

December 31, 2018

COMMENTS IN OPPOSITON FROM NOVANT HEALTH, INC.

Regarding Rowan Endoscopy, PLLC/Brenner Ave, LLC's CON Application
Project I.D. #F-11628-18 to Establish a GI-Endoscopy Facility

Rowan Endoscopy, PLLC ("Rowan Endoscopy") proposes to spend \$200,000 to establish a "new ambulatory surgery center facility" with 2 GI-endoscopy procedure rooms converted from 2 existing medical office-based procedure rooms in Rowan County. Rowan Endoscopy will be located at 1809 Brenner Avenue, Suite 102, Salisbury, North Carolina in Rowan County.

Rowan Endoscopy states on page 9 of its Application that the facility currently has 2 procedure rooms that are fully equipped and operational with a pre- and post-procedure area with 6 bays and a scope processing room for high-level disinfection. Rowan Endoscopy also indicated its intent that the center will become a "Medicare approved Ambulatory Surgery Center" and the current facility will be renovated to comply with "DHSR ASC Licensure regulations along with Life Safety Code, NFPA 2012 standards."

Novant Health, Inc. ("Novant Health") asserts that the Rowan Endoscopy application is fundamentally nonconforming since it states in the Project Description on page 5 and in the Scope of Project on page 9 that Rowan Endoscopy is establishing an Ambulatory Surgery Center ("ASC"). This certificate of need review period starting December 1 is solely for Category I projects involving new or additional gastrointestinal rooms or the relocation of existing or approved gastrointestinal rooms with the same service area. See 2018 SMFP, page 17. Rowan Endoscopy proposed to establish a new ASC which is a Category E for CON review purposes and involves projects involving surgical services and "new licensed ambulatory surgical facilities."

Rowan Endoscopy is currently providing gastrointestinal services in its procedure room and receiving third-party reimbursement, therefore it is unclear why there is a need to have these procedure rooms designated as GI-Endoscopy rooms at this time. The low construction costs and the fact that there will be no new equipment purchased does not justify the establishment of an ASC. Though Rowan Endoscopy indicates that they are accredited by the Accreditation Association of Ambulatory Healthcare ("AAHC") that does not guarantee success achieving success in the more rigorous standards required by Medicare ASC certification and state ASC licensure standards.

The proposed project does not improve services to underserved populations. Despite the projected growth in GI procedures there is no appreciable change in the current payor mix for self-pay, charity, and Medicaid patients. Below is Rowan Endoscopy's Projected Payor Source from page 25 of the application:

Payor Source	GI Endo Rooms 01/01/2017- 12/31/2017	GI Endo Rooms 01/01/2018- 12/31/2018	GI Endo Rooms 01/01/2018- 12/31/2018	GI Endo Rooms 01/01/2020- 12/31/2020
Self-Pay	1.76%	1.76%	1.76%	1.76%
Charity Care	0%	0%	0%	0%
Medicare	34.64%	34.64%	34.64%	34.64%
Medicaid	0.24%	0.24%	0.24%	0.24%
Insurance	62.95%	62.95%	62.95%	62.95%
Workers Comp	0%	0%	0%	0%
Tricare	0.14%	0.14%	0.14%	0.14%
Other	0%	0%	0%	0%
Total	100.0%	100.0%	100.0%	100.0%

Rowan Endoscopy states on page 7 that, “*GI procedures performed in the proposed facility will result in less out-of-pocket healthcare costs for patient and will lower overall costs for health plans, including Medicare and Medicaid for endoscopy procedures...The lower out-of-pocket and decreased operating costs overall will provide increased access to all patients, including the medically under-served, especially from an affordability perspective.*” However, Rowan Endoscopy does not indicate how the project will decrease costs nor how it will increase access to the underserved population as evidenced in the chart above. The Agency should note in particular that Rowan Endoscopy proposes to offer 0% charity care.

Performing GI-Endoscopy procedures in its current medical office-based setting is more cost effective than in an ASC setting as Rowan Endoscopy is proposing to develop. The facility fee and the resulting third party reimbursement is higher in an ASC than in a medical office setting. Typically patient copayments and responsibility are more in an ASC than in a medical office setting. There is no patient benefit from a cost aspect to establishing these existing procedure rooms as GI Endoscopy rooms in an ASC.

The proposed project is nonconforming with CON Review Criteria (1), (3), (4), (5), (6), (7), (13) and (18a) as explained in the remainder of this comment. Novant Health respectfully requests that the Agency deny the Rowan Endoscopy application.

