103 Center Condominium Declaration of Condominium, as amended from time to time, and inclusive of the condominium by-laws attached thereto (the "Condo Declaration"), recorded among the Land Records of Howard County, Maryland (the "Land Records") in Liber 14479, folio 486 et seq., and as described. The Property is specifically identified on that certain plat entitled "Condominium Plat 100-103 Center Condominium Buildings One and Two," Sheets One of Four through Four of Four, which plat is recorded among the Land Records of Howard County, Maryland as Plats Nos. 22155 through 22158 (the "Condo Plat"). The Condo Plat is attached hereto as Exhibit B and made a part hereof. The Condo Declaration is attached hereto as Exhibit C and made a part hereof. A copy of the condominium by-laws are attached hereto as Exhibit D and made a part hereof.

B. This Lease and Tenant's rights and obligations set forth herein are subject and subordinate to the provisions of the Condo Declaration as may be amended from time to time. If the Premises and/or Tenant is deemed to be in violation of any terms, conditions or obligations required of the Premises or the operation thereof, pursuant to the provisions of the Condo Declaration, such violation shall be, after the expiration of any relevant cure period, (i) deemed an Event of Default hereunder, and (ii) subject to enforcement under the Condo Declaration. In the event of any conflict between this Lease and the Condo Declaration, the provisions of the Condo Declaration shall prevail.

SECTION 2. TERM.

A. The term of this Lease (including any properly exercised renewal, the "Term") shall commence on the Effective Date and expire ten (10) years from the last day of the calendar month in which the Effective Date falls.

{00093254 v. 1}

B. Provided Tenant is not in default under this Lease, Tenant shall have the right to renew the Term for one (1) additional ten (10) year period by providing Landlord written notice thereof at least one hundred eighty (180) days prior to the expiration of the original Term.

C. This Lease shall terminate at the end of the original Term hereof, or any extension or renewal thereof, without the necessity of any notice from either Landlord (unless otherwise terminated pursuant to the terms of this Lease) or Tenant to terminate the same, and Tenant hereby waives notice to vacate the Premises and agrees that Landlord shall be entitled to the benefit of all provisions of law respecting the summary recovery of possession of premises from a tenant holding over to the same extent as if statutory notice had been given.

D. Tenant shall at its expense, at the expiration of the Term or any earlier termination of this Lease, (i) promptly surrender to Landlord possession of the Premises in good order and repair ordinary wear and tear excepted and broom clean, (ii) remove therefrom the Tenant's signs, goods and effects and any machinery, trade fixtures and equipment which are used in conducting the Tenant's trade or business and are not owned by Landlord, and (iii) repair any damage to the Premises or the Property caused by such removal. This clause shall survive the termination of this Lease.

E. In the event that Tenant enters into occupancy of the Premises prior to the Rent Commencement Date for the purpose of constructing improvements or installing fixtures therein (and without conducting business therein), then all terms of this Lease, except that regarding the payment of Rent and other charges, shall apply to such occupancy.

F. (i) If Tenant continues to occupy the Premises after the expiration of the Term or any earlier termination of this Lease after obtaining the Landlord's express, written consent thereto,

(a) such occupancy shall (unless the parties hereto otherwise agree in writing) be deemed to be under a month-to-month tenancy, which shall continue until either party hereto notifies the other in writing, by at least thirty (30) days before the end of any calendar month, that the notifying party elects to terminate such tenancy at the end of such calendar month, in which event such tenancy shall so terminate;

(b) such month-to-month tenancy shall be upon the same terms and subject to the same conditions as those set forth in the provisions of this Lease; provided, that if Landlord gives Tenant, by at least thirty (30) days before the end of any calendar month during such month-to-month tenancy, written notice that such terms and conditions (including any thereof relating to the amount or payment of Rent) shall, after such month, be modified in any manner specified in such notice, then such tenancy shall, after such month, be upon the said terms and subject to the said conditions, as so modified.

(ii) If Tenant continues to occupy the Premises after the expiration of the Term or any earlier termination of this Lease without having obtained Landlord's express, written consent thereto, then without altering or impairing any of Landlord's rights under this Lease or applicable

law and without further notice, (a) Tenant hereby agrees to pay to Landlord as Rent for the Premises, for each calendar month or portion thereof after such expiration of the Term or such earlier termination of this Lease, as aforesaid, until Tenant surrenders possession of the Premises to Landlord, a sum equaling one hundred fifty percent (150%) of the amount of the monthly Basic Rental (as herein defined) and Additional Rent which would have been due and payable under the provisions of this Lease, had Landlord given its express, written consent to Tenant's occupation of the Premises after the expiration of the Term or earlier termination of this Lease, as aforesaid, and (b) Tenant shall surrender possession of the Premises to Landlord immediately on the Landlord's having demanded the same. Nothing in the provisions of this Lease shall be deemed in any way to give Tenant any right to remain in possession of the Premises after such expiration or termination, regardless of whether Tenant has paid any such Rent to Landlord.

SECTION 3. USE OF THE PREMISES. The Premises shall be used by Tenant solely for an ambulatory surgical center and related uses, and for no other purpose or purposes whatsoever (whether directly or indirectly related to the specific permitted uses set forth above). Tenant will not use or permit any use of the Premises except in a first-class manner.

SECTION 4. RENT. Beginning on May 1, 2013 (the "**Rent Commencement Date**") Tenant covenants and agrees to pay to Landlord, as rental for the Premises an initial basic rental equal to One Hundred Twenty-Five Thousand Seventy Dollars (\$125,070) per year, which amount shall increase by four percent (4%) on each anniversary of the Rent Commencement Date (the "**Basic Rental**").

SECTION 5. PAYMENT OF BASIC RENTALS. The Basic Rental shall be payable, without demand, in equal monthly installments in advance on the first day of each full calendar month during the Term, the first such payment to include also any prorated Basic Rental for the period from the date of the commencement of the Term to the first day of the first full calendar month in the Term. Tenant covenants to pay all Rent when due and payable without set-off or deduction for any reason whatsoever (Rent being an independent covenant). Any monies paid or expenses incurred by Landlord to correct violations of any of the Tenant's obligations hereunder shall be Additional Rent. Any Additional Rent provided for in this Lease becomes due with the next installment of Basic Rental due after receipt of notice of such Additional Rent from Landlord. Rent and statements required of Tenant shall be paid or delivered to Landlord at the place designated for notices to Landlord in accordance with Section 37. Anything in this Lease to the contrary notwithstanding, Tenant shall pay a "late charge" of five percent (5%) of any installment or Rent (basic, percentage or other as may be considered Additional Rent under this Lease) when paid more than ten (10) days after the due date thereof, to cover the extra expense involved in handling delinquent payments. In addition, interest shall accrue on all late payments at the rate of fifteen (15%) per annum from the time such payments are due until the date the same is paid.

SECTION 6. RENTAL YEAR DEFINED. "**Rental Year**" means each successive twelve (12) calendar month period commencing on the first (1st) day of the calendar month immediately following the calendar month containing the Rent Commencement Date, unless the Rent Commencement Date shall be the first (1st) day of a calendar month, in which event the Rental Year shall commence on the Rent Commencement Date.

SECTION 7. CONDOMINIUM FEES. Tenant shall pay its proportionate share of all fees (the “**Condo Fees**”) assessed on the Property pursuant to the terms of the Condo Declaration. The parties hereto acknowledge and agree that Tenant’s proportionate share shall be equal to its proportionate share of the total square footage of the Property. The Condo Fees are to be paid monthly with the Basic Rental in the manner proscribed above. In the event Tenant fails to pay the Condo Fees, Landlord, at its option, shall have the right to declare such failure an Event of Default hereunder.

SECTION 8. REAL ESTATE TAXES AND INSURANCE.

A. For all purposes under this Lease, “**Real Estate Taxes**” shall mean all taxes and assessments, general and special, ordinary and extraordinary, foreseen or unforeseen, levied or assessed upon or against the Property by any governmental or quasi-governmental authority having jurisdiction over the Property, including, without limitation, all impact fees. Tenant shall pay to Landlord, as additional Rent in each Rental Year, Tenant’s proportionate share of all Real Estate Taxes applicable to the Property in each Rental Year (“**Tenant’s Share of Real Estate Taxes**”). The parties hereto acknowledge and agree that Tenant’s Share of Real Estate Taxes shall be equal to its proportionate share of the total square footage of the Property. Tenant’s Share of Real Estate Taxes shall be paid and based on a monthly estimate with a year end reconciliation if necessary.

B. If the Term expires or terminates on a date other than the last day of any tax year, the account of Tenant shall be proportionately adjusted within sixty (60) days after the close of the tax year in the same manner as if the Term had not expired or terminated based on a 365 day year.

C. If, during the course of any tax year, Landlord incurs an unforeseen increase in Real Estate Taxes, Landlord shall have the right to increase the monthly estimate for such unforeseen increase.

D. Tenant shall pay Landlord, as additional Rent upon invoice, any reasonable expense incurred by Landlord in contesting any alteration or increase in Real Estate Taxes.

E. If, during the term of this Lease, the system or method of taxation of the Property prevailing during the initial leasehold year is altered or varied, so that substitute Real Estate Taxes are levied, assessed, or imposed upon the Property, in lieu of, or as a supplement to or substitute for, the whole or any portion of the Real Estate Taxes, Tenant shall pay Landlord, as Additional Rent, the sum of all Real Estate Taxes and substitute Real Estate Taxes based on a monthly estimate with a year end reconciliation as provided below.

F. Should any governmental taxing authority acting under any present or future law, ordinance or regulation, levy, assess, or impose a tax, excise and/or assessment (including a value-added or gross receipts tax, but excluding other income or franchise taxes), upon or against the rent, or any part of it, payable by Tenant to Landlord, either by way of substitution (in whole or in part) for or in addition to any existing tax on land and buildings or otherwise, Tenant shall


IN WITNESS WHEREOF, the parties hereto have executed this Lease under their respective seals as of the day and year first above written.

