

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 13, 2014

PROJECT ANALYST: Michael J. McKillip

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: O-10241-14 / Wilmington Health, PLLC / Convert a single specialty ambulatory surgery center to a multispecialty ambulatory surgery center / New Hanover County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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 the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Wilmington Health, PLLC [**Wilmington Health**] proposes to convert a single specialty ambulatory surgery center, Wilmington Health Endoscopy Center, to a multispecialty ambulatory surgery center. The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP). There are no policies in the 2014 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.
- (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 area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, Wilmington Health, proposes to convert a single specialty ambulatory surgery center, Wilmington Health Endoscopy Center, to a multispecialty ambulatory surgery center. Effective April 30, 1990, Wilmington Health was issued a certificate of need to develop an ambulatory surgery center “providing only gastroenterology surgical procedures.” Condition #2 requires that Wilmington Health obtain “an additional certificate of need” before it may perform other types of surgical procedures. In Section II.1, pages 13-14, the applicant describes the project as follows:

“Wilmington Health Endoscopy Center, an existing licensed and certified ambulatory surgical facility, is limited to providing only gastroenterology surgical procedures by its current certificate of need. Wilmington Health proposes to expand the scope of procedures provided by adding additional specialties which include, but are not limited to the following: urology, general surgery, plastics, and ENT. The proposed addition of specialties will convert Wilmington Health’s existing specialty ambulatory surgical program to a multispecialty ambulatory surgical program. ... Wilmington Health recognizes that the proposed project is rather unique. While some providers have been approved to convert a specialty ambulatory surgical program (with operating rooms and surgical cases) to a multispecialty ambulatory surgical program (with operating rooms and surgical cases), the proposed project involves a licensed ambulatory surgical facility with no operating rooms. ... Although the three procedure rooms at Wilmington Health appear on the list of gastrointestinal/endoscopy rooms shown on Table 6E of the 2014 SMFP, it should be noted that the rooms were developed many years before the term ‘gastrointestinal endoscopy room’ was incorporated in the CON statute, and, as explained above, the ambulatory surgical facility was limited by the conditions of its certificate of need to perform only ‘gastroenterology surgical procedures.’ It is clear, however, that Wilmington Health’s existing rooms are procedure rooms and not operating rooms, as they are listed separately from the operating room inventory in the SMFP.”

In Section II.1, pages 15-16, the applicant states:

“Wilmington Health’s ambulatory surgical facility occupies 2,462 square feet of space on the third floor of the building located at 1202 Medical Center Drive in Wilmington. Wilmington Health is licensed for and currently operates three gastroenterology surgical procedure rooms in its ambulatory surgical facility, as illustrated in the line drawings in Exhibit 4. ... As noted previously, Wilmington Health is proposing to expand the scope of procedures provided at its existing ambulatory surgical facility by adding specialties and thereby converting its existing specialty ambulatory surgical program to a multispecialty ambulatory specialty program. The proposed addition of specialties does not include any renovation or construction. Rather, the procedures Wilmington Health’s physicians propose to perform at the existing ambulatory surgical facility can be performed appropriately in the three existing procedure rooms as they are either non-incision procedures or procedures that can be performed in an office-based setting and therefore do not require an operating room. ... Since Wilmington Health is not proposing to increase its inventory of procedure rooms, but rather to better utilize the rooms that currently,

exist, the existing support areas are adequate to support the proposed multispecialty ambulatory surgical program.”

In Section II.6, page 5, the applicant states,

“Please note that the existing ambulatory surgical facility is referred to as Wilmington Health Endoscopy Center as it is limited to providing only gastroenterology surgical procedures by its current certificate of need. However, upon completion of the proposed project, the ambulatory surgical facility will be referred to as Wilmington Health Ambulatory Surgery Center (ASC) in order to accurately reflect the expanded scope of services provided by the facility.”

Population to be Served

In Section III.6, page 65, the applicant provides projected patient origin for Wilmington Health Ambulatory Surgery Center (ASC) in the first two years of operation (CY2015-CY2016), as shown in the table below.

