

IN THE MATTER OF

*

BEFORE THE

*

INNOVATIONS

*

MARYLAND HEALTH

*

SURGERY CENTER, P.C.

*

CARE COMMISSION

*

Docket No. 18-15-EX001

*

STAFF REPORT & RECOMMENDATION

**EXEMPTION FROM CERTIFICATE OF NEED TO ESTABLISH
AN AMBULATORY SURGICAL FACILITY**

June 21, 2018

I. INTRODUCTION

A. Background

In January 2018, an updated version of COMAR 10.24.11, the General Surgical Services chapter of the State Health Plan (“SHP”) became effective. Among the changes included in this update of Certificate of Need (“CON”) regulations were provisions for establishing ambulatory surgical facilities (“ASFs”) with two operating rooms through an exemption from CON rather than review and approval of a CON application.

For purposes of CON regulation, an "ambulatory surgical facility" is “a health care facility that: (a) Has two or more operating rooms; (b) Operates exclusively for the purpose of providing surgical services to patients requiring postoperative observation but who do not require hospitalization and in which the expected duration of services would not exceed 24 hours following admission; (c) Seeks reimbursement from payors as an ambulatory surgical facility, as defined in Health-General Article §19-3B-01, Annotated Code of Maryland; and (d) Is physically separate from any hospital.”

Prior to January 15, 2018, establishing an ambulatory surgical facility required approval of a CON in all cases. The amendments to the SHP that went into effect earlier this year allow the Maryland Health Care Commission (“MHCC”) to issue an exemption from Certificate of Need review to permit the establishment of an ambulatory surgical facility with two sterile operating rooms when such facility establishment is requested by the office of one or more health care practitioners or a group practice, as defined in §1-301 of the Health Occupations Article, provided that MHCC determines that all applicable general and project review standards are met.

B. The Applicant and the Request

Innovations Surgery Center, P.C. (“Innovations”) is, for purposes of CON regulation, classified as a “physician outpatient surgical center” or “POSC.” A POSC is a “center, service, office, facility, or office of one or more health care practitioners that has no more than one sterile operating room, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services.” These centers are licensed in Maryland as “freestanding ambulatory surgical facilities” and certified by Medicare as “ambulatory surgical centers” or “ASCs” in the same way that larger outpatient surgical facilities with two or more operating rooms are licensed and certified. However, establishment of a POSC does not require CON approval. POSCs can be established through issuance of a determination of coverage by MHCC, which certifies that they are facilities that fall below the two-operating room threshold requiring issuance of a CON. Most outpatient surgical facilities in Maryland are POSCs.

Innovations seeks approval of an exemption from CON to add a second operating room, establishing itself as an ambulatory surgical facility (“ASF”). Innovations was established in 2013 as a specialty gynecological surgery center and is located at 3206 Tower Oaks Boulevard, Suite

100, in Rockville (Montgomery County). It is owned by Paul MacKoul, M.D., who is one of thirteen physicians identified as practitioners at the facility, all identified as specializing in gynecologic surgery. Dr. MacKoul is board certified in Gynecology and Gynecologic Oncology. The center has a single sterile operating room (“OR”) and a single non-sterile procedure room. The proposed project would involve renovation of this procedure room to a second sterile operating room and the addition of two additional bays for post-anesthesia recovery.

In 2015, Dr. MacKoul requested and received a second determination of coverage from MHCC to establish a second POSC on the same premises as Innovations. Such premise-sharing is allowed by the Office of Health Care Quality, the office of the Maryland Department of Health that licenses ASFs. It is also allowed under Medicare certification rules for ASCs under specific circumstances. The ASCs must operate under separate schedules with a specified time lapse (one hour) between close of operation by one ASC and the start-up of operation by the second ASC. In this case, Innovations specified an operating schedule of three weekdays, Wednesday through Friday, 6:00 AM to 5:00 PM, and the second POSC, ultimately licensed in 2016 and operating now with the name GYN Surgi-Center Rockville, P.C. (“GSCR”), specified an operating schedule of Monday and Tuesday, with the same business hours. Seven physicians, including Dr. MacKoul, were identified as surgical practitioners at this second POSC. As with Innovations, all the practitioners are gynecologists and GSCR was identified as a specialty POSC for gynecologic surgery.

In February 2018, GSCR informed MHCC that it had not been using its full schedule of hours as anticipated in the 2015 determination of coverage request and, with Innovations, was planning to alter the schedule, so that GSCR would operate on Thursdays and Fridays and Innovations would operate on Mondays through Wednesdays. GSCR also informed MHCC that it was not using the non-sterile procedure room.

In March 2018, Innovations informed MHCC, in response to questions concerning the request for exemption from CON, that Innovations had been using the OR “up to 5 days per week” given that GSCR “has not been using the space.” Innovations clarified that it was requesting approval of a second operating room under the same premise-sharing arrangement reviewed by MHCC in 2015 with Innovations using two ORs for three to five days per week and GSCR, authorized without MHCC approval as a POSC, limiting itself to use of one OR. The Innovations plan was to eventually realize more case volume for GSCR, reaching a point where the stated space sharing schedule (three days, 33 hours per week of operation for Innovations for each of two ORs and two days and 22 hours of operation for GSCR in a single OR). Innovations also informed MHCC at this time, that only three practitioners would be performing surgery at Innovations going forward, himself, Dr. Natalya Danilyanta, and Dr. Rupen Baxi, rather than the 13 physicians identified in the original request for an exemption.

In April 2018, Dr. MacKoul outlined his business objectives for GSCR, which he stated had performed approximately 10 cases. He clarified that Innovations was proposing that MHCC issue an exemption from CON authorizing two ORs on the premises of Innovations, which would, through the project approval, become an ASF, and on the premises of GSCR, a POSC, which would only use one of the two ORs on its premises. MHCC staff noted the problem with such an arrangement, under current law and regulation, given that, by definition, a POSC established by a determination of coverage is not legitimately allowed to have two ORs on its premises.

In May 2018, Innovations informed MHCC that it “would like to proceed with its request to add a second operating room and is willing to relinquish its determination of coverage for GSC as a condition of granting the second OR for Innovations.”

C. The Project

Innovations proposes to convert the existing non-sterile procedure room to a second sterile OR. It does not propose replacement of the non-sterile procedure room. This conversion to a two-OR ambulatory surgical facility is estimated to cost approximately \$200,000.

D. Staff Recommendation

MHCC staff recommends that the Commission approve Innovation’s request for an exemption from Certificate of Need to establish itself as a two-operating room ambulatory surgical facility conditioned on relinquishment of the ASF license of GSCR. A review of the basis for this recommendation follows.

II. PROJECT CONSISTENCY WITH REVIEW CRITERIA

COMAR 10.24.11.06 is the regulation specifying the review criteria and standards for consideration of a request of exemption from CON review for establishment of an ASF.

A. Applicability.

Dr. MacKoul, the sole owner of Innovations, is a health care practitioner performing surgery at the POSC. As such, the request for an exemption from CON review meets the “applicability” criteria at COMAR 10.24.11.06A.

B. General and Project Review Standards.

(1) General Standards.

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the applicable standards in Regulation .05A(1)-(4) of this chapter.

The general standards at COMAR 10.24.11.05 cover availability of information on charges and procedure volume, charity care, and quality of care. Appendix 1 to this report provides these standards.

Staff Review:

Innovations has provided responses to the general standards that indicate compliance with the standards. It states that information on prices and procedure volume are available to the public upon inquiry.

With respect to charity care, Innovations notes that it has not provided surgery on a charity care basis during its operation as a POSC. It provided a charity care policy that complies with the requirements of the standard. It projected provision of approximately \$52,000 in charitable service

in its first year of operation, based on 2017 operating expenses and the 2016 statewide reported average level of charity care by ASFs (0.52% of total operating expenses). It stated that it will provide information on its charity care policy on its website and reception desk, and to the Montgomery County Department of Health and Human Services and the Montgomery Cares program, a program that facilitates medical care for uninsured adults in Montgomery County.

With respect to the quality of care standard, Innovations is licensed in good standing by MDH, it is Medicare-certified, and it is accredited by the Accreditation Association for Ambulatory Health Care, a CMS-approved accreditation organization. It is enrolled in the recently-initiated CMS Ambulatory Surgery Center Quality Reporting Program. Maryland state government does not currently require ASFs to submit information on performance on any specific quality measures. Appropriate documentation was provided.

(2) Need.

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall:

- (a) Demonstrate the need for two sterile operating rooms at the proposed ambulatory surgical facility utilizing the operating room capacity assumptions and other guidance included in Regulation .07 of this chapter; and**
- (b) Demonstrate that optimal capacity, as defined in Regulation .07 of this chapter will be reached for both operating rooms within three years of establishing the proposed ASF.**

Staff Review:

Innovations reported 1,664 operating room hours for calendar year 2016 (991 cases) in its most recent response to MHCC's annual survey of outpatient surgical facilities and centers, equivalent to 102% of optimal capacity for a dedicated general purpose OR, as defined in the SHP. It stated, in its January 2018 request for an exemption from CON review, that its "current utilization rate" is equivalent to 1,731 hours of use, or 106% of optimal capacity.

In responding to questions from staff, Innovations stated that it handled 1,141 OR cases in 2015 that generated 1,712 hours of OR use, 1,237 OR cases in 2016, yielding 1,856 hours of OR use, and 1,335 OR cases in 2017, with 2,003 hours of use, equivalent to 105%, 114%, and 123% of optimal capacity for a single OR, respectively, in those years. It projects a 64% increase in case volume between 2017 and 2020, with a projected 3,294 hours of OR use in 2020, equivalent to 101% of optimal capacity use of two ORs.

While these projections assume a high rate of growth in demand for surgery at the facility and inconsistencies between use reported to MHCC in surveys and historic use reported in the request, the lowest levels of reported historic use indicate that use of a single OR has reached the optimal capacity use level assumed in the SHP.

Staff concludes that the exemption request is in compliance with this standard.

(3) Design Requirements.

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the following design requirements:

- (a) The proposed expanded or new facility must be designed in conformance with the requirements for outpatient surgical facilities included in the current FGI Guidelines. An operating room shall be located in a restricted area. A non-sterile procedure room shall not be located in a restricted area. The clean and soiled work areas shall be physically separated; and**
- (b) Design or equipment features of a proposed expanded or new facility at variance with the current FGI Guidelines must be justified. Commission staff may consider the opinion of staff at the Facility Guidelines Institute, which publishes the Guidelines, in determining whether the proposed variance is acceptable.**

Staff Review:

Innovations states that the facility's design is compliant with this standard. Staff's review of the design does not indicate that it is at variance with the FGI guidelines in any substantive way. This standard is met by the applicant.

(4) Location.

- (a) An applicant seeking to establish an ASF with two operating rooms must identify a specific location for the proposed ASF and may not locate or operate the proposed ASF in a way that effectively results in the establishment of an ASF with three or more operating rooms.**
- (b) An applicant seeking to establish an ASF with two operating rooms through relocation of operating rooms from a hospital shall locate the proposed ASF within the service area of the hospital.**
- (c) A general hospital seeking an exemption to convert to a freestanding medical facility that is also seeking to establish an ambulatory surgical facility in conjunction with this exemption process shall locate the proposed ambulatory surgical facility on the campus of the freestanding medical facility or an immediately adjacent location.**

Staff Review:

This standard is not applicable to this project. Innovations is not relocating and, if authorized to add an OR, will not be located or configured in a way that effectively results in the establishment of an ASF with three or more ORs. No relocation of hospital ORs is part of this project.

(5) Efficiency.

- (a) An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under this regulation shall demonstrate how its project will result in the more efficient and effective delivery of surgical services by presenting an analysis that compares the level of efficiency and effectiveness of establishing a POSC instead of the proposed ASF.**
- (b) A hospital proposing to establish an ASF in conjunction with closure of two operating rooms shall demonstrate that the proposed ASF will result in an adjusted**

global budget that accounts for the lower surgical capacity of the hospital and is budget neutral or results in cost savings for Medicare and other payers, with respect to the global budget of the hospital, as determined by HSCRC.

Staff Review:

Innovations cites recent OR utilization, which slightly exceeds optimal capacity use as defined in the SHP, the growth in demand experienced by Innovations, and the addition of physicians at the center as the basis for a finding that this proposed expansion to a two-OR ASF is a more efficient and effective alternative than expanding OR capacity through development of an additional POSC.

The comparative analysis called for in this standard is more relevant to a proposal by a physician or group practice to develop a new two-OR ASF rather than a proposal such as that presented by Innovations, in which an established POSC is establishing an ASF through renovations to add a second OR. These latter types of proposals are inherently more efficient alternatives from the standpoint of capital costs and staffing and have the important characteristic of placing additional capacity at the established center location.

The request for exemption from CON review complies with this standard.

(6) Construction Costs.

The estimated construction cost per square foot of the new construction required to establish an ambulatory surgical facility through an exemption from Certificate of Need under this regulation shall be reasonable and consistent with current industry cost experience.

(a) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction for outpatient surgical centers given in the Marshall Valuation Service® guide. This standard does not apply to the costs of renovation or the fitting out of shell space.

(b) 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 necessity and reasonableness of the construction costs. An applicant may provide additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility to support the applicant's analysis of the reasonableness of the construction costs.

Staff Review:

This standard is not applicable. The project will not involve new building construction. It will be limited to renovation of existing space.

C. Transferability and Procedural Requirements.

This regulation notes, among other things, that an exemption from Certificate of Need may be issued with conditions if the Commission determines that approval with conditions is appropriate. In this case, because a shared-premises arrangement is in place between Innovations

and a second POSC on the premises of Innovations, a conditional approval is necessary and appropriate. That condition is as follows:

Prior to first use approval of the addition of a second operating room at Innovations Surgery Center, P.C., Dr. Paul MacKoul will relinquish the ASF license issued to operate another surgical facility on the same premises as Innovations Surgery Center, P.C. Dr. MacKoul will provide MHCC, as part of a request for first use approval, with documentation that this licensed facility, currently doing business as GYN Surgi-Center Rockville, P.C., no longer exists.

III. RECOMMENDATION

Based on the information considered in this review, MHCC staff concludes that Innovations Surgery Center, P.C. meets the requirements for an exemption from Certificate of Need review in accordance with COMAR 10.24.11.06. MHCC staff recommends that the Commission approve an exemption from Certificate of Need Review, authorizing Innovations to renovate the existing surgery center to create a second operating room at an estimated cost of \$200,000, with the following condition:

Prior to first use approval of the addition of a second operating room at Innovations Surgery Center, P.C., Dr. Paul MacKoul will relinquish the ASF license issued to operate another surgical facility on the same premises as Innovations Surgery Center, P.C. Dr. MacKoul will provide MHCC, as part of a request for first use approval, with documentation that this licensed facility, currently doing business as GYN Surgi-Center Rockville, P.C., no longer exists.

Appendix 1

COMAR 10.24.11.05

A. General Standards.

The following general standards reflect 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.

(1) Information Regarding Charges.

Information regarding charges for surgical services shall be available to the public.

(a) A physician outpatient surgery center, ambulatory surgical facility, or a general hospital 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.

(b) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.

(c) Making this information available shall be a condition of any CON issued by the Commission.

(2) Information Regarding Procedure Volume.

A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location where an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

(3) 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 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 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, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.

(iii) Criteria for Eligibility. A hospital shall comply with applicable State statutes and Health Services Cost Review Commission ("HSCRC") regulations regarding financial

assistance policies and charity care eligibility. An ASF, at a minimum, shall include the following eligibility criteria in its 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 HSCRC 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 its 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 make a commitment 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 its historic level of charity care was appropriate to the needs of the population in the proposed service area.

(4) 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.
- (b) A hospital shall document that it is accredited by the Joint Commission.
- (c) An existing ambulatory surgical facility or POSC shall document that it is:
 - (i) In compliance with the conditions of participation of the Medicare and Medicaid programs;
 - (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; and
 - (iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.
- (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; and
 - (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.
- (e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care provided at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.