WITNESS:

LANDLORD:

FRECKLED OSTRICH PROPERTIES, LLC

Kriste Bernard

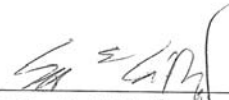
By:  (SEAL)
Scott E. Laborwit
Manager

WITNESS:

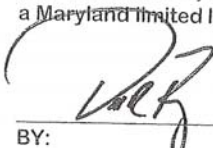
TENANT:

COLUMBIA SURGICAL INSTITUTE, LLC

Kriste Bernard

By:  (SEAL)
Name: Scott E. Laborwit
Title: President

IN WITNESS WHEREOF, the Grantor has caused this writing to be executed and delivered in its name and on its behalf on the day and year first above written.

✓ 100-103 CENTER, LLC,
a Maryland limited liability company

BY: _____ (SEAL)
Member

STATE OF MARYLAND, COUNTY OF Howard, TO WIT:

I HEREBY CERTIFY, that on this 20th day of November, 2012, before me, the subscriber, a Notary Public of the State and County aforesaid, personally appeared Donald B. Brewer, Jr. who acknowledged himself to be the authorized Member of 100-103 Center, LLC and that he as such Member, being authorized so to do, executed the foregoing instrument for the purpose therein contained.

IN WITNESS WHEREOF, I hereunto set my hand and official Seal.

Debbie A. Zile
Notary Public

My Commission Expires



Appendix D
KasCon Estimate



November 29, 2016

Scott LaBorwit
Select Eye Care
6020 Meadowridge Center Drive
Elkridge, MD 21075

RE: PROCEDURE ROOM CONVERSION TO DR PRICING OPTIONS

Dear Scott:

We are pleased to present our budget to provide construction services for the project referenced above. Our estimate has been prepared in accordance with the following documents:

| <u>DOCUMENT</u> | <u>DATE</u> | <u>BY</u> |
|-----------------|-------------|------------------------|
| SK100 Option 1 | 11/10/16 | James Lloyd Architects |

The proposed scope of work and estimated price to perform Options 1 is provided below. As discussed Option 1 is less intrusive would not require additional drawings or a building permit and could be performed in a short amount of time.

We appreciate the opportunity to present this budget. As more information becomes available, we would be happy to meet and refine our proposal. If you have any questions, please do not hesitate to call.

SINCERELY,
KASCON, INC.



JEFFREY A. KASSMAN
PRESIDENT

cc: Peter Tracy

6325 WOODSIDE COURT, SUITE 300, COLUMBIA, MD 21046
PHONE 410.740.7479 * 301.621.4288 FAX 410.740.9204
WWW.KASCONINC.COM

SCOPE OF WORK

Option #1

- Expose existing framed opening between Clean Assembly and OR #2. Furnish and install new prefinished door (best possible match to existing), door frame, and hardware.
- Remove existing door, frame and hardware at sterile corridor. Set items in vacant suite on lower level. Install new cased opening hollow metal frame.
- Cut and cap plumbing supply and sanitary lines at two (2) sinks.
- Remove and dispose of countertops with sink cut outs
- Replace countertops with new, best possible plastic laminate match.
- Paint hollow metal frames
- Repair flooring at threshold location and as needed at sterile corridor frame
- Note: 42" existing entry door to OR #2 to remain as is per verbal instruction

Concept Estimate Value: \$8,092.00

Appendix E
Fee Schedule

| CPT | Description | Self Pay | Medicare Allowable | Commercial Average |
|------------|---|-----------------|---------------------------|---------------------------|
| 65285 | Repair of Eye Wound | 1,650.00 | 1,769.23 | 1,235.97 |
| 65400 | Excision of lesion, cornea (lamellar Keratectomy) | 600.00 | 384.23 | 430.89 |
| 65420 | Removal of Eye Lesion | 700 | 772.72 | 642.60 |
| 65426 | Pterygium excision with graft | 700.00 | 772.24 | 786.07 |
| 65730 | Keratoplasty, Phakic | 1,600.00 | 1,769.23 | 1,293.16 |
| 65750 | Keratoplasty, Aphakic | 1,600.00 | 1,769.23 | 1,227.45 |
| 65755 | Keratoplasty, Pseudophakic | 1,600.00 | 1,769.23 | 1,265.91 |
| 65756 | Keratoplasty, Endothelial (DSEK) | 1,600.00 | 1,769.23 | 1,350.05 |
| 66170 | Trabeculectomy | 900.00 | 962.75 | 804.87 |
| 66172 | Trab. Previous Surg. | 900.00 | 962.75 | 821.20 |
| 66175 | Transluminal Dialation of Aqueous Outflow canal | 1,600.00 | 1,769.23 | 1,493.44 |
| 66180 | Implant eye shunt | 1,600.00 | 1,769.23 | 1,285.90 |
| 66183 | Trabeculectomy w/shunt | 1,600.00 | 1,769.23 | 1,158.22 |
| 66711 | Ciliary endoscopic ablation | 900.00 | 962.75 | 697.88 |
| 66825 | Reposition IOL | 900.00 | 962.75 | 804.87 |
| 66840 | Removal of lens material, aspiration | 600.00 | 962.75 | 730.81 |
| 66982 | Phaco IOL, Complex | 900.00 | 962.75 | 993.94 |
| 66984 | Phaco IOL | 900.00 | 962.75 | 974.54 |
| 66985 | Secondary IOL | 900.00 | 962.75 | 895.40 |
| 66986 | Exchange IOL | 900.00 | 962.75 | 903.18 |
| 67041 | PPV for Macular Pucker | 1,000 | 962.75 | 1,047.11 |
| 67042 | PPV for Macular Hole | 1,600 | 1,769.23 | 1,489.22 |
| 67108 | Repair of Detached Retina | 1,600 | 1,769.23 | 1,478.29 |
| 67904 | Repair eyelid defect (Ptosis repair?) | 700 | 772.74 | 512.89 |
| 0191T | iStent | 1,500 | 1,769.23 | 1,325.48 |
| 65855 | SLT Laser | No Facility Fee | 172.32 | 245.65 |
| 66761 | YAG PL Laser | No Facility Fee | 182.56 | 248.42 |
| 66821 | YAG PC Laser | No Facility Fee | 242.87 | 300.51 |

Appendix F Financial Assistance Policy and Program

Policy - Financial Assistance Program

CSI provides services to patients regardless of the ability to pay but within the financial capability of the Center, to ensure health care delivery is consistent with each person's needs and with respect for each person's dignity.

General Policy:

1. The Financial Assistance Program meets State statutes and Health Services Cost Review Commission (HSCRC) regulations for policy and charity care eligibility.
2. Public notice and information regarding the program shall be published on an annual basis in the Howard County Resource Guide.
3. Notices shall also be posted in CSI's registration area and business office, in reception areas of associate surgeons, and on CSI's website - www.columbia-surgical.com.
4. Notice of the program shall be provided to persons having surgery, by staff of associate surgeon's, with pre-operative education materials and paperwork.
5. Request for financial assistance is preferred least 5 days prior to service being provided.
6. To request assistance, persons complete the Financial Assistance Application and provide required supportive documentation.
7. Within two business days following a person's request for assistance CSI administration shall make a decision about probable eligibility and inform the person.

Eligibility Criteria

1. Persons with family income below 100% of the current poverty level are eligible for services free of charge.
2. Persons above 100% of the current poverty level are eligible for discounted service based on a sliding scale.
3. Proof of income and verification of the number of dependents is based upon the previous year's tax return must be provided. If this is not available, the last two months paycheck stubs will be accepted. Dependents must meet IRS definition of dependents to qualify as household members.
4. If the request for assistance is declined and is based on income, CSI shall review the application and consider eligibility on a case-by case basis.

The following formula is used to determine where the patient will fall on the sliding scale:
$$\frac{\text{Gross Income} - 100\% \text{ poverty level}}{100\% \text{ poverty level}}$$

Once that number is determined, the associated percentage will be taken from the fee schedule of SEC/CSI and the discount will be provided.

1. Example:
 - i. A household of two has a net income of \$26,187.
 - ii. The 200% threshold for a family of two is \$32,040.

- iii. $\$26,187 - \$16,020 = \$10,167$
- iv. $\$10,167 / \$16,020 = 63\%$
- v. $100\% - 63\% = 37\%$ discount.
- vi. We will apply 37% discount to the fee schedule, leaving the patient owing the following amounts:
 - $\$800 - 37\% = \504 to SEC
 - $\$900 - 37\% = \567 to CSI
 - $\$175 - 37\% = \110.25 to American Anesthesiology (anesthesia contractor)

2016 Federal Guidelines

| Household Size | 100% | 200% |
|----------------|----------|----------|
| 1 | \$11,880 | \$23,760 |
| 2 | \$16,020 | \$32,040 |
| 3 | \$20,160 | \$40,320 |
| 4 | \$24,300 | \$48,600 |
| 5 | \$28,440 | \$56,880 |
| 6 | \$32,580 | \$65,160 |
| 7 | \$36,730 | \$73,460 |
| 8 | \$40,890 | \$81,780 |

Notification of Eligibility

1. Persons shall receive notice of eligibility, by telephone, within two business days following the request.

Columbia Surgical Institute Financial Assistance Application

| | | | | | |
|--|---|---|--|---------------------|--------------------------|
| Today's Date: | | | Referring Doctor: | | |
| PATIENT INFORMATION | | | | | |
| Patient's last name: | | First: | Middle: | Marital status: | |
| # of persons supporting household: | # of persons dependent upon household income: | Birth date: | | Age: | Sex: |
| Address: [Address/ P.O Box, City, ST ZIP Code] | | | | | |
| Social Security no.: | | Home phone no.: | | Cell phone no.: | |
| Occupation: | | Employer: | | Employer phone no.: | |
| INSURANCE INFORMATION | | | | | |
| (Please give your insurance card to the receptionist.) | | | | | |
| Do you have any public or private insurance: | | Insurance Company: | | Telephone #: | |
| Plan Name: | | Policy ID: | | Group #: | |
| Is the Patient Eligible for Medicare: | Is the patient eligible for Medicare within the next 12 months: | If yes, please provide the date the patient will be Medicare eligible | | Medicare number: | |
| Please indicate primary insurance: | | | | | |
| Subscriber's name: | | Subscriber's Social Security #: | Birth date: | Policy ID: | Group #: |
| Patient's relationship to subscriber: | | | | | |
| Name of secondary insurance (if applicable): | | | Subscriber's name: | | Policy ID: Group #: |
| Patient's relationship to subscriber: | | | | | |
| FINANCIAL INFORMATION | | | | | |
| Please include Copies of the most recent Federal Income Tax return or other proof of income for you and those in your household. Please check this box if you did not file a tax return: <input type="checkbox"/> | | | | | |
| Total Annual Income (Gross): | | | Asset Valuation (Medicare patients only) – Please include checking & savings accounts, certificates of deposit, stocks & bonds, mutual funds, IRAs, cash, and the value of life insurance policies if you turned in your policies for cash right now. Do not include your home, vehicles, burial plots, or personal possessions. | | |
| The above information is true to the best of my knowledge. I authorize my insurance benefits be paid directly to the physician. I understand that I am financially responsible for any balance. I also authorize Columbia Surgical Institute to release any information required to process my claims. | | | | | |
| _____ Patient Signature | | | _____ Date | | |

Columbia Surgical Institute Financial Assistance Program

Our philosophy

CSI provides services to patients regardless of ability to pay but within the financial capability of the center, to ensure health care delivery is consistent with each patient's needs and with respect for each patient's dignity.