**Wilmington Health ASC
Projected Patient Origin, CY2015-CY2016**

| County | Patients Percent of Total |
|-----------------|--------------------------------------|
| New Hanover | 53.8% |
| Brunswick | 22.1% |
| Pender | 12.0% |
| Other Counties* | 12.1% |
| TOTAL | 100.0% |

*The applicant identifies the counties included in the “Other Counties” category on page 65 of the application.

On page 65 of the application, the applicant states, “*To project patient origin, Wilmington Health applied its FFY 2013 historical patient origin, as shown in the response to III.7 [on page 66 of the application] to projected cases.*” The applicant adequately identified the population proposed to be served.

Need for the Project

In Section III.1(a) of the application, the applicant describes the factors supporting the need for the proposed project, including the need to improve utilization of the three existing procedure rooms at Wilmington Health’s ASC (pages 47-49), and the need to improve the quality, access, and value of healthcare services to the residents of the proposed service area (pages 49-56).

In Section IV.1, page 71, the applicant provides the historical and projected number of procedures to be performed in Wilmington Health’s ASC during the first three operating years of the proposed project, which are summarized below:

Wilmington Health ASC Utilization, CY2012 – CY2017

| Year | # of Procedure Rooms | GI/Endo Procedures | Other Specialty Procedures | Total Procedures | Percent Change |
|------------------|----------------------|--------------------|----------------------------|------------------|----------------|
| CY2012 – Actual | 3 | 2,499 | 0 | 2,499 | --- |
| CY2013 – Actual | 3 | 2,717 | 0 | 2,717 | 8.7% |
| CY2014 – Interim | 3 | 2,764 | 0 | 2,764 | 1.7% |
| CY2015 – Year 1 | 3 | 2,812 | 497 | 3,309 | 19.7% |
| CY2016 – Year 2 | 3 | 2,861 | 607 | 3,468 | 4.8% |
| CY2017 – Year 3 | 3 | 2,911 | 771 | 3,682 | 6.2% |

In Section III.1(b), pages 58-59, the applicant describes the assumptions and methodology used to project the number of GI/endoscopy procedures to be performed during the first three years of operation as follows:

“Wilmington Health conservatively assumes that GI/endo procedures performed at the ASC will grow at the projected population growth rate for its service area of 1.74 percent, as shown below.

| | FFY 2013 | FFY 2014 | FFY 2015 | FFY 2016 | FFY 2017 | FFY 2018 | CAGR |
|--------------------------|----------|----------|----------|----------|----------|----------|-------|
| Total GI/Endo Procedures | 2,705 | 2,752 | 2,800 | 2,849 | 2,898 | 2,949 | 1.74% |

This assumed growth rate is conservative as it assumes growth only on the basis of population growth. Moreover, the assumed growth rate is approximately one half of Wilmington Health’s historical growth rate (1.74 percent assumed growth rate / 3.26 percent FFY 2007 to 2013 historical CAGR = 0.53). As the project is expected to be operational January 1, 2015, it was necessary to convert the volume from FFY to CY. The table below provides CY volume.

| | CY 2014 | PY 1 CY 2015 | PY 2 CY 2016 | PY 3 CY 2017 |
|--------------------------|---------|-----------------|-----------------|-----------------|
| Total GI/Endo Procedures | 2,764 | 2,812 | 2,861 | 2,911 |

In Section III.1(b), pages 59-61, the applicant describes the assumptions and methodology used to project the number of other specialty procedures to be performed during the first three years of operation as follows:

“The proposed additional specialties are expected to result in an increase in procedure volume at Wilmington Health. As explained in Sections II.1 and III.1(a), although Wilmington Health includes physicians from more than a dozen specialties, it is initially proposing to expand the services at its existing ambulatory surgical facility by only four additional specialties: urology, general surgery, plastic surgery and ENT. Additional specialties may be added in the future as capacity permits. Wilmington Health physicians currently perform these urology, general surgery,

plastics, and ENT procedures in other locations including hospitals, ASCs, and physician offices. In order to project the number of procedures that will be added as a result of the proposed project, Wilmington Health examined the number of urology, general surgery, plastics, and ENT procedures already performed by its physicians that can be appropriately performed in the facility's existing procedure rooms. Examples of the proposed procedures to be added include, but are not limited to, cystoscopies (urology), breast excisions (general surgery), debridement (plastics), and septoplasties (ENT), all of which can be appropriately and cost effectively provided in the ASC. As shown in the table below, Wilmington Health physician members performed 960 procedures annually in the specialties proposed to be added in this project.