Conformity with CON Statutory Review Criteria

Criterion (1) - NCGS § 131E-183(a)(1): *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on any health service, health service facility, health service facility beds, dialysis stations, or home health offices that may be approved.*

The Rowan Endoscopy application proposes to develop an ASC by converting 2 existing medical office based procedure rooms to GI Endoscopy rooms and does not comply with Policy

GEN-3 and therefore is nonconforming with Criterion (1) because it fails to demonstrate how the project is consistent with applicable policies in the SMFP and will promote safety and quality in the delivery of healthcare services while promoting equitable access in a cost efficient manner.

As previously stated, Rowan Endoscopy filed its CON application in the wrong review cycle. The project proposed by Rowan Endoscopy is a Category E project, not a Category I project. Chapter 3 of the SMFP sets for the schedule for CON reviews. Deviations from that schedule are not allowed. Moreover, the CON Section cannot, on its own accord, “roll over” the application to the next appropriate review cycle. Rather, the applicant is responsible for filing its application at the appropriate time.

Even if this application is to merely convert existing procedure rooms to GI Endoscopy rooms, Rowan Endoscopy has not provided adequate documentation as to the need for this nor how it will provide access to the underserved populations. As previously noted, Rowan Endoscopy is not indicating any increase in self-pay, charity, or Medicaid populations which would benefit greatly from access to early GI endoscopy procedures. In fact, it is proposing no charity care access at all.

There is no need to convert the existing medical office-based procedure rooms to GI Endoscopy rooms in an ASC since the medical office setting is comparably the most cost effective. ASC rates, third party payments, and patient copayments and out-of-pocket expenses are higher in an ASC versus a medical office building. Rowan Endoscopy is already providing GI Endoscopy services and receiving payments in this setting and does not provide support to how the project will improve this already low cost healthcare setting.

For these reasons, plus any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (1) and should be denied.

Criterion (3)

Criterion (3): NCGS 131E-183(a)(3): The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed and the extent to which all residents of the service area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups likely to have access to the services proposed.

It is worth noting again that Rowan Endoscopy is projecting increased volumes but no increase in self-pay, charity, or Medicaid patients. Also as indicated on page 24 of its application, though the service area indicated shows total racial minority (American Indian, Asian, Black or African American, and Other) population percentages of about 25%, Rowan Endoscopy shows it had no patients in these categories. The application does not document how Rowan Endoscopy will provide access to their services to these underserved population. For these reasons, plus any

additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (3) and should be denied.

Criterion (4)

Criterion (4) NCGS § 131E-183(a)(4): Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

Rowan Endoscopy is nonconforming with Criterion (4) because the application does not propose the least costly or most effective alternative to meet the healthcare needs of the service area. The least costly or most effective alternative is for Rowan Endoscopy to continue to operate its existing medical office-based procedure rooms for gastrointestinal services. Establishing an ASC will lead to increased facility charges, third party payments, and patient copayments and out-of-pocket expenses for patients.

For the foregoing reasons, plus any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (4) and should be denied.

Criterion (5)

Criterion (5) NCGS § 131E-183(a)(5): Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

Since Rowan Endoscopy has failed to meet Criterion (1) and Criterion (3) by not demonstrating the need for the development of a new ASC in Rowan County, the financial and operational projections for the project do not satisfy the requirements of Criterion (5). In addition, as explained in Criterion (7) below, Rowan Endoscopy has understated its staffing expense, which impacts the financial feasibility of the project.

For that reason and any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (5) and should be denied.

Criterion (6)

Criterion (6) NCGS § 131E-183(a)(6): The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Since Rowan Endoscopy has failed to meet Criteria (1) and (3) by not demonstrating the need for the development of a new ASC in Rowan County, the application does not demonstrate how the

project will not result in unnecessary duplication of existing or approved health service facilities as required by Criterion (6).

For that reason and any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (6) and should not be approved.

Criterion (7)

Criterion (7) NCGS § 131E-183(a)(7): The applicant shall show evidence of the availability of resources, including manpower and management personnel, for the provision of the services proposed to be provided.

The Rowan Endoscopy application fails to document that the center will be properly staffed to ensure that patient care is delivered to under a high level of quality and safety. Novant Health, Inc. recently opened in April 2018 the Novant Health Brunswick Endoscopy Center in Brunswick County, North Carolina, which operates 2 GI Endoscopy rooms and is anticipated to have volumes similar to Rowan Endoscopy projections. The following table contrasts the non-physician staffing at the Novant Health Brunswick Endoscopy Center with the Rowan Endoscopy staffing proposed in Form H. of the application:

Position	Rowan Endoscopy FTEs- PY 3 2021	Novant Health Brunswick Endoscopy Center –Current FTEs	Difference
RN Administrator	0	1	-1
Scheduler/Receptionist	1	1	0
RNs	1	5	-4
Surgical Technicians	2	3	-1
LPNs	1	0	1
CRNAs	1	2	-1
Total FTEs	6	12	-6

First, Rowan Endoscopy does not indicate that there is an Administrator or Director of the center. Licensed and certified ASCs typically have a dedicated Administrator who is often an RN. It is unclear who is overseeing the clinical operations of the facility. Secondly, sterile processing duties are also not fully explained. Novant Health Brunswick Endoscopy staffs with 3 surgical technicians, one of whom is dedicated solely to scope washing. Thirdly, the RN staffing seems inadequate to staff 2 rooms and also provide pre- and post-operative care. Novant Health Brunswick Endoscopy Center has 5 RNs with a majority of them caring for patients in the pre- and post-operative areas. Rowan Endoscopy does not appear to have accounted for the RNs or clinical staff in the pre-and post-operative areas at all in the application.

In addition, the anesthesia coverage appears to be deficient for a 2 room ASC. Rowan Endoscopy has indicated only 1 contracted CRNA for the facility. ASC standards state that the same person providing anesthesia and monitoring the patient should not be the same person that is documenting the procedures. As such, there should be 2 CRNAs to accommodate the volume

of procedures projected by Rowan Endoscopy. It also seems unlikely that Rowan Endoscopy's projected staffing level will remain the same for all the project years while the procedure volumes increase at the rate projected. Given that the projected staffing in Rowan Endoscopy's application is understated and is unrealistically remaining flat as procedure volumes ramp up, Rowan Endoscopy has understated its salary and benefit expense which impacts the financial feasibility of the project.

For the foregoing reasons, plus any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (7) and should be denied.

Criterion (13)

Criterion (13) NCGS § 131E-183(a)(13): The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For purposes of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which the medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;***
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;***
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and***
- (d) That the applicant offers a range of means by which a person will have access to its service. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.***

The Rowan Endoscopy application is nonconforming to Criterion (13) since the application indicates that Rowan Endoscopy provides **zero** charity care in its existing medical office setting and projects to provide **zero** charity care in its proposed ASC operations. The Rowan Endoscopy application also indicates that the facility historically and in the future will provide minimal access to Medicaid patients – specifically less than 1 percent of its total payor mix. The lack of access for charity, Medicaid, and other underserved populations is unacceptable and the application is further deficient in that Rowan Endoscopy does not demonstrate that it will improve access to the underserved population as is required by Criterion (13).

For these reasons and any additional reasons the Agency may discern as it reviews the

Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (13) and should be denied.

Criterion (18a)

Criterion (18a) NCGS § 131E-183(a)(18a): The applicant shall demonstrate that the effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application for a services on which competition would not have a favorable impact.

The Rowan Endoscopy application provided no substantive analysis of how its approval would affect competition and the competitive balance in Rowan County. The absence of a reasonable analysis of the impact of the application on competition and the effect of more or less competition on the cost effectiveness, quality, and access to the services proposed make the application nonconforming with this criterion.

For the foregoing reasons, plus any additional reasons the Agency may discern as it reviews the Rowan Endoscopy application, the Rowan Endoscopy application is nonconforming with Criterion (18a) and should be denied.

Conclusion

The Rowan Endoscopy application is fundamentally nonconforming since Rowan Endoscopy's application is to establish a licensed and certified ASC and was submitted in the wrong review period and should be deemed unacceptable prior to review. The Rowan Endoscopy application also fails to adequately document and project the need for converting the 2 existing procedure rooms to 2 GI Endoscopy rooms in a licensed and certified ASC setting. Rowan Endoscopy has failed to show how the project will improve access to underserved populations, be lower cost, properly staffed, and enhance competition in Rowan County. As such, the Rowan Endoscopy application to establish 2 GI-Endoscopy rooms in an ASC should be denied because it is non-conforming with CON Review Criteria (1), (3), (4), (5), (6), (7), (13) and (18a).