Who is eligible?

- Persons with family income below 100% of the current poverty level are eligible for services free of charge.
- Persons above 100% of the current poverty level are eligible for discounted service based on a sliding scale.

Where can I learn more?

- When you arrive for your appointment, ask your physician or discuss this when you are scheduling your surgery.

How do I apply?

- Applications are available from all physicians associated with CSI.
- Applications are available on our website: Columbia-Surgical.com



Dear Optometrist,

We are happy to announce that Columbia Surgical Institute and Select Eye Care are creating a payment assistance program that would go into effect in January 2017. This program is intended to support uninsured and underinsured patients at or below the poverty level, by providing low and no cost surgery for eligible patients. Often times, patients have to make tough choices and prioritize other health needs before vision care, but we know how important the vision is for quality of life. To qualify, patients must complete a few forms that we are happy to provide. While we are still working out a few of the program details, we will soon be sending you enrollment packets to share with patients.

Another announcement is about "Dropless Cataract Surgery". In response to current research on endophthalmitis, we are now incorporating intracameral antibiotic to every case. After researching the available literature, the evidence was overwhelming. Even though few surgeons are doing this in the United States, they decided that each patient should receive a dose of an antibiotic in the anterior chamber at the end of surgery. This change not only improved the efficacy of prophylaxis, but it also reduced compliance problems and it reduced the cost for patients.

The next step is to introduce a long-acting steroid at the end of surgery. This initiative will improve the post-op healing process and reduce the cost for patients even further. Not all patients will be good candidates for this program, but we estimate that most patients will be able to have cataract surgery and not use any eye drops afterwards. We chose to shift the cost to us so patients can save on costs of medications.

Columbia Surgical Institute and Select Eye Care strive to provide superior ophthalmic care to all of our patients and appreciate your confidence through patient referrals. If you have any questions regarding our Payment Assistance Program or our Dropless Cataract Surgery, please contact Gledson Hanelt, RN at ghanelt@columbia-surgical.com or call (443) 275-7800.

Sincerely,

Scott E. LaBorwit, MD

Appendix G
DHMH Certificate



STATE OF MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY
SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MARYLAND 21228

License No. A1541

Issued to: COLUMBIA SURGICAL INSTITUTE
6020 Meadowridge Center, Suite H
Elkridge, MD 21075

Type of Facility or Community Program: AMBULATORY SURGICAL CENTER

Date Issued: July 1, 2016

SPECIALTIES: Ophthalmology

Authority to operate in this State is granted to the above entity pursuant to The Health-General Article, Title 19 Annotated Code of Maryland, including all applicable rules and regulations promulgated there under. This document is not transferable.

Expiration Date: July 1, 2019

Patricia Tomoko May, MD

Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

Appendix H
AAAASF Certificate

American Association for Accreditation of
Ambulatory Surgery Facilities, Inc.

presents this certificate to

Columbia Surgical Institute, LLC

for having met the standards of a CLASS C-M ambulatory surgery facility in which minor or major surgical procedures are performed under intravenous or parenteral sedation (including Propofol), analgesia, or dissociative drugs.

AAAASF President

Foad Nahai, MD

Foad Nahai

Secretary/Treasurer

Lawrence S. Reed, MD

Lawrence S. Reed



Certified from 6/9/2016 to 6/9/2017

Certification Number 6159

Appendix I
Transfer Agreement

**PATIENT TRANSFER AGREEMENT
BETWEEN
FACILITY: COLUMBIA SURGICAL INSTITUTE
AND
HOWARD COUNTY GENERAL HOSPITAL, INC.**

THIS AGREEMENT, made as of this 9th day of May, 2013 by and between HOWARD COUNTY GENERAL HOSPITAL, INC. (herein called "Hospital") and FACILITY: COLUMBIA SURGICAL INSTITUTE (herein called "Facility").

WHEREAS, Hospital and Facility desire, by means of this Agreement, to insure continuity of care and treatment appropriate to the needs of the patients, (hereinafter referred to as "patients") in the Hospital and the Facility, utilizing the knowledge and other resources of both facilities in a coordinated and cooperative manner to improve the health and care of patients.

NOW, THEREFORE, THIS AGREEMENT WITNESSETH: That in consideration of the mutual advantages accruing to the parties hereto, Hospital and Facility hereby covenant and agree with each other as follows:

I. HOSPITAL AND FACILITY AGREE:

- A. To the timely transfer of patients between Facility and Hospital, as hereinafter provided, upon the recommendation of an attending physician who is a member of the medical staff of the Hospital, that such transfer is medically appropriate; and further agree that such patient shall be admitted to Hospital as promptly as possible under the circumstances.
- B. That Facility shall send with each patient to Hospital at the time of transfer an abstract of pertinent medical and other information necessary to continue the patient's treatment without interruption and provide essential identifying information. Facility agrees to supplement the information as necessary for the maintenance of the patient at Hospital. Both parties agree to maintain the confidentiality of the medical information so as to comply with all state and federal laws, rules and regulations regarding the confidentiality of patient records, including the Health Insurance Portability and Accountability Act ("HIPAA").
- C. That Facility shall have responsibility for obtaining the patient's consent to the transfer to Hospital prior to the transfer, if the patient is competent. If the patient is not competent, Facility shall attempt to obtain consent from any reasonably available legally responsible person acting on the behalf of the patient.
- D. That Facility shall have the responsibility for arranging transportation of the patient to Hospital. Hospital's responsibility for the patient's care shall begin when the patient arrives at Hospital.
- E. That Facility shall arrange for appropriate and safe handling of patients' valuables.

V:\Legal\Contracts\Columbia Surgical Institute\13-751 HCGH Patient Transfer\Execution Copy - Patient Transfer Agreement-CSI-HCGH (pbk) 05-09-13.docx



- F. That clinical records of a patient transferred shall contain evidence that the patient was transferred.
- G. That the transfer procedure is made known to the patient care personnel of each of the parties.
- H. That neither party shall use the name of the other in any promotional or advertising material without the prior written approval of the other party.
- I. That governing bodies of each institution shall have exclusive control of their policies, management, assets and affairs of their respective institutions.
- J. That neither party assumes liability for any debts, or other obligations for the other party's action.

II. EACH PARTY REPRESENTS AND WARRANTS UPON EXECUTION AND THROUGHOUT THE TERM OF THIS AGREEMENT THAT:

- A. It is appropriately licensed by the state in which it is located for the types of services it provides and, if applicable, is accredited by the Joint Commission;
- B. All medical professionals providing services to patients at its facility are licensed in their profession by the state in which, it is located and credentialed by Hospital or Facility, as applicable, and that services provided to patients shall, be within the scope of said medical professional's privileges;
- C. It shall perform the services required hereunder in accordance with: (i) all applicable federal, state, and local laws, rules and regulations; and (ii) all applicable standards of the Joint Commission and any other relevant accrediting organizations;
- D. It has, and shall maintain throughout the term of this Agreement, all appropriate federal and state licenses and certifications which are required in order to perform the services required hereunder; and
- E. Neither it nor any of its staff is sanctioned or excluded from any federally funded health care programs as provided in Sections 1128 and 1128A of the Social Security Act (42 U.S.C. 1320a-70).

III. BILLING:

Bills incurred with respect to services performed by Hospital or Facility for patient care shall be collected by the institution rendering such services directly from the patient, third party insurance coverage, or other sources normally billed by the institution. No clause of this Agreement shall be interpreted to require Hospital or Facility to compensate the other for services rendered to a patient transferred under this Agreement.