| <i>Specialty</i> | <i>Procedures</i> |
|------------------------|-------------------|
| <i>Urology</i> | <i>326</i> |
| <i>General Surgery</i> | <i>298</i> |
| <i>Plastics</i> | <i>196</i> |
| <i>ENT</i> | <i>140</i> |
| Total | 960 |

Source: Wilmington Health internal data for January – June 2013 annualized. Please note that Wilmington Health believes this data is representative of its historical annual volume for these types of procedures.

Although volume for these procedures is likely to increase at a faster rate, particularly with the development of this project and the resulting availability of a lower cost, high quality setting, Wilmington Health assumes that, similar to the GI/endo procedures, the volume for the above specialties will grow at a rate equal to the projected population growth rate of the service area, as shown in the table below.

| | CY 2013 | CY 2014 | CY 2015 | CY 2016 | CY 2017 | CAGR |
|--|--------------------|--------------------|--------------------|--------------------|--------------------|-------------|
| <i>Urology, General Surgery Plastics, ENT Procedures</i> | 960 | 977 | 994 | 1,011 | 1,029 | 1.74% |

While Wilmington Health believes that all of these cases could be added to its ASC, it has conservatively assumed that it will shift only a portion of these cases to account for patient preference or any other factors, and that the shift will ramp up over time. Wilmington Health assumes that in Project Year 1, 50 percent of these procedures will be shifted to the ASC by its physicians. Wilmington Health assumes 60 percent and 75 percent will shift in Project Years 2 and 3, respectively. The table below demonstrates the assumed shifts and total volume for the ASC when combined with GI/Endo cases projected above.

Wilmington Health ASC Projected Utilization

| CY | GI/Endo Procedures | Potential Procedures to Shift | Percentage Shifted | Actual Procedures Shifted | Total Procedures |
|-----------|-------------------------------|--|-------------------------------|--|-----------------------------|
| | | | | | |

| | | | | | |
|------------|-------|-------|-----|-----|-------|
| 2014 | 2,764 | 977 | | | 2,764 |
| 2015 (PY1) | 2,812 | 994 | 50% | 497 | 3,309 |
| 2016 (PY2) | 2,861 | 1,011 | 60% | 607 | 3,468 |
| 2017 (PY3) | 2,911 | 1,029 | 75% | 771 | 3,682 |

As discussed above, Wilmington Health believes these projections area reasonable based on numerous factors. The patients having these procedures performed are already Wilmington Health patients; thus, they are likely to follow their doctor to the ASC, if that is where the doctor prefers to do the procedure. The physicians are members of Wilmington Health, PLLC, so performing the procedure at the ASC is clearly beneficial from a financial, quality and continuity of care standpoint. Thus, Wilmington Health believes the projected volume will be easily achieved as projected above. In particular, the projected number of procedures for Year 3 represents only 80 percent of the volume for these cases in CY 2013.”

The following table shows the historical utilization of the Wilmington Health ASC from FY2007 through FY2013 as reported to the Division of Health Service Regulation by the applicant in its License Renewal Application for Ambulatory Surgical Facility forms for 2008-2014.

**Wilmington Health ASC
 GI/Endoscopy Procedures, FY2007-FY2013**

| Fiscal Year | GI/Endoscopy Procedures | Percent Change |
|--------------------|--------------------------------|-----------------------|
| FY2007 | 2,772 | --- |
| FY2008 | 3,042 | 9.7% |
| FY2009 | 3,003 | -1.3% |
| FY2010 | 2,716 | -9.6% |
| FY2011 | 2,591 | -4.6% |
| FY2012 | 2,430 | -6.2% |
| FY2013 | 2,705 | 11.3% |

Source: Applicant’s *License Renewal Application for Ambulatory Surgical Facility* forms for 2008-2014.

On page 57, the applicant states,

“This time period includes the economic downturn that resulted in declines in utilization across the healthcare sector. Despite the downturn, Wilmington Health’s ambulatory surgical facility has experienced growth in procedure volumes.”

