

Craig Tanio, M.D.
CHAIR



Ben Steffen
ACTING EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners

FROM: Paul E. Parker, Director
Center for Hospital Services *pep*

DATE: July 19, 2012

SUBJECT: Cosmetic Surgery Center of Maryland d/b/a Bellona Surgery Center
Establishment of a Freestanding Ambulatory Surgical Facility
Docket No. 12-03-2327

Cosmetic Surgery Center of Maryland, d/b/a Bellona Surgery Center (“BSC”) is a licensed physician’s office surgery center with one operating room and one non-sterile procedure room located in Baltimore County. BSC proposes to add a second operating room through renovation of existing space. Thus, this proposal would be defined as the establishment of a health care facility, namely, an ambulatory surgical facility, which, in Maryland, is a facility with two or more operating rooms.

The project consists of renovation of approximately 1,726 square feet of existing building space. The total estimated cost of the project is \$104,500. The source of funds for the renovation is cash provided by Bellona Surgery Center. The project is anticipated to be completed within three (3) months of the start of renovation.

Commission Staff recommends approval of this project with a condition.

IN THE MATTER OF
COSMETIC SURGICENTER
OF MARYLAND d/b/a
BELLONA SURGERY CENTER
DOCKET NO. 12-03-2327

* BEFORE THE
* MARYLAND
* HEALTH CARE
* COMMISSION
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STAFF REPORT AND RECOMMENDATION

July 19, 2012

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I. INTRODUCTION

Applicant and Project

Cosmetic Surgery Center of Maryland, d/b/a Bellona Surgery Center (“BSC”) is a licensed physician’s office surgery center with one operating room and one non-sterile procedure room located at 8322 Bellona Avenue, Suite 380, in Baltimore County. BSC was established in July 2004 and is owned by Michael Cohen, M.D. (50%) and Mrs. Shari Cohen (50%). Because it has only one operating room, it currently falls below the threshold definition of a health care facility regulated under the Maryland Certificate of Need (“CON”) program.

BSC opened as a single specialty center providing plastic surgical services. In 2008, with additional surgeons utilizing surgical capacity at the center, BSC identified the facility as a multi-specialty center and identified general surgery, otolaryngology, podiatry and urology as practicing specialties at BSC. However, based on the Maryland Health Care Commission’s annual surveys, for each year from inception through 2010, plastic surgery reportedly accounted for over 95% of all case volume at BSC and only dipped below that level, to approximately 92%, in 2011. BSC projects an increase in use of the facility for specialties other than plastic surgery.

Bellona Surgery Center proposes to add a second operating room (“OR”) through renovation of existing space. Thus, this proposal would be defined as the establishment of a health care facility, namely, an ambulatory surgical facility, which, in Maryland, is a facility with two or more operating rooms.

The project consists of renovation of approximately 1,726 square feet of existing building space. The renovated facility’s two ORs will be approximately 255 and 310 square feet in size. The existing procedure room is 96 square feet in size.

**Table 1: Current and Proposed Surgical Capacity
Bellona Surgery Center**

	Current	Proposed	Post-Project
Operating Rooms	1	1	2
Non-Sterile Procedure Rooms	1	0	1
Total Rooms	2	1	3

Source: CON application (DI#10, Attachment A).

The total estimated cost of the project is \$104,500. Building renovations, including architect/engineering fees/permits, etc., constitutes the bulk of the expenditures at \$72,000, the remaining \$32,500 being allocated to major movable equipment. The space used by BSC is leased from Bellona Lane Orthopaedic Associates, LLC. The second operating room will be located adjacent to the current operating room. The source of funds for the renovation is cash provided by Bellona Surgery Center. The project is anticipated to be completed within three (3) months of the start of renovation.

II. PROCEDURAL HISTORY

A. Record of the Review

On October 14, 2011, BSC submitted a Letter of Intent to apply for a CON to add one (1) operating room to an existing one (1) operating room and one (1) procedure room facility located in Baltimore County. [Docket Item (DI) # 1].

On January 12, 2012, BSC submitted a Certificate of Need application proposing construction and renovation plans to convert existing space to add one class "C" operating room to an existing one operating and one procedure room facility. (DI # 2) and Letters of Support (DI # 3).

On January 13, 2012 the Commission acknowledged receipt of the application in a letter to Bellona Surgery Center (DI#4) and subsequently requested publication of notification of receipt of the BSC's proposal in the *Baltimore Sun* on January 13, 2012 (DI # 5) and the *Maryland Register* on January 27, 2012 (DI # 6). Notification was published in the *Maryland Register* on January 27, 2012 (DI # 6) and the *Baltimore Sun* on February 7, 2012 (DI # 8).

On January 27, 2012, following a completeness review of the proposal, Commission staff requested addition information needed to begin a formal review of the con application (DI #7).

On February 7, 2012, the Commission responded to and granted BSC's request for an extension, to respond to MHCC's January 27, 2012 request for information and clarification, until February 17, 2012 (DI # 9).

On February 17, 2012 the Commission received a response to the January 27, 2012 request for additional information and clarification of the application (DI # 10). Acknowledgement of receipt of BSC's response and a second round of completeness questions was sent to BSC on March 2, 2012 (DI # 11).

On March 8, 2012, MHCC responded to BSC's request for an extension and granted BSC an extension until March 19, 2012 to respond to the additional questions (DI # 12).

On March 19, 2012, the Commission received BSC's response to the March 2, 2012 request for additional information and clarification (DI # 13).

On April 2, 2012 the Commission requested a third round of completeness questions for BSC's application (DI # 14).

On April 4, 2012 the BSC requested an extension until April 24, 2012 to respond to completeness questions and the Commission agreed (DI # 15).

On April 20, 2012, the Commission received a response to completeness questions requested by the Commission. on April 2, 2012 (DI # 16).

On May 4, 2012, the Commission notified BSC that its application would be docketed effective May 18, 2012, with a notice in the *Maryland Register* published on that day (DI # 17). On that same day, the Commission requested publication of the docketing notice in the next edition of the *Baltimore Sunpapers* (DI # 18) and requested that notice be provided in the *Maryland Register* that the application for BSC had been docketed the date of May 18, 2012 (DI # 19).

On May 4, 2012, a copy of the application was sent to the Baltimore County Health Department for review and comment (DI # 20).

Notification from the *Baltimore Sunpapers* was received on April 16, 2012 that the Notice of Docketing was published on May 12, 2012 (DI # 21).

The Commission received notification from The Baltimore County Health Department on June 8, 2012 that they chose not to comment on the proposed project (DI # 22).

B. Interested Parties

There are no interested parties in this review.

C. Support

Indications of project support from affected practitioners are part of the record. No comments were provided by the local health department.

III. BACKGROUND

Ambulatory or outpatient surgery is surgery which does not require overnight hospitalization for recovery or observation. Preparation of the patient for the surgical procedure, the procedure itself, post-operative recovery, and discharge of the patient from the surgical facility are accomplished on a single day. Outpatient surgery case volume has seen significant growth in recent decades. Strong growth has been driven by changes in technology, including both surgical and anesthetic techniques, patient preferences, cost control efforts, and the development of new procedures. Many surgical procedures once limited to provision on an inpatient basis are now performed as outpatient surgeries.

Since 1995, Maryland has exempted single operating room surgical facilities from CON regulation. Prior to that time, it exempted single-specialty facilities with up to four operating rooms. Maryland has maintained one of the highest levels of Medicare-certified ambulatory surgery centers ("ASCs") per capita in the Nation and a very high proportion of its total freestanding facilities have a single operating rooms (48%) or no true sterile operating rooms at all (36%) based on data for CY2010. Freestanding facilities without operating rooms have non-sterile procedure rooms that are suitable for closed endoscopic or urologic procedures and needle injection or biopsy procedures. A high proportion of Maryland's freestanding facilities also identify themselves as single-specialty (77.6%). Of the facilities identified as multi-specialty,

14.6% identify themselves as multi-specialty, while 7.8% identify themselves as limited specialty; defined as facilities that performed cases in two or three specialties only.

In Maryland, the number of freestanding ambulatory surgery centers, both single specialty and multi-specialty, grew from seven to 54 between 1985 and 1990. By 2010, there were 335 licensed ambulatory surgery centers statewide. In Baltimore County, where BSC is located, the number of freestanding ambulatory surgical facilities increased from 40 in calendar year 1997 to 64 in calendar year 2005 and 71 in calendar year 2010. In 1997, freestanding ambulatory surgery facilities had a 34% share of the 527,009 total outpatient surgery cases reported for the State. By 2005, freestanding ambulatory surgery facilities performed 501,893 surgeries, 55% of the total Maryland's 922,836 outpatient surgery cases. From 2006 to 2010, the distribution of outpatient case volume between hospitals and freestanding ambulatory surgery facilities has remained fairly steady.