Appendix J Service Area Zip Codes

| | | | | |
|-------|-------|-------|-------|-------|
| 13027 | 20759 | 21045 | 21210 | 21754 |
| 17314 | 20763 | 21045 | 21212 | 21758 |
| 17325 | 20770 | 21045 | 21214 | 21765 |
| 17408 | 20772 | 21046 | 21215 | 21770 |
| 18518 | 20774 | 21047 | 21216 | 21771 |
| 19355 | 20776 | 21048 | 21217 | 21774 |
| 19709 | 20777 | 21050 | 21218 | 21774 |
| 19808 | 20781 | 21054 | 21220 | 21776 |
| 19945 | 20785 | 21060 | 21221 | 21784 |
| 19947 | 20794 | 21061 | 21222 | 21787 |
| 19950 | 20794 | 21061 | 21223 | 21794 |
| 19952 | 20815 | 21074 | 21224 | 21797 |
| 19958 | 20832 | 21075 | 21225 | 21811 |
| 20180 | 20833 | 21075 | 21226 | 21903 |
| 20194 | 20838 | 21076 | 21227 | 22003 |
| 20197 | 20850 | 21078 | 21227 | 22405 |
| 20619 | 20851 | 21090 | 21228 | 25438 |
| 20629 | 20852 | 21093 | 21229 | 25443 |
| 20639 | 20853 | 21102 | 21230 | 28451 |
| 20646 | 20854 | 21104 | 21231 | 33040 |
| 20657 | 20862 | 21108 | 21233 | 33412 |
| 20659 | 20866 | 21111 | 21234 | 33455 |
| 20664 | 20871 | 21113 | 21236 | 33709 |
| 20678 | 20872 | 21114 | 21237 | 46901 |
| 20685 | 20876 | 21117 | 21239 | 48375 |
| 20705 | 20882 | 21122 | 21244 | 66213 |
| 20705 | 20902 | 21123 | 21286 | 79734 |
| 20706 | 20904 | 21128 | 21401 | 95672 |
| 20707 | 20905 | 21131 | 21403 | 20748 |
| 20708 | 20906 | 21133 | 21409 | 20751 |
| 20709 | 20910 | 21136 | 21601 | 21043 |
| 20711 | 21009 | 21140 | 21617 | 21044 |
| 20715 | 21012 | 21144 | 21619 | 21208 |
| 20716 | 21020 | 21146 | 21620 | 21209 |
| 20720 | 21028 | 21152 | 21625 | 21738 |
| 20721 | 21029 | 21154 | 21629 | 21742 |
| 20723 | 21030 | 21157 | 21631 | |
| 20724 | 21032 | 21158 | 21655 | |
| 20724 | 21035 | 21162 | 21658 | |
| 20732 | 21036 | 21163 | 21666 | |
| 20735 | 21037 | 21202 | 21679 | |
| 20736 | 21041 | 21204 | 21701 | |
| 20740 | 21042 | 21206 | 21702 | |
| 20747 | 21043 | 21207 | 21737 | |

3.7 Specific Requirements for Outpatient Surgical Facilities

Appendix material, shown in shaded boxes at the bottom of the page, is as

■ 3.7-1 General

3.7-1.1 Application

3.7-1.1.1 This chapter of the *Guidelines* applies to outpatient facilities where surgery is performed.

3.7-1.1.2 The general requirements set forth in Chapter 3.1, Common Elements for Outpatient Facilities, shall apply to outpatient surgical facilities with the modifications set forth in this chapter.

*3.7-1.2 Functional Program

3.7-1.2.1 See sections 1.2-2 (Functional Program) and 3.1-1.2 (Functional Program) for requirements in addition to those in this section.

3.7-1.2.1.1 The extent (number and type) of the diagnostic, clinical, and administrative facilities to be provided will be determined by the services contemplated and the estimated patient load described in the functional program.

*3.7-1.2.1.2 Provisions shall be made for medical and

nursing assessment, nursing care, preoperative testing, and physical examination for outpatient surgeries.

2.7-1.2.2 Reserved

3.7-1.2.3 Shared Services

If the outpatient surgical facility is part of an acute care hospital or other medical facility, services shall be permitted to be shared to minimize duplication as acceptable to authorities having jurisdiction.

3.7-1.3 Site

3.7-1.3.1 Reserved

3.7-1.3.2 Parking

For requirements, see Section 1.3-3.3 (Parking) and the following:

3.7-1.3.2.1 Four parking spaces shall be provided for each room routinely used for surgical procedures plus one space for each staff member.

*3.7-1.3.2.2 Parking space(s) shall be reserved or designated for pickup of patients after recovery.

APPENDIX

A3.7-1.2 Staffing, patient types, hours of operation, function and space relationships, transfer provisions, and availability of off-site services should be described in the functional program.

A3.7-1.2.1.2 Recovery care center. Outpatient surgery is performed without anticipation of overnight patient care, and most outpatient procedures do not require an overnight stay. However, some require extended patient observation for up to "23 hours and 59 minutes" of care.

- a. This extended care possibility should be addressed in a recovery care center that provides facilities for adequate sleeping, bathroom, and nutrition services for the patient.

- b. Recovery care centers should have adequate waiting areas for family, including children and adolescents, and privacy (noise barriers and sight barriers) for meetings between physicians and other professionals with family. The areas should be large enough for translators or have available translation equipment.
- c. A key element to housing patients is the communication system and the ability to obtain additional assistance as necessary.

A3.7-1.3.2.2 This parking space(s) should be located on the shortest possible accessible route from the intended surgery discharge door. The route from the door to the patient pickup point should be sheltered from weather by overhangs or canopies.

3.7-1.3.3 Location and Layout

3.7-1.3.3.1 The surgical suite shall be located and arranged to prevent unrelated traffic through the suite.

3.7-1.3.3.2 The patient care area shall be designed to facilitate movement of patients and personnel into, through, and out of defined areas in the surgical suite.

3.7-1.3.3.3 Signs that clearly indicate where surgical attire is required shall be provided at all entrances to semi-restricted areas.

***3.7-1.3.3.4** The outpatient surgical facility shall be divided into three designated areas—unrestricted, semi-restricted, and restricted.

■ 3.7-2 Reserved

■ 3.7-3 Diagnostic and Treatment Areas

3.7-3.1 General

APPENDIX

A3.7-1.3.3.4 Areas in the outpatient surgical facility

Unrestricted area: Any area of the building other than the semi-restricted and restricted areas as defined in the glossary and shown below.

Traffic is not limited in this area, and street clothes are permitted. Locker rooms are located here. The unrestricted area may contain preoperative patient preparation rooms, the post-anesthesia care unit (PACU), and access to procedure rooms (e.g. endoscopy rooms, rooms in which laser procedures are performed that do not require cutting of the skin or mucous membranes) may be located in the unrestricted area.

Semi-restricted area: The area that separates a restricted area from unrestricted areas with specific signage, physical barriers, and/or security controls and protocols. In the surgical suite, this is where peripheral support areas, including storage areas for clean and sterile supplies, sterile processing rooms, scrub sink areas, and corridors leading to restricted areas of the surgical suite, are located.

A central control point may be established to monitor the entrance of patients, personnel, and materials from the unrestricted area into the semi-restricted areas. Traffic in semi-restricted areas is limited to authorized personnel and patients. Personnel in these areas are required to wear surgical attire and cover head and facial hair.

3.7-3.1.1 Diagnostic Services

Facilities for diagnostic services shall be provided on- or off-site for pre-admission tests as described in the functional program.

3.7-3.1.2 Examination Room

An examination room is not required, but when one is provided it shall comply with the requirements in Section 3.1-3.2.2 (General Purpose Examination/Observation Room).

3.7-3.2 Procedure Room (formerly Class A Operating Room)

*3.7-3.2.1 Application

3.7-3.2.1.1 This section shall apply to a room designated for the performance of procedures that are not defined as an invasive procedure and do not require location in the restricted area of a surgical suite but may use sterile instruments or equipment.

3.7-3.2.1.2 This section shall not apply to the specific procedure rooms defined in the following sections:

The semi-restricted area may contain entrances to locker rooms, the PACU, and sterile processing areas. Sterile processing is a semi-restricted environment but can be entered directly from the unrestricted area or from another semi-restricted area.

Semi-restricted areas have one or more of the following attributes: specific signage; physical barriers; security controls; and protocols that delineate requirements for monitoring, maintenance, attire, and use.

Restricted area: A designated space in the semi-restricted area of the surgical suite that can be reached only through the semi-restricted area.

The restricted access is primarily intended to support a high level of asepsis control, not necessarily for security purposes. Traffic in the restricted area is limited to authorized personnel and patients. Personnel in restricted areas are required to wear surgical attire and cover head and facial hair. Masks are required where open sterile supplies or scrubbed persons may be located.

A3.7-3.2.1 Non-invasive procedures (e.g., pain management, laser procedures in which there is no cutting of the skin or mucous membranes) may be performed in an operating room, but surgical procedures may not be performed in a procedure room even if it is located in the semi-restricted area.

- (1) Section 3.5-3.2.2 (Urgent Care Procedure Room)
- (2) Section 3.8-3.1 (Office-Based Procedure Room)
- (3) Section 3.9-3.2.2 (Endoscopy Procedure Room)
- (4) Section 3.11-3.3.2.2 (Electroconvulsive therapy procedure room)

3.7-3.2.1.3 Use of this procedure room as an examination room shall be permitted.

3.7-3.2.2 Location

The procedure room is an unrestricted area and shall be permitted to be accessed from the semi-restricted corridors of the surgical suite or from an unrestricted corridor.

3.7-3.2.3 Space Requirements

3.7-3.2.3.1 Area. Procedure rooms shall have a minimum clear floor area of 150 square feet (13.95 square meters) with a minimum clear dimension of 12 feet (3.65 meters).

3.7-3.2.3.2 Clearances. Procedure rooms shall have a minimum clearance of 4 feet (1.22 meters) on each side and at the head and foot of the procedure table or gurney.

*3.7-3.3 Outpatient Operating Rooms (formerly Class B and C Operating Rooms)

3.7-3.3.1 Space Requirements

***3.7-3.3.1.1 Operating room.** In new construction and renovation, each operating room shall have a minimum clear floor area of 250 square feet (23.25 square meters) with a minimum clear dimension of 15 feet (4.58 meters) between fixed cabinets and built-in shelves.

***3.7-3.3.1.2 Operating room for surgical procedures that require additional personnel and/or large equipment.** Where provided, such operating rooms shall be sized to accommodate the personnel and equipment planned to be in the room during procedures.

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A3.7-3.3 Provisions for patients with airborne infectious diseases. When invasive procedures need to be performed on persons who are known or suspected of having airborne infectious disease, these procedures are ideally performed in a room meeting airborne infection isolation (AII) ventilation requirements or in a space using local exhaust ventilation. If the procedure must be performed in the operating suite, follow recommendations outlined in the CDC "Guidelines for Environmental Infection Control in Health-Care Facilities" or the CDC "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities."