As discussed above, the applicant projects the GI/endoscopy procedure volumes will increase at the projected population rate of growth of 1.74 percent per year through the first three operating years of the project. Using its own internal data from the first six months of 2013, the applicant identified all the procedures currently performed by its member physicians and surgeons at other locations that would be appropriate for Wilmington Health’s ASC. The applicant projects that 50, 60, and 75 percent of those procedures will be shifted to the three procedure rooms at Wilmington Health in operating years one, two, and three, respectively.

Based on these assumptions, the applicant projects a total of 3,682 procedures in the three procedure rooms at the Wilmington Health ASC in the third year of operation (CY2017). Exhibit 21 contains letters from the physicians and surgeons of Wilmington Health expressing support for the proposed project. The projected utilization of the procedure rooms at the Wilmington Health ASC is based on reasonable, credible and supported assumptions. Wilmington Health adequately demonstrates the need for the proposed project.

Access

The applicant projects 66.4% of the patients will be covered by Medicare (64.8%) and Medicaid (1.6%). The applicant demonstrates adequate access for medically underserved groups to the proposed services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (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.

CA

In Section III.8, pages 66-68, the applicant discusses the alternatives it considered prior to submitting this application, which include:

- a) Maintaining the status quo, which the applicant states was rejected because it is not an effective use of the existing ASC facility which has capacity to accommodate these procedures in a manner that is more convenient and accessible for the patients in the proposed service area.
- b) Developing an additional procedure room in which to perform the other specialty procedures, which the applicant states was rejected because it is a less cost-effective alternative than simply performing the other specialty procedures in the existing procedure rooms at Wilmington Health's ASC.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative.

Furthermore, the application is conforming to all other statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Wilmington Health, PLLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Wilmington Health, PLLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
 - 3. Wilmington Health, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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.

C

In Section VIII.1, page 98, the applicant projects the capital cost for the project will be \$26,951. In Section VIII.3, the applicant states Wilmington Health will finance the capital costs with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 19, the applicant provides a letter from the Chief Financial Officer for Wilmington Health, which states

"As a requirement of the Certificate of Need application process, I have been asked to document the availability of funds for the conversion of the ambulatory surgical facility's existing ambulatory surgical program to a multispecialty ambulatory surgical program through the addition of specialties that include, but are not limited to urology, general surgery, plastics, and otolaryngology.

As the Chief Financial Officer for Wilmington Health, I am responsible for the financial operations of Wilmington Health. As such, I am very familiar with the organization's financial position. Wilmington Health has more than sufficient reserves to fund all the costs associated with the proposed

ambulatory surgery center project, which is estimated to total \$26,951. There are no start-up costs related to this project.

Wilmington Health will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects as there are no other projects currently underway or planned at this time. For verification of availability of funds and our ability to finance this project internally, please refer to the financial statements included with this CON application.”

Exhibit 20 of the application contains audited financial statements for Wilmington Health, PLLC and Affiliate for the year ended December 31, 2012, which document that Wilmington Health had \$1.2 million in cash and cash equivalents as of December 31, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In the pro forma financial statements for the ASC (Form B), the applicant projects revenues will exceed expenses in each of the first three operating years, as shown below:

Wilmington Health ASC

| | CY2015 Year 1 | CY2016 Year 2 | CY2017 Year 3 |
|-------------------|--------------------------|--------------------------|--------------------------|
| Total Revenue | \$1,346,148 | \$1,459,341 | \$1,605,795 |
| Total Expenses | \$1,013,000 | \$1,060,148 | \$1,115,584 |
| Net Income (Loss) | \$333,149 | \$399,194 | \$490,210 |

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to convert a single specialty ambulatory surgery center, Wilmington Health Endoscopy Center, to a multispecialty ambulatory surgery center. The applicant does not propose to increase the number of health care facilities, operating rooms, GI endoscopy procedure rooms or other types of procedure rooms. Rather, the applicant proposes to make better use of its existing rooms by performing other types of procedures in those rooms.