Changes in the supply of surgical facilities and the demand for outpatient surgery in Baltimore County, Anne Arundel County (the jurisdictions from which BSC draws the majority of its patients), and Maryland are shown in the following table.

Table 2.
Outpatient Surgical Facilities in Maryland, Baltimore County, and Anne Arundel County
Calendar Years 2000, 2005, and 2010
Inventory and Case Volume

	CY2000			CY2005			CY2010		
	Maryland	Baltimore County	Anne Arundel County	Maryland	Baltimore County	Anne Arundel County	Maryland	Baltimore County	Anne Arundel County
GENERAL ACUTE CARE HOSPITAL SURGICAL FACILITIES									
Facilities	47	4	2	47	4	2	46	4	2
Operating Rooms	515	78	28	541	74	31	573	77	42
Procedure Rooms	158	11	9	204	24	10	239	27	10
Outpatient Surgical Cases	369,271	67,831	21,866	422,309	69,842	32,578	504,407	64,897	31,536
FREESTANDING AMBULATORY SURGICAL FACILITIES									
Facilities	248	64	24	295	69	30	335	71	36
Operating Rooms	298	72	27	299	63	30	303	61	35
Procedure Rooms	274	72	38	386	92	54	406	81	62
Outpatient Surgical Cases	301,501	87,014	30,579	501,893	122,392	49,850	504,407	129,704	73,909

Source: MHCC Annual Freestanding Ambulatory Surgery Surveys and HSCRC Ambulatory Database, CYs 2000, 2005, and 2010.

IV. STAFF REVIEW AND ANALYSIS

The Commission considerations in the review of CON applications are outlined at COMAR 10.24.01.08G (3), (a) through (f). The first of these is considerations is the relevant State Health Plan standards and policies.

A. The State Health Plan for Facilities and Services

The relevant State Health Plan for Facilities and Services (“SHP”) chapter in this review is COMAR 10.24.11, Ambulatory Surgical Services.

A. SYSTEM STANDARDS: All hospital-based ASFs and all freestanding ambulatory surgical facilities (FASFs) including HMOs sponsoring a FASF, shall meet the following standards, as applicable.

(1) Information Regarding Charges. Each hospital-based ASF and each FASF shall provide to the public, upon inquiry, information concerning charges for and the range and types of services provided.

BSC states that it provides to the public, upon inquiry, information regarding charges for the range and types of services provided. (DI # 10, Attachment C).

(2) Charity Care Policy.

(a) Each hospital-based ASF and FASF shall develop a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services regardless of an individual’s ability to pay.

(b) Public notice and information regarding a hospital or a freestanding facility’s charity care policy shall include, at a minimum, the following:

(i) Annual notice by a method of dissemination appropriate to the facility’s patient population (for example, radio, television, newspaper);

(ii) Posted notices in the admission, business office, and patient waiting areas within the hospital or the freestanding facility; and

(c) Within two business days following a patient’s request for charity care services, application for Medicaid, or both, the facility must make a determination of probable eligibility.

BSC has a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services, regardless of an individual’s ability to pay. BSC posts notices regarding the availability of charity care in its patient waiting area and committed to communicate this policy through an annual notice in a least one newspaper within its drawing area. The written policy states that a “Determination of probable eligibility for financial assistance will be made within two business days after initial submission of the Financial Assistance application.”(DI # 13, Attachment A).

While BSC has sufficiently committed to comply with this standard, which only requires the maintenance, posting, and publication of a charity care policy, it has never reported the provision of any charitable care to MHCC in its annual FASF survey. As a facility primarily engaged in cosmetic plastic surgery, established through a determination of coverage, this is not surprising finding. It has never been required to have any policy in place until necessitated by the CON requirements associated with this proposed facility expansion. We note that MHCC recently adopted proposed regulations that will require FASFs proposing projects subject to CON review to document the provision of a minimum level of charitable services.

The following condition is recommended for a CON issued by MHCC for this project, to assure compliance with the commitment made by this facility in the review of the project:

Prior to approval of first use of this project, Bellona Surgery Center will document that it has provided public notice and information regarding its charity care policy by a method of dissemination appropriate to the facility's patient population.

(3) Compliance with Health and Safety Regulations. Unless exempted by an appropriate waiver, each hospital-based ASF and FASF shall be able to demonstrate, upon request by the Commission, compliance with all mandated federal, State, and local health and safety regulations.

BSC is licensed, in good standing, by the State of Maryland, Office of Health Care Quality ("OHCQ"), as a Freestanding Ambulatory Surgical Facility (DI # 10, Attachment D) and certified by the Centers for Medicare and Medicaid Services ("CMS") as an Ambulatory Surgical Center. This indicates that the applicant complies with all applicable regulations, accreditation and certification standards, and commits to continue to meet all mandated federal, state, and local health and safety regulations. The applicant complies with this standard.

(4) Licensure, Certification and Accreditation.

(a) Existing FASFs and HMOs that sponsor FASFs shall obtain state licensure from the Maryland Department of Health and Mental Hygiene, certification from the Health Care Financing Administration as a provider in the Medicare program, and from the Maryland Department of Health and Mental Hygiene as a provider in the Medicaid program.

(b) Except as provided in (c), existing FASFs and HMOs that sponsor FASFs shall obtain accreditation from either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAAHC).

(c) If another accrediting body exists with goals similar to JCAHO or AAAHC, and is acceptable to this Commission, accreditation by this organization may be substituted.

As noted above, BSC is licensed by OHCQ. The applicant is also certified by CMS as a provider in the Medicare program and is accredited by the Accreditation Association for Ambulatory Health Care, Inc. ("AAAHC"), (DI %10, Attachment D)..

(5) Transfer and Referral Agreements.

(a) Each hospital-based ASF shall have written transfer and referral agreements with:

(i) Facilities capable of managing cases which exceed its own capabilities; and

(ii) Facilities that provide inpatient, outpatient, home health, aftercare, follow-up, and other alternative treatment programs appropriate to the types of services the hospital offers.

(b) Written transfer agreements between hospitals shall meet the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, 19-308.2, Annotated Code of Maryland.

(c) Each FASF shall have written transfer and referral agreements with one or more nearby acute general hospitals.

(d) For both hospital-based ASFs and FASFs, written transfer agreements shall include, at a minimum, the following:

(i) A mechanism for notifying the receiving facility of the patient's health status and services needed by the patient prior to transfer;

(ii) That the transferring facility will provide appropriate life-support measures, including personnel and equipment, to stabilize the patient before transfer and to sustain the patient during transfer;

(iii) That the transferring facility will provide all necessary patient records to the receiving facility to ensure continuity of care for the patient; and

(iv) A mechanism for the receiving facility to confirm that the patient meets its admission criteria relating to appropriate bed, physician, and other services necessary to treat the patient.

(e) If an FASF applying for a Certificate of Need has met all standards in this section except (c)-(d) of this standard, the Commission may grant a waiver upon:

(i) Demonstration that a good-faith effort has been made to obtain such an agreement; and

(ii) Documentation to the Commission of the facility's plan regarding transfer of patients.

(f) An FASF shall establish and maintain a written transportation agreement with an ambulance service to provide emergency transportation services.

BSC provided a copy of a signed transfer agreement with Greater Baltimore Medical Center (GI # 10, Attachment F). BSC maintains a written *Policy and Protocol for Hospital Transfers* (DI # 10, Attachment F). Emergency transfer of patients (ambulance service) is provided by the Emergency Medical System by calling 911. BSC meets this standard.

(6) Utilization Review and Control Program. *Each hospital and FASF shall participate in or have utilization review and control programs and treatment protocols, including a written agreement with the Peer Review Organization contracting with the Health Care Financing Administration, or other private review organizations.*

BSC has documented its utilization review and control programs and treatment protocols and provided a description of its *Continuous Quality Improvement Program*, (DI # 13, Attachment B.) BSC is accredited by AAAHC which requires ambulatory care facilities to meet core standards which support the requirements of this State Health Plan standard (DI #13 Attachment B). BSC meets this standard.

B. CERTIFICATE OF NEED REVIEW STANDARDS. An applicant proposing to establish or expand a hospital-based ASF or an FASF, including an HMO sponsoring an FASF, shall demonstrate compliance with the following standards, as appropriate:

(1) Compliance with System Standards.

(a) Each applicant shall submit, as part of its application, written documentation of proposed compliance with all applicable standards in section A of this regulation.

(b) Each applicant proposing to expand its existing program shall document ongoing compliance with all applicable standards in section A of this regulation, including meeting Standard A (4) within 18 months of first opening.

BSC has demonstrated substantial compliance with the system standards. Because it has developed a charity care policy for the first time as a requirement for this project review, it is recommended that a condition be attached to an approval of the project assuring that the facility follow through on its commitment to publish notice concerning this policy prior to implementation of the project.

(2) Service Area. Each applicant shall identify its proposed service area, consistent with its proposed location.

BSC defines its primary service area as Baltimore County, surrounding counties, Washington, D.C. and Virginia. BSC reports that 35% of their patients are from Baltimore County and Anne Arundel County. Additionally, BSC states that the service area reflects the office locations of the practitioners, two of which are relocating their offices to the Bellona Office Building where BSC is located.

(3) Charges. Each applicant shall submit a proposed schedule of charges for a representative list of procedures and document that these charges are reasonable in relation to charges for similar procedures by other freestanding and hospital providers of ambulatory surgery in its jurisdiction.

BSC provided a schedule of charges for operating room and anesthesia services by time spent in the operating room in the CON application (DI # 10), Attachment E).

BSC reports gross and net patient service revenue of \$1,823,119 in CY2010 and 617 total cases in that same period (operating room and procedure room revenue and cases). This yields an average billed charge and net revenue of \$2,955. It will be noted that the lack of any contractual adjustment or other review adjustments by the applicant is consistent with the nature of this facility, which has historically concentrated on cosmetic plastic surgery, a full fee, out-of-pocket service that does not involve third party payor contracts. In recent CON reviews involving FASFs, both Commission reviewers and staff have concluded that this standard, which focuses on comparability of charges is not one which provides a meaningful basis for understanding any of the key considerations outlined in the CON regulations, given that charges do not reflect payment for surgical services, other than procedures such as cosmetic surgery, and actual reimbursement tends to be highly controlled by payors. Medicare and Medicaid set fee schedules and private payers have strong leverage in negotiating with facilities to dictate payment rates. We note that this standard is not proposed for inclusion in the proposed revision of the State Health Plan recently approved by MHCC.

Table 3 profiles outpatient surgical charges for selected Central Maryland hospitals and FASFs. The FASFs selected for comparison were based on specialty status comparable to that of the applicant. The applicant's reported average billed charge per case and net revenue in 2010 were well above the average for the comparable Central Maryland FASFs. Its average reported

charge was approximately 23-31% higher than that of the two facilities most comparable, i.e., facilities with very little contractual adjustment of gross billed charges. This may be because BSC projects longer than average surgical minutes per case, a function of its particular case mix of cosmetic surgical procedures, which results in a higher per case charge.

**Table 3
Charge and Revenue Comparisons: Selected Hospitals, CY 2009 and CY 2010
and Freestanding Ambulatory Surgery Facilities CY 2010**

Hospital Ambulatory Surgery Charges, 2009 and 2010		
Facility	Average Outpatient Surgery Charge per Case CY 2009	Average Outpatient Surgery Charge per Case CY 2010
Anne Arundel Medical Center	\$2,927	\$2,862
Baltimore Washington Medical Center	\$3,342	\$2,998
Greater Baltimore Medical Center	\$1,891	\$2,231
Mercy Medical Center	\$2,073	\$2,207
Sinai Hospital	\$4,089	\$4,224
St. Joseph Medical Center	\$2,490	\$2,706
The Johns Hopkins Hospital	\$2,493	\$2,679
Upper Chesapeake Medical Center	\$3,902	\$3,688
All Maryland Hospitals	\$2,716	\$2,834
Freestanding Ambulatory Surgical Facilities in Baltimore and Anne Arundel Counties with a majority of cases in the plastic surgery specialty		
Average Billed Charge per Case CY 2010		
Facility A		\$1,437
Facility B		\$1,264
Facility C		\$2,412
Facility D		\$1,318
Facility E		\$2,265
Facility F		\$1,969
Average of six reporting facilities		\$1,810
Average Net Revenue per Case CY 2010		
Facility A		\$1,293
Facility B		\$1,224
Facility C		\$2,399
Facility D		\$740
Facility E		\$2,214
Facility F		\$1,435
Average of six reporting facilities		\$1,425

Source: MHCC Annual FASF Survey CY 2010 and HSRC Hospital Ambulatory Data, CY2009 and 2010.

Because of the problems in using this standard in a meaningful way for a project of this type, in which a facility has historically obtained payment for its service on the basis of what “the market will bear” because it is charging patients upfront and out-of-pocket for cosmetic

surgery, MHCC staff recommends that it not be used as a basis for denying this proposed project. The facility will have to negotiate payment rates with private third-party payors and live with Medicare payment rates for the non-cosmetic cases which it proposes to accommodate through expansion of its facilities.

(4) Minimum Utilization for the Expansion of Existing Facilities. Each applicant proposing to expand its existing program shall document that its operating rooms have been, for the last 12 months, operating at the optimal capacity stipulated in Regulation .05A(3) of this chapter, and that its current surgical capacity cannot adequately accommodate the existing or projected volume of ambulatory surgery.

This standard is not applicable. While a facility expansion project, this project, from a legal perspective, involves establishment of a health care facility because it will expand BSC to a capacity that brings it within the regulatory scope of CON regulation.

(5) Support Services. Each applicant shall agree to provide either directly or through contractual agreements, laboratory, radiology, and pathology services.

BSC states that pathology services are currently being provided by Lab Corp, Quest and Derm Path Diagnostics. Any patient requiring laboratory tests or radiology are referred to the appropriate facility according to their insurance (DI #10). The applicant meets this standard.

(6) Certification and Accreditation. Except as provided in (c), each new FASF applicant or HMO that sponsors a new FASF shall agree to seek and to obtain, within 18 months of first opening, licensure, certification and accreditation from the following organizations:

(a) The Maryland Department of Health and Mental Hygiene for state licensure, the Health Care Financing Administration for certification as a provider in the Medicare program, and the Maryland Department of Health and Mental Hygiene for certification in the Medicaid program; and

(b) Accreditation from either the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care.

(c) If an applicant can demonstrate that an alternative accrediting body exists with goals similar to JCAHO and AAAHC, and is otherwise acceptable to the Commission, accreditation by this organization may be substituted.

BSC is licensed by the Maryland Department of Health and Mental Hygiene, Office of Health Care Quality, and is certified as a provider in the Medicare program. BSC is accredited by the Accreditation Association for Ambulatory Health Care (AAAHC).

(7) Minimum Utilization for New Facilities. Each FASF applicant shall demonstrate, on the basis of the documented caseload of the surgeons expected to have privileges at the proposed facility, that, by the end of the second full year of operation, the facility can draw sufficient patients to utilize the optimal capacity of the proposed number of operating rooms, measured according to Regulation .05A of this Chapter.

This standard requires that the applicant support the establishment of a two operating room facility by demonstrating that, by the end of the second full year of operation, the facility will draw sufficient patients to utilize the facility at optimal capacity. This target is 1,152 cases per year for each general purpose operating room, or 576 cases per year for each special purpose operating room. (A general purpose operating room is defined by the SHP as an operating room used for any type of surgical procedure or specialty; a special purpose operating room is defined as an operating room dedicated to a specific purpose or surgical specialty.) These benchmarks for optimal capacity in the State Health Plan are based on four key assumptions: (1) a case is defined as one discreet visit by a patient who undergoes one or more procedures identified by Current Procedural Terminology (CPT) procedure codes. (2) the average time per case is assumed to be 85 minutes, 55 minutes for surgical time and 30 minutes for clean up and preparation time between cases. (3) ambulatory surgery facilities can operate 255 days per year, eight hours per day; and (4) optimal capacity is 80% of full capacity. BSC has a general purpose OR and proposes the addition of a second general purpose OR.

While optimal capacity is stated in the SHP to be 1,152 cases per year, it is better defined as 97,920 minutes of utilization per OR per year. If the applicant's average time per case is significantly longer or shorter than 85 minutes, it is possible to meet or exceed the same optimal capacity benchmark with a case count that is less than or exceeds 1,152 cases per year.

BSC provided letters from the following practitioners, in which data on historic and projected use of BSC was provided. That data is profiled in the following table.

Table 4
Projected Cases at BSC by Practitioners

Practitioner*	2011	Projected	Transferred
	Cases	2012 Increase	
Michael Cohen, M.D.	452	25	220
Larry Lickstein, M.D.	185	20	230
Patrick Byrne, M.D.	51	15	250
Kelly Geoghan, D.P.M	6	100	100
Karen Boyle*	<u>9</u>	<u>50</u>	<u>50</u>
Totals	703	210	850

*An additional physician Karen Boyle, M.D. will also perform surgical cases at BSC, Dr. Boyle performed 9 cases in 2011, she projects an increase to 50 cases in 2012 and projects transfer of 50 cases.

Based on the physicians projections, considering population growth in Central Maryland and the availability of additional surgery time, BSC projects an annual overall increase of 20%, bringing total projected cases to 3,636 by the first full year of operation. If achieved, 3,636 would provide more than enough operating room time for optimal capacity use of two operating rooms. BSC has demonstrated compliance with this standard.

(8) *Reconfiguration of Hospital Space.* Each hospital applicant proposing to develop or expand its ASF within its current hospital structure shall document plans for the reconfiguration of hospital space for recovery beds, preparation rooms, and waiting areas for persons accompanying patients.

This standard is not applicable because the applicant is not a hospital.

B. Need

COMAR 10.24.01.08G (3)(b) requires that the Commission 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.

The State Health Plan includes a “minimum utilization” standard (see Project Review Standard 7 above) that is definitive with respect to the need criterion applicable to a proposal such as this, which is a regulated project because it expand institutional operating room capacity. It does not include a population-based projection method for assessing need for surgical facilities or operating rooms. Because the project complies with this standard, it has demonstrated need for the OR addition proposed.

C. Availability of More Cost-Effective Alternatives

COMAR 10.24.01.08G(3)(c) requires the Commission to compare the cost-effectiveness of providing the proposed service through the proposed project with the cost-effectiveness of providing the service at alternative existing facilities, or alternative facilities which have submitted a competitive application as part of a comparative review.

The applicant facility is proposing to add a second OR because it has experienced growth in use of its single OR which exceeds optimal capacity use (the facility reported 1,844 hours of OR use in CY2011 compared to the SHP’s optimal capacity assumption of 1,632 hours per OR per year). This level of use coupled with the expressed interest of practitioners to bring more case volume to the facility demonstrates that it is likely that BSC can utilize a second operating room at an efficient level within a short time after expansion. It estimates that it can implement this addition at a relatively modest renovation cost. Its case for the cost effectiveness of this approach focuses on its desire to provide capacity for growth in case volume for its practitioners.

Obviously, given the range of alternative settings available in Baltimore County, growth in demand by BSC practitioners could be accommodated at other facilities. However, given the high level of use already achieved by BSC and the relatively low cost estimate, this is a cost effective approach to meeting the preferences of these physicians and their patients.

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) requires the Commission to consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project

within the time frame set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

Projects such as that proposed, involving the renovation of existing surgical facility space, can have a wide array of cost, depending on the current configuration of the facility and the extent of renovation required. The estimated cost of this project is minimal, relative to most recent capital projects considered by MHCC to create additional OR capacity and the applicant has stated that it is highly confident of the cost estimate it has obtained because of its historic experience with the contractor providing the estimate. The project budget estimated by the applicant is as follows:

**Table 5
BSC OR Addition: Project Budget**

USE OF FUNDS	
Renovations	
Building	\$60,000
Permits/Architect/Engineering Fees	\$12,000
<i>Subtotal</i>	\$72,000
Other Capital Costs	
Major Movable Equipment	\$32,500
<i>Subtotal</i>	\$32,500
Total Uses of Funds	\$104,500
SOURCE OF FUNDS	
Cash	\$104,500

Source: MASC CON Application

The total cost of this project is \$104,500. The applicant has supplied a letter from its owners' accountant attesting to the availability of liquid assets sufficient to provide the required project funding.

BSC projects revenues and expenses for the facility as follows. The project is estimated to have a construction period of two months.

Table 13
Bellona Surgery Center
Projected Revenues and Expenses, 2012-2015

	2012	2013	2014	2015
Revenues	\$2,228,000	\$2,736,000	\$3,283,200	\$3,939,840
Allowance for Bad Debt	4,000	4,500	5,500	6,500
Contractual Allowance	N/A	N/A	N/A	N/A
Charity Care	3,000	3,500	4,000	4,500
Net Patient Services Revenue	\$2,221,000	\$2,728,000	\$3,273,700	\$3,928,840
Operating Expenses	\$2,394,070	\$2,696,410	\$3,055,140	3,469,376
Income from Operation	(173,070)	31,590	218,560	459,464
Operating Rooms	1	2	2	2
Procedure Rooms (PRs)	1	1	1	1
Surgical Minutes	133,128	159,754	191,704	230,045
Total Minutes in PRs	2,250	2,550	2,850	3,150
Surgical Cases	844	1,013	1,216	1,459
Procedures	75	85	95	105
Inc. in Surgical Minutes		20%	20%	20%
Inc. in PR Minutes		13%	12%	11%
Inc. in Surgical Cases		17%	14%	13%
Inc. in Procedures		13%	12%	11%

Source: BSC Application (DI # 13, page 17 and DI # 10, pages 13)

The applicant has projected revenues and expenses through 2015. It projects being able to move from a net loss in the current fiscal year to a positive margin position, with projected volume growth in the out years. Expense and staffing assumptions are reasonable for the aggressive growth projections.

The proposed project is feasible and if case volume grows at or near projected levels, the facility should be viable over the long-term.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e) requires the Commission to consider the applicant's performance with respect to all conditions applied to previous Certificates of Need granted to the applicant.

Neither BSC, nor its physicians, have applied for previous Certificates of Need.

F. Impact on Existing Providers

COMAR 10.24.01.08G(3)(f) requires the Commission to consider information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, including the impact on geographic and demographic access to services, on occupancy when there is a risk that this will increase costs to the health care delivery system, and on costs and charges of other providers.

The impact of this project on hospitals in the area is small. The shift in case volume projected by the practitioners as possible with additional OR capacity at BSC is as follows: Northwest Hospital Center: 220 cases; Greater Baltimore Medical Center: 120 cases; Johns Hopkins Hospital; 100 cases; and St. Joseph Medical Center; 120 cases. For Northwest Hospital Center, this represents about 2.4% of the most recently published outpatient case volume. For the other larger hospitals, these case volumes range from 0.2% to 0.9% of the most recently published case volumes. BSC also projects pulling about 240 cases away from other freestanding facilities if it is able to implement this project.

There is sufficient growing demand for surgical services in Baltimore County such that the impact of a single OR addition should be very limited in scope and time. To the extent that it creates more competitive market conditions among the county's multi-specialty FASFs, it should benefit private payers, their covered members, and BSC patients although this impact would also be minimal. There is no basis for finding that this project will have a negative impact warranting denial of approval.

V. SUMMARY AND STAFF RECOMMENDATION

BSC seeks to increase operating room capacity by expanding its existing freestanding surgery center capacity from one operating room to two operating rooms, thereby becoming a freestanding ambulatory surgery facility. Based on this review and analysis of its Certificate of Need application, the expansion project proposed by BSC is consistent with the general Certificate of Need review criteria at COMAR 10.24.01.08G(3)(a) through (f) and meets the standards in the State Health Plan for Ambulatory Surgical Services at COMAR 10.24.11.

Staff recommends that the Commission grant a Certificate of Need for Bellona Surgery Center to construct an additional operating room at a cost of \$104,500 with the following condition:

Prior to approval of first use of this project, Bellona Surgery Center will document that it has provided public notice and information regarding its charity care policy by a method of dissemination appropriate to the facility's patient population.

IN THE MATTER OF
COSMETIC SURGICENTER
OF MARYLAND d/b/a
BELLONA SURGERY CENTER
DOCKET NO. 12-03-2327

* BEFORE THE
*
* MARYLAND
*
* HEALTH CARE
*
* COMMISSION
*
*

FINAL ORDER

Based on the analysis of compliance with applicable criteria and standards, it is this 19th day of July, 2012 **ORDERED**, that the application for Certificate of Need by Bellona Surgery Center to expand an existing office-based, Medicare-certified ambulatory surgery center, establishing a second sterile operating room a total project cost of \$104,500, thus establishing the Center as an ambulatory surgical facility, as defined in Health-General Article §19-114(b), Annotated Code of Maryland, is APPROVED with the following condition:

Prior to approval of first use of this project, Bellona Surgery Center will document that it has provided public notice and information regarding its charity care policy by a method of dissemination appropriate to the facility's patient population.

MARYLAND HEALTH CARE COMMISSION

APPENDIX

Floor Plan