A3.7-3.3.1.1 Determining operating room space requirements. The minimum square footage for an operating room was determined by combining the square footage of the minimum amount of equipment required, the square footage for the minimum number of people required, and a space of approximately 4 feet (1.22 meters) for a minimum safe traffic pathway on all four sides of the sterile field. The sterile field includes the OR table width of 1.75 feet (53.34 centimeters) plus 2 feet (60.96 centimeters) on each side to accommodate personnel and outstretched patient armrests. The safe traffic pathway of 4 feet includes space for two people to meet and pass each other without touching either personnel wearing sterile attire who are standing at the sterile field or non-sterile surfaces (e.g., walls, people, or equipment) on the other side. This distance permits two people, both of whom are within the sterile field, to pass each other without contaminating their sterile attire by touching unsterile surfaces. An open traffic

pathway is required on all four sides to provide space for personnel to set up a sterile field prior to the procedure, assist with safe patient evacuation using a stretcher in case of an emergency, pass between the back table and the wall during the procedure, and to pass at the head of the patient without interfering with care being provided by the anesthesia care provider.

The assumption was made when calculating the square footage needed to accommodate the minimum amount of required equipment, that all equipment would fit tightly together; however, this frequently does not occur due to the shape of the equipment.

The minimum equipment for a surgical procedure includes an anesthesia machine, anesthesia supply cart, anesthesia professional chair, intravenous pole or table, case cart/equipment delivery system cart, prep stand, portable documentation station with chair, back instrument table, ring stand, two trash containers, soiled linen container, hazardous waste receptacle, mayo stand, kick bucket, surgical field suction attached to a wall, image viewers, and a sharps disposal receptacle. The required personnel include the surgeon, scrub nurse/technician, circulating nurse, and anesthesia care provider. A 9-square-foot (.84-square-meter) rectangle is required to allow for clear door swing when a stretcher is in the room.

A3.7-3.3.1.2 Space requirements for operating rooms for procedures requiring more space

a. When operating rooms for surgical procedures that require additional personnel and/or large equipment (e.g., those used for some

3.7 SPECIFIC REQUIREMENTS FOR OUTPATIENT SURGICAL FACILITIES

3.7-3.3.2 Emergency Communication System

3.7-3.3.2.1 All operating rooms shall be equipped with an emergency communication system that incorporates push activation of an emergency call switch.

3.7-3.3.2.2 For nurse call requirements, see Table 3.1-2 (Locations for Nurse Call Devices in Outpatient Facilities).

3.7-3.3.3 Documentation Area

Accommodations for written or electronic documentation shall be provided.

3.7-3.3.4 Image Viewer

Each operating room shall have access to at least one medical image viewer.

3.7-3.3.5 Medical Gas Requirements

See Table 3.1-3 (Station Outlets for Oxygen, Vacuum, and Medical Air Systems in Outpatient Facilities) for requirements.

3.7-3.4 Pre- and Postoperative Patient Care Areas

2.2-3.4.1 General

3.7-3.4.1.1 Patient care station design

- (1) Bays, cubicles, or single-patient rooms shall be permitted to serve as patient care stations.
- (2) When determining the area for a patient care station, space shall be provided for additional equipment described in the functional program.

3.7-3.4.2 Preoperative Patient Care Area

3.7-3.4.2.1 General

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orthopedic and neurological procedures) are included in a facility, these rooms should have a minimum clear floor area of 600 square feet (55.74 square meters) with a clear dimension of 20 feet (6.10 meters).

- b. Where complex orthopedic and neurosurgical surgery is performed, equipment storage rooms should be provided in the semi-restricted area of the surgical suite, preferably adjoining the specialty operating

- (1) Application. In facilities with two or more operating rooms, area(s) with patient care stations shall be provided to accommodate stretcher patients as well as seating space for patients and for visitors.
- (2) Location. The preoperative patient care area shall be:
 - (a) An unrestricted area.
 - (b) Under the direct visual control of the nursing staff.
 - (c) Permitted to be part of the Phase II recovery area.
- (3) Size of preoperative patient care area. The minimum number of patient care stations in the preoperative patient care area shall be one per operating room.

3.7-3.4.2.2 Space requirements

(1) Area of patient care stations

- (a) Where bays are used, a minimum clear floor area of 60 square feet (5.58 square meters) shall be provided for each patient in a lounge chair or stretcher.
- (b) Where cubicles are used, each station shall have a minimum clear floor area of 80 square feet (7.43 square meters).
- (c) Where single-patient rooms are used, a minimum clear floor area of 100 square feet (9.29 square meters) shall be provided.

* (2) Clearances in patient care stations

- (a) Where bays are used, a minimum clearance of 5 feet (1.52 meters) shall be provided between the sides of patient beds/stretchers; 4 feet (1.22 meters) between the sides of patient beds/stretchers and adjacent walls or partitions; and 3 feet (91.44 centimeters) between the foot of beds/stretchers and the cubicle curtain.

ing rooms, for storage of the large equipment used to support these procedures.

A3.7-3.4.2.2 (2) Clearances do not include any area that would have to be shared to meet the standard. Clearances noted around gurneys are between the normal use position of the gurney and any adjacent fixed surface or between adjacent gurneys.

(b) Where cubicles and single-patient rooms are used, a minimum clearance of 3 feet (91.44 centimeters) shall be provided between the sides and foot of lounge chairs/stretchers and adjacent walls or partitions.

(3) If the preoperative patient care area will serve other uses (e.g., an overflow Phase I post-anesthesia recovery area or a holding area at the end of the day), see Section 3.7-3.4.3.2 (2) (Phase II recovery area—Space requirements) for area and clearance requirements.

3.7-3.4.2.3 Reserved

3.7-3.4.2.4 Patient privacy. Provisions such as cubicle curtains shall be made for patient privacy.

3.7-3.4.2.5 Hand-washing station(s). See Section 3.1-3.6.5 (Hand-Washing Station) for requirements.

3.7-3.4.3 Postoperative Recovery Areas

3.7-3.4.3.1 Phase I post-anesthesia recovery room(s). Room(s) shall be provided for Phase I post-anesthesia recovery in outpatient surgical facilities.

(1) General

(a) Location

- (i) Phase I post-anesthesia recovery rooms are unrestricted areas.
- (ii) At least one door to the recovery room shall provide access directly from the semi-restricted area of the surgical suite without crossing a public corridor.
- (iii) Preoperative patient care areas and recovery areas shall be permitted to share the same space if all patient care stations meet the most restrictive requirements of both areas.

*(b) Size of Phase I recovery area. A minimum of 1.5 recovery patient care stations per operating room shall be provided.

(c) If pediatric surgery is part of the program, the following requirements shall be met:

- (i) Pediatric recovery stations shall be separate from adult stations.
- (ii) Pediatric stations shall provide space for parents.
- (iii) Pediatric recovery stations shall be visible from the nurse station.

(2) Space requirements

- (a) Area. A minimum clear floor area of 80 square feet (7.43 square meters) shall be provided for each patient bay or cubicle.
- (b) Clearances. Each post-anesthesia recovery bay or cubicle shall provide the following minimum clearances:
 - (i) 5 feet (1.52 meters) between patient stretchers or beds
 - (ii) 4 feet (1.22 meters) between patient stretchers or beds and adjacent walls or other fixed elements (at the stretcher's sides and foot)
 - (iii) At least 3 feet (91.44 centimeters) from the foot of the stretcher or bed to the closed cubicle curtain

(3) Reserved

(4) Patient privacy. Provisions for patient privacy such as cubicle curtains shall be made.

(5) Hand-washing stations. See Section 3.1-3.6.5 (Hand-Washing Station) for requirements.

(6) For nurse call requirements, see Table 3.1-2 (Locations for Nurse Call Devices in Outpatient Facilities).

3.7-3.4.3.2 Phase II recovery area

(1) General

- (a) Application. A Phase II recovery area shall be provided if required in the functional program.
- (b) Location

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A3.7-3.4.3.1 (1)(b) Determining the number of Phase I patient care stations. When use of the formula results in a fraction for the number of patient care stations to be provided, the fraction should be rounded up to the next whole number.

When designing the recovery area and determining the number of recovery positions required, at minimum consideration should be given to the types of surgery and procedures performed, types of anesthesia used, average recovery periods for patients, and anticipated staffing levels.

3.7 SPECIFIC REQUIREMENTS FOR OUTPATIENT SURGICAL FACILITIES

- (i) The Phase II recovery area is an unrestricted area.
- (ii) Location of the Phase II recovery area in the Phase I post-anesthesia recovery area shall be permitted, but the Phase II area shall be identifiable as a separate and distinct part of the post-anesthesia recovery area.
- (iii) The same area shall be permitted to serve as the preoperative area and the Phase II recovery area.

(2) Space requirements

(a) Area

- (i) Where patient bays are used, a minimum of 60 square feet (5.58 square meters) shall be provided for each patient in a lounge chair or stretcher.
- (ii) Where cubicles are used, each patient care station shall have a minimum clear floor area of 80 square feet (7.43 square meters).
- (iii) Where single-patient rooms are used, a minimum clear floor area of 100 square feet (9.29 square meters) shall be provided in each room.

(b) Clearances

- (i) Where bays are used, a minimum clearance of 4 feet (1.22 meters) shall be provided between the sides of lounge chairs or stretchers.
- (ii) In all patient care stations, a minimum clearance of 3 feet (91.44 centimeters) shall be provided between walls or partitions and the sides and foot of lounge chairs or stretchers.

(3) Reserved

(4) Patient privacy. Provisions for patient privacy such as cubicle curtains shall be made.

(5) Hand-washing station. See Section 3.1-3.6.5 (Hand-Washing Station) for requirements.

(6) For nurse call requirements, see Table 3.1-2 (Locations for Nurse Call Devices in Outpatient Facilities).

(7) Patient toilet room(s)

- (a) A patient toilet with direct access to the Phase II recovery unit shall be provided for the exclusive use of patients.

- (b) Additional toilets shall be provided at the ratio of one patient toilet for each eight patient care stations or fewer and for each major fraction thereof.

3.7-3.5 Support Areas for Patient Care

3.7-3.5.1 General

See Section 3.1-3.5 (Support Areas for Patient Care—General) for requirements.

3.7-3.5.2 Support Areas for Pre- and Postoperative Patient Care Areas

3.7-3.5.2.1 General. All support areas shall be permitted to serve the preoperative patient care area and the recovery areas if they are directly accessible to the patient care areas served.

3.7-3.5.2.2 Support areas for all patient care areas.