On page 69, the applicant states,

“As explained thoroughly in Section III.1, the proposed project will enable Wilmington Health to serve patients in its own facility. As such, other providers cannot meet the need Wilmington Health is proposing to address. The proposed procedures to shift are already being performed by Wilmington Health physicians in other settings, such as hospitals and doctor’s offices. By shifting these procedures out of a hospital setting, Wilmington Health can lower costs for patients.”

In Section IV.1, page 71, the applicant provides the historical and projected number of procedures to be performed in Wilmington Health’s ASC during the first three operating years of the proposed project, which are summarized below:

Wilmington Health ASC Utilization, CY2012 – CY2017

| Year | # of Procedure Rooms | GI/Endo Procedures | Other Specialty Procedures | Total Procedures | Percent Change |
|------------------|-----------------------------|---------------------------|-----------------------------------|-------------------------|-----------------------|
| CY2012 – Actual | 3 | 2,499 | 0 | 2,499 | --- |
| CY2013 – Actual | 3 | 2,717 | 0 | 2,717 | 8.7% |
| CY2014 – Interim | 3 | 2,764 | 0 | 2,764 | 1.7% |
| CY2015 – Year 1 | 3 | 2,812 | 497 | 3,309 | 19.7% |
| CY2016 – Year 2 | 3 | 2,861 | 607 | 3,468 | 4.8% |
| CY2017 – Year 3 | 3 | 2,911 | 771 | 3,682 | 6.2% |

As shown in the table above, Wilmington Health projects to perform 3,682 procedures in its three procedure rooms in the third operating year of the project. Wilmington Health adequately demonstrated the need to convert its single specialty ambulatory surgery center, Wilmington Health Endoscopy Center, to a multispecialty ambulatory surgery center. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant’s service area. Therefore, the application is conforming with this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1 and VII.2, page 89, Wilmington Health provides the current and projected staffing for the second operating year of the ASC, as shown below in the table.

| Position | Current Staffing | Proposed Staffing Year 2 |
|--------------------------|-------------------------|---------------------------------|
| Clinic Manager | 1.0 | 1.0 |
| Registered Nurse | 3.5 | 3.5 |
| Licensed Practical Nurse | 1.0 | 1.0 |
| Nursing Aides | 1.5 | 1.5 |
| Surgical Technicians | 0.0 | 1.0 |

| | | |
|--|------------|------------|
| All 'non-health professionals' and 'technical' personnel | 1.5 | 1.5 |
| TOTAL | 8.5 | 9.5 |

Source: Tables VII.1 and VII.2, page 89.

In Section VII.3, page 90, the applicant states it proposes to add one full-time equivalent (FTE) surgical technician position as part of the proposed project. In Section VII.7, page 93, the applicant describes its recruitment and retention procedures, and indicates that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.9, page 95, the applicant identifies Matthew Mlot, M.D. as the Chief of Staff for the ASC. Exhibit 12 contains Dr. Mlot's curriculum vitae and Exhibit 21 contains a letter from Dr. Mlot expressing his support for the project. Exhibit 21 of the application contains copies of letters from Wilmington Health physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section II.2, pages 19-20, and Exhibit 3, the applicant documents that all of the necessary ancillary and support services for the proposed services will be provided by the applicant or through a "*Comprehensive Services and Personnel Agreement*" with Wilmington Health, PLLC. Exhibit 3 also contains copies of service agreements between Wilmington Health ASC and providers of anesthesia, laboratory, and maintenance services. In Section V.2, page 74, the applicant states, "*As an existing healthcare provider in the area, Wilmington Health has established relationships with area healthcare providers.*" Exhibit 7 contains a copy of a transfer agreement between Wilmington Health ASC and New Hanover Regional Medical Center. Exhibit 21 contains copies of letters from physician and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The

availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(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 the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which 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;

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In Section VI.12, page 86, the applicant reports the payer mix for Wilmington Health ASC for CY2013, which is summarized in the following table:

| Wilmington Health ASC Payer Category | CY2013 Surgical Cases as % of Total |
|---|--|
| Self Pay/Indigent | 1.0% |
| Commercial Insurance | 29.3% |
| Medicare/Medicare Managed Care | 64.8% |
| Medicaid | 1.6% |

| | |
|--------------------|---------------|
| Other (Government) | 3.3% |
| Total | 100.0% |