The following support areas shall be provided in accordance with the requirements for such areas in Section 3.7-3.6 (Support Areas for the Surgical Suite).

(1) Documentation area

(2) Medication safety zone

(3) Equipment and supply storage

(a) Clean linen storage

(b) IV supply storage and work counter

(c) Countertop areas as needed to support the function of the space

(d) Storage space for supplies and equipment, including (but not limited to) wheelchairs and stretchers/gurneys

(e) Parking area for equipment

3.7-3.5.2.3 Further support areas for postoperative recovery areas

(1) Nurse station with documentation space. A direct sight line is not required in the Phase II recovery area.

(2) Clinical sink. Location of this sink in the soiled workroom required in Section 3.7-3.6.10 (Soiled Workroom or Soiled Holding Room) shall be permitted if directly accessible to recovery areas.

(3) Nourishment facilities. These shall be provided for the Phase II recovery area.

(4) Provisions for soiled linen and waste holding.

Location of these provisions in the soiled workroom required in Section 3.7-3.6.10 (Soiled Workroom or Soiled Holding Room) shall be permitted if directly accessible to recovery areas.

3.7-3.5.3 Support areas for staff. In facilities with more than two operating rooms, a staff toilet shall be located within the recovery areas.

3.7-3.5.4 Support areas for patients

3.7-3.5.4.1 In facilities with more than two operating rooms, access to a toilet from preparation and recovery areas without entering public spaces or areas outside of staff control shall be provided for patient use.

3.7-3.5.4.2 Seating space for visitors shall be provided in the Phase II recovery area if one is provided. Space for at least one seat for a visitor shall be provided within the boundaries of each patient station.

3.7-3.6 Support Areas for the Surgical Suite

The following shall be provided in surgical service areas:

3.7-3.6.1 Nurse or Control Station

3.7-3.6.1.1 A nurse or control station(s) shall be located at the point of primary ingress and may be in the unrestricted or semi-restricted area.

3.7-3.6.1.2 The nurse or control station(s) shall permit direct visual observation of all traffic into the suite. Access through all other entries shall be controlled.

3.7-3.6.2 – 3.7-3.6.4 Reserved

3.7-3.6.5 Hand Scrub Facilities

See Section 3.1-3.3 (Hand Scrub Facilities) for requirements.

3.7-3.6.6 Medication Safety Zone

See Section 3.1-3.6.6 (Medication Safety Zones) for requirements.

3.7-3.6.7 Reserved

3.7-3.6.8 Ice-Making Equipment

If ice-making equipment is provided, it shall be located in an unrestricted area. Location in a Phase I post-anesthesia recovery room(s) or Phase II recovery area shall be permitted.

*3.7-3.6.9 Clean Supply Room

3.7-3.6.9.1 Storage space for sterile and clean supplies shall be provided.

3.7-3.6.9.2 Location

- (1) The clean supply room shall be separate from soiled storage rooms.
- (2) The clean supply room shall have an entrance from the semi-restricted area.

3.7-3.6.10 Soiled Workroom or Soiled Holding Room

A soiled workroom or holding room shall be provided.

3.7-3.6.10.1 General

- (1) This shall be permitted to be the same workroom described in Section 3.7-5.1.1.3 (A room for gross decontamination and holding of instruments).
- (2) Soiled and clean workrooms or holding rooms shall be separated.
- (3) The soiled workroom or holding room shall be directly accessible to the semi-restricted area of the surgical suite.
- (4) Sharing of the soiled workroom or holding room with the unrestricted area or another semi-restricted area shall be permitted if direct access is provided from the semi-restricted area of the surgical suite and a separate entrance is provided from the unrestricted area.
- (5) The soiled workroom or holding room shall not have direct connection with operating rooms or other sterile activity rooms.

3.7-3.6.10.2 Soiled workroom. The soiled workroom shall contain the following:

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A3.7-3.6.9 Equipment and sterile supplies used in an operating room, including anesthesia equipment, may be stored in one room, which may be the clean workroom in Section 3.7-3.6.9 (Clean Supply Room) or the equipment and supply storage room in Section 3.7-3.6.11 (Equipment and Supply Storage).

3.7 SPECIFIC REQUIREMENTS FOR OUTPATIENT SURGICAL FACILITIES

- (1) A flushing-rim clinical sink or equivalent flushing-rim fixture
- (2) A hand-washing station
- (3) A work counter
- (4) Space for waste receptacles and soiled linen receptacles
- (5) Storage for supplies

3.7-3.6.10.3 Soiled holding room. Omission of the flushing-rim clinical sink and work counters shall be permitted in rooms used only for temporary holding of soiled material. However, if the flushing-rim clinical sink is omitted, other provisions for disposal of liquid waste shall be provided.

3.7-3.6.11 Equipment and Supply Storage

3.7-3.6.11.1 Reserved

3.7-3.6.11.2 Surgical equipment and supply storage. Storage shall be provided for equipment and supplies used in the surgical suite.

- (1) Area. The combined area of equipment and clean clinical supply storage room(s) shall have a minimum floor area of 50 square feet (4.65 square meters) for each operating room(s) up to two and an additional 25 square feet (2.33 square meters) per additional operating room.
- (2) Location
 - (a) Equipment and supply storage room(s) shall be located in the semi-restricted area.
 - (b) Location of this equipment and supply storage in the clean assembly/workroom described in Section 3.7-5.1.1.2 shall be permitted.

3.7-3.6.11.3 Storage space for stretchers and wheelchairs

- (1) A stretcher storage area for at least one stretcher shall be provided.
- (2) Wheelchair storage space shall be immediately accessible to areas of high use. See Section 3.1-

3.6.11.3 (Wheelchair storage and parking space) for requirements.

3.7-3.6.11.4 Emergency equipment storage.

Emergency equipment storage shall be provided in accordance with Section 3.1-3.6.11.4 (Emergency equipment storage) except as amended in this section.

- (1) At a minimum, emergency equipment storage shall be provided in both the surgical suite and recovery areas.
- (2) This storage area shall be permitted to be a portion of the storage required in Section 3.7-3.6.11.2 (Surgical equipment and supply storage).

3.7-3.6.11.5 Medical gas storage. Provisions shall be made for the medical gas(es) used in the facility. Adequate space for supply and storage, including space for reserve cylinders, shall be provided and protected in accordance with NFPA 99: *Standard for Health Care Facilities*.

*3.7-3.6.12 Environmental Services Room

An environmental services room shall be provided in accordance with Section 3.1-5.5.1 (Environmental Services Room).

3.7-3.6.12.1 The environmental services room shall be located in the surgery suite and shall not be shared with other areas.

3.7-3.6.12.2 The environmental services room is to be accessed from the semi-restricted corridor/area.

*3.7-3.6.13 Sterile Processing Room

When sterilization processes are conducted in the surgical suite, a sterile processing room shall be provided. For other sterilization facility requirements, see Section 3.7-5.1 (Sterilization Facilities).

3.7-3.6.13.1 General

A3.7-3.6.13 If a separate area for immediate-use sterilization is needed for the surgical services provided, this area may be combined with the sterilization facilities in Section 3.7-5.1.2 (On-Site Sterilization Facilities).

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A3.7-3.6.12 Environmental services room

- a. The door to the environmental services room may swing out.
- b. Space for docking liquid waste collection devices outfitted per the manufacturer's installation recommendations should be considered when determining the size of the environmental services room.

- (1) The sterile processing room shall consist of a decontamination area and a clean work area.
- * (2) Location. The sterile processing room shall be designed to provide a one-way traffic pattern of contaminated materials/instruments to clean materials/instruments to the sterilizer equipment.
 - (a) Entrance to the contaminated side of the sterile processing room shall be from the semi-restricted area.
 - (b) Exit from the clean side of the sterile processing room to the semi-restricted area or to an operating room shall be permitted.
- * (3) The sterile processing room shall be permitted to be shared between two or more operating rooms.

3.7-3.6.13.2 Decontamination area

- (1) The decontamination area shall be equipped with the following:
 - (a) Countertop
 - (b) Hand-washing station separate from the instrument-washing sink
 - (c) Sink for washing instruments
 - (d) Storage for supplies
- (2) To avoid splash, the decontamination sink shall be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If a screen is used, it shall extend a minimum of 4 feet (centimeters) above the sink rim.

3.7-3.6.13.3 Clean work area. The clean work area shall be equipped with the following:

- (1) Countertop
- (2) Sterilizer as required for the services provided
- (3) Hand-washing station
- (4) Built-in storage for supplies

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A3.7-3.6.13.1 (2) One-way traffic in sterile processing. The one-way flow of contaminated materials/instruments to clean materials/instruments helps decrease the potential for cross-contamination of sterile instruments.

The process for sterilization is for the circulating nurse to take a contaminated material/instrument in a tray into the decontamination area of the sterile processing room, clean and sterilize the material/

3.7-3.6.14 Fluid Waste Disposal Facilities

3.7-3.6.14.1 In the operating room area, a clinical sink or equivalent equipment in the soiled workroom in Section 3.7-3.6.10 (Soiled Workroom or Soiled Holding Room) shall meet this requirement.

3.7-3.6.14.2 In the recovery area, a toilet equipped with a bedpan-cleaning device or a separate clinical sink shall meet this requirement. See Section 3.7-3.4.3.2 (7) (Phase II recovery area—Patient toilet rooms).

3.7-3.6.15 Storage for blood, organs, and pathological specimens

3.7-3.6.15.1 When storage of blood, tissue, and pathological specimens is required, a refrigerator shall be provided.

***3.7-3.6.15.2** Provisions for proper storage of blood and tissue, including equipment, temperature controls, alarms, and monitoring, shall meet the requirements of the Clinical Laboratory Improvements Amendments (CLIA) and other applicable regulatory requirements and professional standards.

3.7-3.7 Support Areas for Staff

3.7-3.7.1 Staff Lounge

A staff lounge shall be provided in facilities with three or more operating rooms.

3.7-3.7.2 Staff Changing Area and Toilet Facilities

An area with one or more private changing rooms or separate areas shall be provided for male and female staff working in the surgical suite. Provision of a unisex locker area with one or more private changing rooms shall be permitted.

instrument, and return it to the point of use via the clean work area. This creates the one-way traffic pattern.

A3.7-3.6.13.1 (3) The sterile processing room can be shared between two operating rooms or be located off the semi-restricted area and shared between several operating rooms.

A3.7-3.6.15.2 CLIA is enforced by the Centers for Medicare & Medicaid Services.

3.7-3.7.2.1 Staff changing area(s) shall contain the following:

- (1) Lockers
- (2) Toilets
- (3) Hand-washing stations
- (4) Space for donning surgical attire
- (5) Provision for separate storage for clean and soiled surgical attire

3.7-3.7.2.2 Staff changing area(s) shall be an unrestricted area.

3.7-3.7.3 Staff Shower

At least one staff shower shall be provided that is readily accessible to the surgical suite and recovery areas.

3.7-3.8 Support Areas for Patients

3.7-3.8.1 Patient Changing and Preparation Area

3.7-3.8.1.1 Space shall be provided for patients to change from street clothing into hospital gowns and to prepare for surgery.

- (1) This changing area shall be permitted to consist of private holding room(s) or cubicle(s) and/or a separate changing area.
- (2) Combination of this space with a patient station in the preoperative patient care area shall be permitted.
- (3) This area shall include the following:
 - (a) Place or method of storage for patient clothing
 - (b) Access to toilet(s) without passing through a public space
 - (c) Clothing change or gowning area(s)
 - (d) Space for administering medications

3.7-3.8.1.2 Provisions shall be made for securing patients' personal effects.

3.7-3.8.2 Toilet Room

3.7-3.8.2.1 The patient toilet room(s) shall be separate from public use toilet(s) and located to permit access from pre- and postoperative patient care areas.

3.7-3.8.2.2 For specific requirements for the patient toilet room in a Phase II recovery area, see Section

3.7-3.4.3.2 (7) (Phase II recovery area—Patient toilet rooms).

3.7-4 Reserved

3.7-5 General Support Facilities

3.7-5.1 Sterilization Facilities

A system for sterilizing equipment and supplies shall be provided.

3.7-5.1.1 Support Areas for Off-Site Sterilization

When sterilization is provided off-site, the following on-site support spaces shall be provided:

3.7-5.1.1.1 A room for breakdown (receiving/unpacking) of clean/sterile supplies

3.7-5.1.1.2 A room for on-site storage of clean and sterile supplies

3.7-5.1.1.3 A room for gross decontamination and holding of instruments. The room described in Section 3.7-3.6.10 (Soiled Workroom or Soiled Holding Room) shall be permitted to serve this purpose.

3.7-5.1.2 On-Site Sterilization Facilities

When sterilization occurs on-site, the requirements in Section 3.7-3.6.13 (Sterile Processing Room) shall be met.

3.7-5.2 Linen Services

Designated separate spaces shall be provided for clean linen storage and soiled linen holding.

3.7-5.2.1 Clean linen storage area shall be permitted to be located in the unrestricted area.

3.7-5.2.2 Soiled linen storage shall be permitted to be a portion of the soiled workroom in Section 3.7-3.6.10 (Soiled Workroom or Soiled Holding Room).

3.7-5.3 – 3.7-5.4 Reserved

3.7-5.5 Environmental Services

3.7-5.5.1 Environmental Services Rooms

3.7-5.5.1.1 Environmental services room(s) shall be provided in accordance with Section 3.1-5.5.1.1 (Environmental Services Rooms—Number) and 3.1-5.5.1.2 (Environmental services room for facility-based environmental services).

3.7-5.5.1.2 If a fluid management system (see Section 3.7-3.6.14—Fluid Waste Disposal Facilities) is used, electrical and plumbing connections shall be provided in accordance with the manufacturer's requirements and additional space shall be provided for the docking station(s).

■ 3.7-6 Public and Administrative Areas

3.7-6.1 General

The following shall be provided:

3.7-6.2 Public Areas

*3.7-6.2.1 Entrance

A minimum of one drop-off area or entrance reachable from grade level shall be provided.

3.7-6.3 Administrative Areas

3.7-6.3.1 Reserved

3.7-6.3.2 Interview Space

3.7-6.3.2.1 Space(s) for private interviews relating to admission shall be provided separate from public and patient areas.

3.7-6.3.2.2 Shared use of an office, multipurpose, or consultation room for this purpose shall be permitted.

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A3.7-6.2.1 When a roof overhang or canopy is provided, it should extend as far as practicable to the face of the driveway or curb of the passenger access door of the transport vehicle. Vehicles in the loading area should not block or restrict movement of other vehicles in the drive or parking areas immediately adjacent to the facility.

*3.7-6.3.3 Office Space

Office space shall be provided for general and individual office(s) for business transactions.

3.7-6.3.4 Multipurpose or Consultation Room(s)

3.7-6.3.4.1 At least one private multipurpose or consultation room shall be provided as part of the unrestricted area.

3.7-6.3.4.2 Shared use of an office or interview room for this purpose shall be permitted.

3.7-6.3.5 Medical Records

For requirements regarding medical records, see Section 3.1-6.3.5 (Medical Records).

3.7-6.3.6 Equipment and Supply Storage

See Section 3.1-3.6.11 (Equipment and Supply Storage) for requirements.

3.7-6.4 Support Areas for Staff

See Section 3.1-6.4.2 (Storage for Employees) for requirements.

■ 3.7-7 Design and Construction Requirements

3.7-7.1 Building Codes and Standards—Reserved

3.7-7.2 Architectural Details, Surfaces, and Furnishings

In addition to the requirements in 3.1-7.2 (Architectural Details, Surfaces, and Furnishings), the requirements in this section shall be met.

3.7-7.2.1 Reserved

A3.7-6.3.3 The space needs for business transactions, medical and financial records, and administrative and professional staff should be defined in the functional program.

3.7-7.2.2 Architectural Details

3.7-7.2.2.1 Corridor width. The requirements in Section 3.1-7.2.2.1 (Corridor width) shall be met as amended in this section:

- (1) Public corridors shall have a minimum width of 5 feet (152 centimeters).
- (2) Where patients are transported on stretchers or beds, at least one corridor that connects the surgical suite and the PACU to an exit shall have a minimum width of 6 feet (183 centimeters).
- (3) The corridor connecting the surgical suite and the PACU shall have a minimum width of 8 feet (244 centimeters) to accommodate transport of patients between pre-operative, procedure, and post-anesthesia recovery areas.
- (4) Staff-only corridors shall be permitted to be a minimum of 3 feet 8 inches (112 centimeters) wide unless a greater width is required by occupant load calculations per local and state building codes.

3.7-7.2.2.2 Reserved**3.7-7.2.2.3 Doors and door hardware**

- (1) Door openings
 - (a) Door openings serving occupiable spaces shall have a minimum clear width of 2 feet 10 inches (86.36 centimeters).
 - (b) Door openings requiring gurney/stretchers access shall have a minimum clear width of 3 feet 8 inches (1.12 meters).
- (2) Toilet rooms. Toilet rooms for patient use in surgery and recovery areas shall comply with the following:
 - (a) These toilet rooms shall be equipped with doors and hardware that permit access from the outside in emergencies.
 - (b) When such rooms have only one opening or are small, the doors shall open outward or be otherwise designed to open without pressing against a patient who may have collapsed within the room.

3.7-7.2.3 Surfaces

3.7-7.2.3.1 General. Surfaces shall comply with NFPA 101.

3.7-7.2.3.2 Flooring. Floor finishes shall be appropriate for the areas in which they are located and shall be as follows:

- (1) Floor finishes shall be cleanable.
- (2) Floor finishes in areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and Class A operating rooms shall be washable, smooth, and able to withstand chemical cleaning.
- (3) Floor finishes in areas such as operating rooms, delivery rooms, and trauma rooms shall be scrubbable, able to withstand chemical cleaning, and monolithic, with an integral base.
- (4) All floor surfaces in clinical areas shall be constructed of materials that allow the easy movement of all required wheeled equipment.

3.7-7.2.3.3 Walls. Wall finishes shall be appropriate for the areas in which they are located and shall be as follows:

- (1) Wall finishes shall be cleanable.
- (2) Wall finishes in areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and minor surgical procedure rooms shall be washable, smooth, and able to withstand chemical cleaning.
- (3) Wall finishes in areas such as operating rooms, delivery rooms, and trauma rooms shall be scrubbable, able to withstand chemical cleaning, and monolithic.

3.7-7.2.3.4 Ceilings. Ceiling finishes shall be appropriate for the areas in which they are located and shall be as follows:

- * (1) Semi-restricted areas
- (a) Ceiling finishes in semi-restricted areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and Class A operating rooms shall be smooth, scrubbable,

APPENDIX

A3.7-7.2.3.4 (1) Ceilings in semi-restricted areas. If a lay-in ceiling is provided, it should be gasketed or each ceiling tile should weigh one pound per square foot to prevent the passage of particles from the cavity above the ceiling plane into the semi-restricted environment.

nonabsorptive, nonperforated, capable of withstanding cleaning with chemicals, and without crevices that can harbor mold and bacteria growth.

- (b) Perforated, regular, serrated, or highly textured tiles shall not be used.

(2) Restricted areas

- (a) Ceilings in restricted areas such as operating rooms shall be monolithic, scrubbable, and capable of withstanding chemicals. Cracks or perforations in these ceilings are not allowed.
- (b) All access openings in ceilings in restricted areas shall be gasketed.

- (3) Mechanical and electrical rooms. Suspended ceilings may be omitted in mechanical and electrical rooms/spaces unless required for fire safety purposes.

■ 3.7-8 Building Systems

3.7-8.1 Reserved

3.7-8.2 Heating, Ventilation, and Air-Conditioning (HVAC) Systems

See Section 3.1-8.2 (HVAC Systems) for requirements.

3.7-8.3 Electrical Systems

See Section 3.1-8.3 (Electrical Systems) for requirements.

3.7-8.4 Plumbing Systems

See Section 3.1-8.4 (Plumbing Systems) for requirements.

3.7-8.4.1 Medical Gas Systems

Flammable anesthetics shall not be used in outpatient surgical facilities.

3.7-8.5 Communications Systems

3.7-8.5.1 See Section 3.1-8.5 (Communications Systems) for requirements in addition to those in this section.

3.7-8.5.2 Emergency Communication System

All operating rooms and Phase I post-anesthesia recovery room(s) shall be equipped with an emergency communication system designed and installed to summon additional staff support with no more than push activation of an emergency call switch.

3.7-8.6 Fire Alarm System

A fire alarm system shall be provided in accordance with Section 3.1-8.6 (Fire Alarm Systems).

3.7-8.7 Special Systems

See Section 3.1-8.7 (Special Systems) for requirements.

Appendix L
Howard Bank Letter



6011 University Boulevard, Suite 370
Ellicott City, MD 21043
(P) 410-750-0020
(F) 410-750-8588

January 23, 2017

Kevin McDonald, Chief
Certificate of Need Division
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Dr. Scott LaBorwit/Columbia Surgical Institute, LLC

Dear Mr. McDonald:

Dr. LaBorwit has maintained a depository and lending banking relationship with Howard Bank since 2011. All accounts are handled as agreed with no issues or concerns. Additionally, Columbia Surgical Institute has a \$250,000 line of credit available to assist with any working capital or equipment needs.

Dr. LaBorwit is a valued client and we look forward to continuing our support of his growing practice.

I am available at 410-750-7993 should further information be required.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Marasco'.

Christopher Marasco
Senior Vice President
Howard Bank

Appendix M
Letter of Support



Lenard H. Hammer, M.D., F.A.C.S.
Gordon Lui, M.D.
Scott B. Becker, M.D.
Brian J. Winter, M.D.
Vanessa Lima, M.D.
Cristina F. Rouiller, O.D.
Jessica E. Chan, M.D.

12/9/2016

Kevin McDonald, Chief
Certificate of Need Division
Maryland Health Care Commission
4160 Paterson Avenue
Baltimore MD 21215

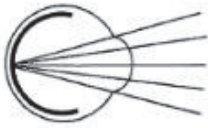
I am writing on behalf of Columbia Surgical Institute's application for a Certificate of Need. As an ophthalmologist who has been in practice for more than 20 years I have found that most eye surgeons prefer doing surgery at an Ambulatory Surgery Center (ASC) versus a hospital setting. Because the majority of eye surgeries are performed on an outpatient basis, there is little need for an ophthalmologist to use a hospital operating room. Not only are ASC's more patient friendly, efficient and easier to use, they are also more cost effective to patients and insurance companies. Recently I have heard some colleagues expressing frustration of hospitals not allowing ophthalmologists to schedule blocks of time for surgery due to reimbursement issues. This will support the need for more ophthalmologists to use ASC's that don't have these issues. While the demographically aging population is expected to burden all areas of health care, ophthalmologists will particularly be affected as they provide 90% of their surgical procedures to seniors. It has been forecast that the demand for cataract surgery may increase over 100% in the next few decades. I believe this facility will address the current and future ophthalmologic needs of our aging population in a safe, patient friendly and efficient outpatient setting. I hope you will consider these factors in Columbia Surgical Institute's application for an additional operating room.

Sincerely,

Gordon Lui, MD

A handwritten signature in black ink, appearing to read 'Gordon Lui MD', with a stylized flourish at the end.

8860 COLUMBIA 100 PARKWAY, COLUMBIA, MD 21045 . PHONE (410) 997-9900 . FAX (410) 997-4498
3402 OLANDWOOD COURT, OLNEY, MD 20832 . PHONE (301) 774-2750 . FAX (301) 774-2756
WWW.MEDICALEYECENTER.NET



Retina
Consultants, P.C.

David L. Parver, MD
Leonard M. Parver, MD
Robert F. Stephens, MD
Fadi P. Nasrallah, MD
Jordan L. Heffez, MD
Nishi Gulati, MD

Washington, DC
1145 Nineteenth St., NW
Suite 500
Washington, DC 20036
T: 202.833.1668
F: 202.833.4698

Bethesda, MD
6410 Rockledge Dr.
Suite 400
Bethesda, MD 20817
T: 301.530.5200
F: 301.493.6577

Annandale, VA
3289 Woodburn Rd.
Suite 270
Annandale, VA 22003
T: 703.849.8601
F: 703.849.8605

Satellite Offices

Towson, MD
T: 410.821.6400
F: 410.296.4722

Columbia, MD
T: 410.872.1600
F: 410.872.9299

January 5, 2017

Kevin McDonald, Chief
Certificate of Need Division
Maryland Health Care Commission
4160 Paterson Avenue
Baltimore, MD 21215

Dear Mr. McDonald,

I would like to share my perspective and experience as a retinal specialist operating at the Columbia Surgical Institute (CSI). I have used the center for retinal procedures on my patients for over one year.

This surgery centers' focus on only eye surgery, efficiency of care, and commitment to advanced technology are reasons I prefer to perform surgery at CSI. When operating in larger hospital based operating rooms my patients get lost in the crowd and I'm often starting cases significantly late. This may be a result of lengthy cases from other surgical specialties that run into my block time, frequent emergencies that create delays, or inefficiencies that are abundant in a large hospital based system. Recently at the hospital, a patient was held in the operating room for over 30 minutes after the case was finished, waiting for a space in the overcrowded recovery room. At CSI, the staff and anesthesia team is tuned to a surgeon and patients needs for eye surgery. I start on time, room turn over is very fast and anesthesia is very familiar with my case time and sedates patients appropriately.

At this outpatient surgical center my patients are not hassled with a parking garage and ticket. Patients are elated not to have to change into a hospital gown. In addition, Columbia Surgical Institute has state of the art retinal equipment allowing me to perform advanced retinal surgeries with quicker recovery and excellent outcomes.

There are patients with retinal detachments or severe intraocular infections that require urgent surgery, some within hours of presentation. If CSI were able to have a second operating room then it would increase the opportunity for me to allow for efficient and essential care of these patients.

I appreciate the opportunity to support the Columbia Surgical Institute's effort to have a second operating room. I promote encouraging growth of a facility that creates efficiency, engages technology, focuses on a single specialty and can concentrate on patient's experience and outcomes.

Sincerely,

Jordan L. Heffez, MD

Senator James Robey, (Retired)
6150 Shadywood Road #402
Elkridge, MD 21075
410-540-9023

Kevin McDonald, Chief
Certificate of Need Division
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

January 15, 2017

Dear Chief McDonald:

My name is James Robey, former Howard County Executive, and Retired Maryland Senator. I am writing in support of a Certificate of Need for a second operating room at Select Eye Care located at 6020 Meadowridge Center Drive, Elkridge, MD.

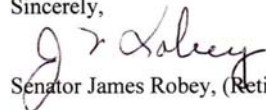
I believe my 48 years of public service qualifies me to comment on the needs of my County and State. During my terms in office, I was able to attend many health care facilities, both in patient and out patient. While in patient facilities are critical to the community health, I saw the need for convenient and efficient out patient services.

Select Eye Care, unlike hospitals, with large parking lots and expansive buildings, provides easy and convenient access for older patients including me and my wife. As long time patients of Dr. Scott LaBorwit we have enjoyed the friendly and professional service provided by the Select Eye Care staff.

The expansion of Dr. LaBorwit's office will address the needs of Howard County's and the regions rapidly expanding senior population. On a recent visit to Select Eye Care I talked with patients from Montgomery and Frederick Counties who, given the Center's easy access from Interstate 95 and Maryland 100, found it a far less cumbersome commute and a shorter process required at in patient facilities.

I hope you will give a favorable review to Select Eye Care Center in Howard County.

Sincerely,


Senator James Robey, (Retired)

Appendix N
Physician Attestations of Projected Volumes



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Misty Wray attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

A handwritten signature in black ink, appearing to read "Misty Wray" with a large flourish at the end.



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Sonny Goel, MD attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

"Sonny" Sonny D. Goel, MD


Columbia
Surgical Institute
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

020-H Meadowridge Center Drive

Attestation

I Jessica Chan, MD attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,



Signature

12/18/16

Date



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I SALMAN ALI attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

A handwritten signature in black ink, appearing to read "Salman Ali".

12/19/16



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Jacey Hanna attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

Jacey Hanna 12/21/16



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Gordon Luong attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflects the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

Gordon Luong
Gordon Luong
12/12/16



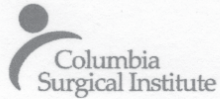
020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Ramya Swamy attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

Ramya N Swamy




020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I **Sadiq Syed, MD** attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

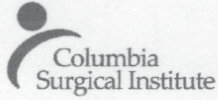
Sincerely,



Signature

12/21/16

Date



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Eugene Sulvo attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

Eugene Sulvo

12/12/16



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I ALLAN RUTZON, MD attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

Allan Rutzon MD



225 H. Mearnsbridge Center Drive
Bridge, Maryland 21075
443-223-1800 (Phone)
410-796-0700 (Fax)

Attestation

I Scott Colborn attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely, 
12-13-16



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I, VANESSA LIMA, attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

A handwritten signature in black ink, appearing to be "V. Lima".

12.15.16



020-H Meadowridge Center Drive
Elkridge, Maryland 21075
443-275-7800 (Phone)
410-796-0700 (Fax)

Attestation

I Jordan Heffez attest that the caseload projections on Appendix A for the years 2016 to 2021 accurately reflect the number of procedures I made or anticipate making in my capacity as ophthalmic surgeon. I hereby attest that this information is true and complete to the best of my knowledge.

Sincerely,

A handwritten signature in black ink, appearing to be "J. Heffez", written over a horizontal line.

12/15/16

Appendix O
Affirmations

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this CON Application and its attachments for Columbia Surgical Institute, LLC are true and correct to the best of my knowledge, information and belief.




Scott Elliot LaBorwit, MD



Date


AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this CON Application and attachments for Columbia Surgical Institute, LLC are true and correct to the best of my knowledge, information and belief.


Gledson Hanelt, R.N. 01/30/17 _____
Date

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this CON Application and its attachments for Columbia Surgical Institute, LLC are true and correct to the best of my knowledge, information and belief.



Penelope Williams, RN, MS

January 30, 2017

Date