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

| County | Total # of Medicaid Eligibles as % of Total Population June 2010 | Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010 | % Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) |
|---------------|---|--|---|
| New Hanover | 13% | 5.7% | 20.4% |
| Brunswick | 7% | 2.8% | 19.8% |
| Pender | 17% | 7.4% | 21.0% |
| Statewide | 17% | 6.7% | 19.7% |

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the surgical services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

- (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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 86, the applicant states:

“Wilmington Health has no federal obligation to provide uncompensated care. The facility will continue to comply with all access requirements for the Americans with Disabilities Act, as documented in the facility’s Admission Policy included in Exhibit 17.”

In Section VI.10 (a), page 85, the applicant states that no Office of Civil Rights complaints have been filed against it in last five years. The application is conforming to this criterion.

- (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

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In Section VI.14, page 87, the applicant provides the projected payer mix for the second full fiscal year of operation (CY2016) for the ASC, as shown in the table below.

| Wilmington Health ASC Payer Category | CY2016 Surgical Cases as % of Total |
|---|--|
| Self Pay/Indigent | 1.0% |
| Commercial Insurance | 29.3% |
| Medicare/Medicare Managed Care | 64.8% |
| Medicaid | 1.6% |
| Other (Government) | 3.3% |
| Total | 100.0% |

On page 87, the applicant states, *“The above percentages are based on historical experience as payor mix is not expected to be affected by the proposed project.”* The applicant demonstrates that medically underserved populations will have adequate

access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 84, the applicants describe the range of means by which a person will have access to the proposed services. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 of the application, the applicant states Wilmington Health ASC has existing relationships with area health professional training programs, and that the ASC will continue to be available as a clinical training site to those same programs. On page 73, the applicant states that it has clinical training arrangements with UNC-Wilmington School of Nursing, Cape Fear Community College School of Nursing and Practical Nursing, and the Miller-Motte Business School (Medical Office Assistant Program). The information provided in Section V.1 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected 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 is for a service on which competition will not have a favorable impact.

C

The applicant proposes to convert a single specialty ambulatory surgery center, Wilmington Health Endoscopy Center, to a multispecialty ambulatory surgery center. The applicant does not propose to increase the number of health care facilities, operating rooms, GI endoscopy procedure rooms or other types of procedure rooms. Rather, the applicant proposes to make better use of its existing rooms by performing other types of procedures in those rooms.

In Section V.7, page 78, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed surgical services. The applicant states,

“The proposed project will result in the development of a multispecialty ambulatory surgical program in New Hanover County. Competition will be enhanced because the proposed facility will improve access to high-quality services, specifically outpatient surgical procedures, in New Hanover County and surrounding areas.

In addition, as a freestanding ASC, patient co-pays will be low. This continued enhancement to the services proposed at Wilmington Health’s ASC fosters competition with hospital-based providers.

Finally, the proposed facility will foster competition by improving the quality of care for the patients to be served at the ASC. The facility will be dedicated to the needs of outpatients and the environment will be conducive to the quick recovery times anticipated for these patients. For these reasons, the proposed project represents an effective alternative for fostering competition in the area.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to convert a single specialty ambulatory surgery center to a multispecialty ambulatory surgery center and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it will provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

Wilmington Health Endoscopy Center is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. A Medicare Recertification Survey was conducted on July 25, 2013, and the facility was found out of compliance with five (5) Medicare Conditions for Coverage (CfC) with twenty-one (21) standards cited, and out of compliance with three (3) State Licensure Rules during the health portion of the recertification survey. On August 8, 2013, the Life Safety Survey was conducted and the facility was cited for four (4) Life Safety Code Tags with six (6) deficiencies. Recertification was not recommended and the facility was placed on a 90-day termination from Medicare. Follow-up surveys were conducted on September 26, 2013 for the Health portion, and on October 22, 2013 and January 23, 2014 for the Life Safety Code. The facility was found to be in compliance with the Medicare CfCs and State Licensure Rules, the 90-day termination was removed, and recertification was recommended. The facility is currently in compliance with the Medicare CfCs and State Licensure Rules. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA