Comments in Opposition to a Certificate of Need Application by Four County Endoscopy Center, LLC to develop a new ambulatory surgical facility in Granville County (Project ID # K-11941-20)

October 1, 2020

In response to a Certificate of Need application submitted by Four County Endoscopy Center, LLC ("FCEC") to develop a new ambulatory surgical facility ("ASF") in Granville County (Project ID # K-11941-20), the County of Granville d/b/a Granville Health System ("GHS") provides the following comments in opposition to this project. These comments are in accordance with N.C. GEN. STAT. § 131E-185(a1)(1), as they include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). Per N.C. GEN. STAT. § 131E-188(c), GHS is an affected person because it is located "*within the service area…to be served by the applicant"* and "*provides services, similar to the services under review, to individuals residing in the service area…proposed to be served by the applicant*." As such, GHS believes that the comments contained herein are particularly relevant to the review by the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency.")

Granville Health System has served the residents of Granville County for more than 100 years. As a county-owned health system, it has a duty to provide care to residents, regardless of their ability to pay. Despite the increasing challenges with providing care in small, rural areas like Oxford and Granville County, GHS has consistently provided access to high quality healthcare services. This commitment to care requires a significant investment of resources, often without receiving enough (if any) reimbursement to offset those costs. As shown on the most recent audited financial statements for GHS in Attachment 1, the system had significant net losses in 2017 and 2018. While recent financial performance has improved somewhat, GHS continues to experience many of the same struggles that have caused hospitals in other counties across the state to reduce services or close. As explained in detail in the comments below, the proposed project will have a direct negative impact on GHS and its ability to continue providing essential and uncompensated care to the residents of Granville County. While the application includes projections that show no adverse impact to GHS, those projections are based on unreasonable assumptions and are clearly derived to obfuscate the real harm that will occur to GHS and Granville County if the project is developed. GHS hopes that these comments provide substantive evidence that will make it clear to the Agency that the proposed project is based on flawed reasoning and erroneous and unsupported assumptions. As such, the application should be denied.

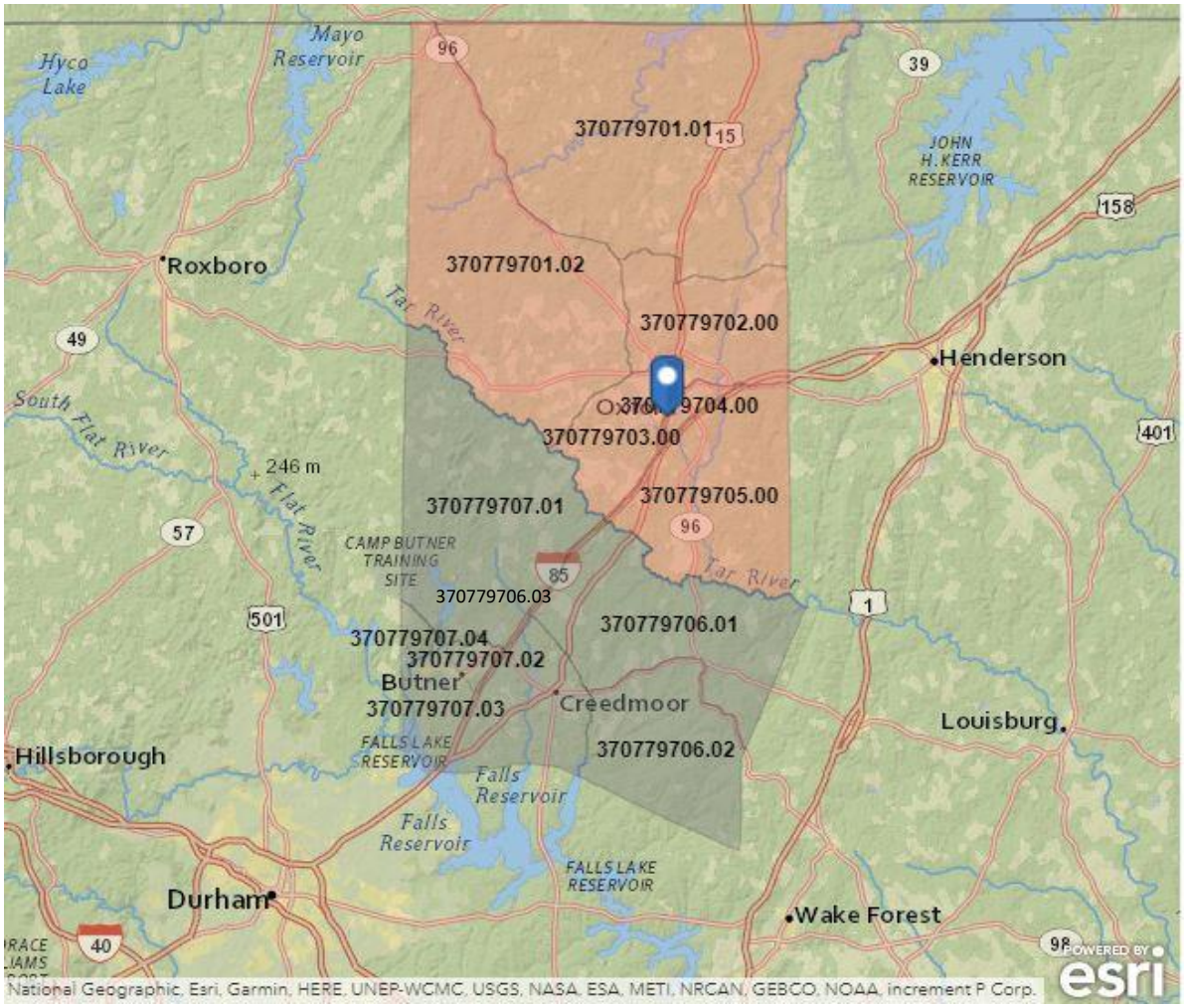
The remainder of these comments provide evidence of the errors and non-conformities in the application, organized by issue.

<u>Incorrect Information Regarding Applicant Entity</u>

Section A.1 of the application states that the applicant entity, Four County Endoscopy Center, LLC, is an existing legal entity and refers to Exhibit A.1 for Articles of Organization. However, Exhibit A.1 provides no Articles of Organization for Four County Endoscopy Center, LLC or any other entity. As of the date of the submission of these comments, no such organization appears on the North Carolina Secretary of State website. Other registered healthcare organizations that include "Four County" in their name appear to be related to Maria Parham Health. Given the letter of support from Maria Parham, it may own or intend to own part of the proposed facility; however, such a relationship is not disclosed in the application. In any case, the information in the application regarding the status of the applicant is incorrect, and no legal applicant entity exists. Accordingly, the validity of any statements regarding the membership of the applicant or its relationship to other entities is questionable and not subject to verification.

Unreasonable Assumptions Regarding Granville County's Population

Like other rural/suburban counties that border large metropolitan counties, residents of the part of Granville County that is closer to Durham and Wake counties are oriented to those counties for their daily activities, while residents of the part farther away from the large counties are oriented to the Oxford area. The two "halves" of Granville County are divided along the Tar River, a natural feature which bisects the county along a diagonal line running between the borders with Franklin and Person counties. The proposed facility would be located in Oxford, north of the Tar River, yet the application makes no distinction in its assumptions regarding the residents of these two separate parts of the county. Since many of the residents of the southern part of the county work, shop and recreate in Durham or Wake counties, they naturally also seek healthcare services outside of Granville County. These residents do not typically travel north towards Oxford for healthcare, but rather south into the larger urban areas, which are closer to parts of southern Granville County than Oxford, with more services available. This difference in the two halves of Granville County is also present in the population statistics. Since the ZIP codes that comprise Granville County are large and also encompass parts of other counties, census tract data are more effective at providing the county's population. The map below provides the location of the county's census tracts and the two halves, separated by the Tar River. The site plotted with the blue arrow is the location of the proposed ASF in Oxford.



The table below provides the population of each of the census tracts that comprise Granville County and demonstrates that the southern portion includes the majority of the county's residents.

Census Tract	*2020 Population*	*2025 Population*	*CAGR* 2020-2025*
370779702.00	4,687	5,395	2.85%
370779705.00	4,184	4,336	0.72%
370779703.00	3,852	3,971	0.61%
370779704.00	4,210	4,310	0.47%
370779701.02	3,727	3,793	0.35%
370779701.01	5,387	5,458	0.26%
Northern subtotal	*26,047*	*27,263*	*0.9%*
370779707.01	5,724	6,275	1.86%
370779706.02	9,685	10,581	1.79%
370779707.02	2,714	2,811	0.70%
370779706.01	6,443	6,925	1.45%
370779706.03	7,437	7,970	1.39%
370779707.04	1,152	1,152	0.00%
370779707.03	4,064	4,056	-0.04%
Southern subtotal	*37,219*	*39,770*	*1.3%*
County Total	**63,266**	**67,033**	**1.1%**

*Compound Annual Growth Rate
Source: Esri.

In 2020, the southern census tracts contain 58.8 percent of the county's population; by 2025, that ratio will increase to 59.3 percent. The highlighted rows show the census tracts that border Wake or Durham counties; by 2025, the residents of those areas will comprise 42.0 percent of the county's population, meaning that nearly one-half of the county population will live in close proximity to these larger counties where they are likely to seek care. This proximity of the population to Durham and Wake counties also drives commuting patterns, as noted above. According to the most recent data available from Carolina Demography[1], part of The University of North Carolina's Carolina Population Center, only 47.2 percent of Granville County's workforce resides in the county. In other words, the majority of workers who live in Granville County, 52.8 percent, work outside the county. Similarly, the majority of Granville residents seek healthcare services in other counties. Traffic congestion has existed in the Triangle region for many years but has not reversed the outmigration from Granville County for work or healthcare.

This information is important to understand, particularly given the assumptions made in the application regarding market share and projected utilization for the proposed ASF. These population statistics also explain the reason that, despite the existence of a hospital in Oxford for more than 100 years, the majority of the county's residents travel to Durham County for inpatient acute care. While some of these patients may seek care unavailable at GHS, such as tertiary or quaternary care, the majority of inpatient acute care can be provided in a community hospital such as GHS. The table below provides these data.

[1] https://www.ncdemography.org/2015/08/17/county-to-county-commuting-nc/

County of Service	*Percentage of Granville County Patients*
Durham	56.8%
Granville	20.3%
Orange	8.4%
Wake	7.8%
Vance	5.6%
Other	1.1%

Source: DHSR, Healthcare Planning and Certificate of Need Section database.

Of note, GHS does provide outpatient healthcare services in southern Granville County at its facilities in Butner and Creedmoor. Given the location of the hospital in Oxford, north of the Tar River, the majority of Granville patients access inpatient acute care in Durham and other counties. Given the location of the population in the county and the availability of other providers in other nearby counties, the data indicate that the majority of patients are likely to continue seeking healthcare services, including GI endoscopy, in Durham or Wake counties, not at a facility in Oxford.

As described in further detail below, the lack of analysis regarding the location of the population in Granville County and historical trends of seeking healthcare services in other nearby counties results in unreasonable and unsupported assumptions in the application.

Incorrect Assumptions Regarding GI Endoscopy

In Section C.4, the application presents data regarding incidence and death rates for colorectal cancer in the service area counties. This analysis leads to the conclusion that the residents of the service area, including Granville County, are receiving fewer GI endoscopy procedures than they should, and that more than 28,000 screening colonoscopies will be needed by 2025. Given the approximate 6,100 GI endoscopy procedures performed on residents of the service area counties in 2019, only a portion of which were colonoscopies, this analysis would suggest a need for nearly five times the number of procedures currently being performed. However, the analysis is based on flawed assumptions.

In particular, the application assumes that 100 percent of individuals in the 55 to 74 age cohort will receive a colonoscopy every 10 years, which is implausible. According to data from the American Cancer Society, in 2018 only 66 percent of the population age 50 and older had a screening test of any kind. See page 22 of Attachment 3. Moreover, the application assumes that the only method of screening used will be colonoscopies, which is also unreasonable. The American Cancer Society states that there "are several recommendations for CRC [colorectal cancer] screening[2]," including colonoscopy as well as at-home stool-based tests and CT colonoscopy. Thus, even if everyone in the identified age group was being screened, not everyone would choose a traditional colonoscopy, as the application suggests.

This issue has been cited by the Agency in previous reviews in which the application was denied. See page 6 of the Agency Findings for Halifax Gastroenterology and pages 5 and 6 of the Agency Findings for Kurt G. Vernon, M.D. in Attachment 2. Based on similar errors in the FCEC application and consistent with previous findings, the Agency should deny the application.

[2] See Attachment 3, page 19.

Incorrect Assumptions Regarding Cost for Care

The application provides data from Blue Cross & Blue Shield ("BCBS") in an attempt to compare the cost of obtaining some GI endoscopy procedures. While GHS understands that some procedures have lower charges in an ASF setting compared to a hospital-based setting, the application fails to point out that there is no cost for most patients, including Medicare patients, for screening tests such as colonoscopies. For Medicare patients, screening colonoscopies, which the application presents as the "preferred colorectal cancer-screening test" on page 18, there is no cost to the patient if the provider accepts Medicare assignment (which GHS does)[3]. Moreover, as noted by data from the Kaiser Family Foundation, Affordable Care Act-compliant commercial plans, which cover more than two-thirds of workers in employer-sponsored plans, are required to provide coverage for screening tests, including colonoscopies, at no cost to the patient[4]. See page 26 of Attachment 3 for information from the American Cancer Society and Table 1 in Attachment 4 for a list of preventative services covered by private insurance plans without cost sharing with the patient. As such, the differences in charges between hospital-based and ASF settings make little difference to the majority of patients receiving the service. Further, as explained above, unlike the proposed ASF, GHS provides essential care to all patients in need, including emergency and inpatient services, often at a loss and without regard to the patient's ability to pay.

Errors in the Utilization Assumptions and Methodology

1. **Projected Utilization Growth of More than 2,800 Percent**

   The application projects to increase the number of GI endoscopy procedures its physicians perform on service area residents by 2,805 percent. While the methodology includes multiple steps with several pages of analysis in an attempt to support this unbelievable assumption, the bottom line is that the application projects that the development of the proposed ASF will increase the number of GI endoscopy procedures performed by its physicians on residents of the service area by this extraordinary growth rate. The following analysis demonstrates why this assumption is unreasonable and unsupported.

   The application claims that the physicians expected to perform cases at the proposed ASF already serve patients from the four-county region. Exhibit C.3.g on page 17 provides these data for the various facilities at which FCEC physicians currently practice. While the total is shown as 1,883, the vast majority of these procedures are from a single source, Dr. Allen, whose sole current site of care is in Mecklenburg County, Virginia. The balance of patients from the three North Carolina counties in the service area (Granville, Vance and Warren) total only 126 patients, only 38 of which are from Granville County. As shown in the table below, the application unreasonably projects the number of procedures performed on residents of these counties to increase exponentially.

[3] https://www.medicare.gov/coverage/screening-colonoscopies
[4] https://www.kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/

County	*2019*	*PY1 (2023)*	*PY2 (2024)*	*PY3 (2025)*	*Growth 2019-2025*
Granville	38	543	1,095	1,104	2,805%
Vance	58	393	788	790	1,262%
Warren	30	171	342	342	1,040%
Mecklenburg (Virginia)	1,757	903	900	898	-49%
Total	**1,883**	**2,010**	**3,125**	**3,134**	**66%**

Source: Application Exhibit C.3.g, Section C.3 page 23, calculations.

While the overall growth rate of 66 percent is itself excessive, the individual county growth rates are completely unbelievable. The application arrives at these incredible projections through a series of unsupported and unreasonable steps in its methodology. The following comments relate to the issues with those individual steps; however, it should be noted that the Agency has previously found similar assumptions in other applications to be unreasonable, leading to the denial of those applications. As noted above, some of those Agency Findings are included in Attachment 2.

Of note, Exhibit C.3.c, page 6, provides historical data for Clayton Endoscopy, a facility in Johnston County owned by members of the applicant. Like Granville County following development of the proposed project, Johnston County has one hospital system and one licensed GI endoscopy ASF. Johnston County's population far exceeds Granville County's, however, with nearly 200,000 people compared to just over 60,000 in Granville County. Yet after operating for over three years in a county with more than three times the population, Clayton Endoscopy reported only 2,178 cases in 2019, substantially less than the more than 3,000 projected for the proposed facility in Year 3. Obviously, the application's projections are grossly overstated, based on the actual experience of a related entity.

2. Unsupported growth in GI endoscopy use rates

In Step 2 of its methodology (page 105), the application projects the use rates for GI endoscopy in the three North Carolina counties in its service area to grow to meet the calculated statewide use rates. This assumption is without any credible support and is unreasonable for several reasons.

- The application lacks any rationale supporting the increase in the use rate for GI endoscopy cases, which it assumes will occur in 2020.
- Even if the use rate changes in the future, there is no evidence to support an immediate change to the same rate, the statewide rate, in all three counties.
    - For example, the 2019 use rate for Vance County shown on page 12 of Exhibit C.3 is calculated to be 53.47.
    - The application projects it to be 52.9 in 2020, a decrease over the most recent year.
    - In contrast, the 2019 use rate for Warren County shown on the same page is 41.1, which is projected to increase to 52.9 in 2020.
    - Similarly, the 2019 use rate for Granville County is 46.62, projected to increase to 52.9 in 2020.

- There is no evidence to suggest that the use rate for any of these counties will change so dramatically in a single year—from 2019 to 2020—particularly the significant increases projected for Warren and Granville counties.
- Although hidden by the calculations, which combine the population and projected case totals for all three counties, the table below uses the population projections and use rate assumptions to demonstrate the projected growth from 2019 to 2020 in GI endoscopy cases for each county.

County	*2019*	*2020*	*One-Year Growth*
Granville	2,863	3,228	12.7%
Vance	2,458	2,371	-3.5%
Warren	823	1,045	27.0%
Total	**6,144**	**6,644**	**8.1%**

Source: Application Exhibit C.3, calculations.

As shown, the application projects growth of over 12 percent in Granville County cases and 27 percent in Warren County cases in a single year—a year that is more than one-half complete as of the filing of the application—and more than two years before the proposed facility would be complete.

In contrast, the actual historical trend in these counties—not shown in the application—has been significantly different. Using data from page 12 of Exhibit C.3, the following table shows the GI endoscopy case growth (decline) since 2016.

County	*2016*	*2019*	*CAGR*
Granville	2,485	2,863	4.8%
Vance	2,058	2,458	6.1%
Warren	1,000	823	-6.3%
Total	**5,543**	**6,144**	**4.6%**

Source: Application Exhibit C.3, calculations.

As shown, while two of the three service area counties have experienced some growth in the past few years, the overall growth has been nearly one-half the rate projected in the application for a single year. For Granville County in particular, the application's projected growth rate is a multiple of the historical rate, which is unreasonable.

- Data from other counties bordering urban counties provide evidence that the use rates will not increase as projected. Specifically, the application notes that the applicant has a related facility in Johnston County, where it has provided GI endoscopy services in an ASF for several years. Despite this fact, data from DHSR indicate that Johnston County's GI endoscopy use rate is lower than the statewide use rate of 52.9, as shown below.

	2017	2018	2019
GI Endoscopy Patients	7,287	7,285	8,055
Population	193,902	199,790	205,951
Use Rate/1,000	37.58	36.46	39.11

Source: DHSR, Healthcare Planning and Certificate of Need Section database; Office of State Budget and Management population estimates; calculations.

As shown, despite the existence of an GI Endoscopy ASF, owned by members of the applicant, Johnston County's use rate is significantly lower than the statewide use rate. As such, the application's implication that the development of its proposed facility will result in an immediate or even a long-term increase in the use rates to match those of the state is without basis.

3. Overstated need for GI endoscopy rooms

In Steps 3 and 4 of the methodology, pages 106 and 107, the application calculates a perceived need for additional GI endoscopy rooms in the service area. The application makes multiple erroneous assumptions which render the projections unreasonable.

- The application equates the performance standard threshold of 1,500 procedures per GI endoscopy room per year with an indication of "need" for a certain number of rooms. While the *State Medical Facilities Plan* ("SMFP") does include a need methodology for certain services, and while the performance standards in the administrative rules may be derived from that methodology in some cases, there is no SMFP methodology for GI endoscopy rooms, nor is there any data to indicate that the maximum number of procedures that should be performed in a GI endoscopy room is 1,500. The use of 1,500 procedures indicates that is a minimum number that may be performed in order to be approved, not a maximum. The application's assumption therefore understates the capacity of GI endoscopy rooms and overstates the need.
- The application includes only GI endoscopy rooms located in the service area counties, not those that are accessible and used by thousands of patients in other counties. While the applicant may suggest that access is needed within a patient's home county, its analysis runs counter to this argument, in that it combines the population of the three counties and assumes that a GI endoscopy ASF in one county (Granville) is needed to serve residents of the other counties.
- As noted in detail above, the majority of residents of Granville County are located in the southern portion of the county, and a plurality are located in the areas adjacent to Durham or Wake counties, where they have more proximate access to existing ASFs and hospitals than they do to existing or proposed facilities in Oxford. Thus, it is not reasonable to assume that these patients would use a facility in Oxford, rather than facilities outside the county, simply because it is in their home county.
- Regarding the analysis for Mecklenburg County, Virginia, the application makes similar errors regarding the "capacity" of GI endoscopy rooms in that county as it does for the North Carolina portion of the service area. In addition, the application states that the county has "no dedicated GI endoscopy rooms." The Commonwealth of Virginia does not license GI endoscopy rooms as North Carolina does; rather, hospitals are defined in administrative code

as including both inpatient and outpatient surgical facilities[5]. Further, hospitals (including what would be ASFs in North Carolina) may have operating rooms, procedure rooms or "exclusive use" rooms. Any of these three categories may be used as GI endoscopy rooms. According to data from Virginia Health Information ("VHI")[6], similar to North Carolina's IBM/Truven database, VCU Community Memorial Hospital is licensed for three endoscopic operating rooms—in addition to its three general operating rooms. As such, Mecklenburg County does have dedicated endoscopy rooms—which are actually operating rooms designated for endoscopy. Further, according to VHI, those rooms performed a total of 3,282 cases in 2018 (the most recent data available). Even assuming the application's projected number of GI endoscopy procedures is accurate, using the VHI data, the existing endoscopy operating rooms in the county performed a higher number of cases, and there is a surplus of endoscopy rooms, not a deficit, in Mecklenburg County, Virginia.

4. Understated growth in GHS GI Endoscopy Cases

In Step 5, on page 108, the application projects what it calls "unserved" GI endoscopy procedures in the service area. This analysis is flawed for multiple reasons, including its reliance on the previous incorrect assumptions. In addition, the application projects growth at existing facilities in the service area, including GHS, to be equal to the population growth rate, which severely understates the actual historical growth rate at GHS. The application lacks any support for this assumption, and it fails to provide the actual historical growth rate for the existing providers in the service area, likely because doing so would undermine its assumption. As shown in the following table, the historical growth rate has been substantial and has been particularly strong in the last year.

	2015	*2016*	*2017*	*2018*	*2019*	*CAGR*
GI Endoscopy Cases	612	696	648	712	1,073	15.1%
GI Endoscopy Procedures	784	930	710	854	1,282	13.1%

Sources: Hospital License Renewal Applications, State Medical Facilities Plans, calculations.

This growth at GHS is expected to continue, driven largely by the successful recruitment of a highly qualified gastroenterologist to GHS, Dr. Abraham. Prior to his recruitment, GI endoscopy services were provided by a general surgeon or a family medicine physician, which limited access to a physician dedicated to the service. The recruitment of Dr. Abraham brought a more focused and specialist approach to GHS's provision of endoscopy services, which has demonstrably improved access to the service for Granville residents. These factors, including the notable growth in the most recent historical year, were completely ignored in FCEC's application.

A more reasonable assumption for growth in GI endoscopy in Granville County would be the actual historical growth rate in these procedures, not the population growth factor assumed in the application. Using these rates, the table below provides a more realistic projection for GHS.

[5] https://law.lis.virginia.gov/admincode/title12/agency5/chapter230/section10/
[6] http://www.vhi.org/

	2020	2021	2022	2023	2024	2025	CAGR
GI Endoscopy Cases	1,235	1,421	1,635	1,881	2,165	2,491	15.1%
GI Endoscopy Procedures	1,450	1,639	1,854	2,096	2,371	2,681	13.1%

As shown, the number of estimated procedures at GHS by 2025 will far surpass the number projected in the application. Even if FCEC's other assumptions were all valid, the number of "unserved" GI endoscopy procedures remaining in Granville County will be far lower than projected, and it will not meet its required minimum utilization threshold.

Moreover, the application assumes, without basis, that the balance of "unserved" procedures will be available to FCEC to be performed at its proposed facility in Oxford. As shown in the table below, the majority of Granville County patients leave the county for GI endoscopy services, primarily for care in Durham County, which is closer to the more highly populated southern portion of the county.

County of Service	Percentage of Granville County Patients
Durham	46.6%
Wake	20.1%
Granville	19.9%
Vance	6.2%
Orange	6.0%
Other	1.2%

Source: DHSR, Healthcare Planning and Certificate of Need Section database for FY 2019

It is unreasonable and unrealistic to assume that these patients, many of whom also work in Durham or Wake counties, will not continue seeking care there, but will instead travel to Oxford to the proposed facility.

5. Unsupported and Overstated Market Share Assumptions

In Step 6, page 109, the application projects to achieve 50 percent market share by the second project year. This assumption is supported by general statements regarding the availability of the service and patient education—without any attempt to demonstrate how that will occur or how that will result in the assumed market share. Further, several of the points raised in the application are untrue or contradicted by actual data, including the following:

- The application asserts that the proposed project will result in an increase in the number of gastroenterologists working in the area. The only "work" being performed in the area is the projected GI endoscopy procedures. The application provides no evidence that any of the gastroenterologists will establish offices in the area; rather, the building to house the proposed ASF will include space for only the ASF. The physicians have no offices in Granville County currently, and there is no expressed plan to develop a presence in the community.

- With no community presence, the pathway for patient referrals is unclear. Patients needing a GI endoscopy procedure are generally referred by their primary care physician or another specialist. Yet despite the 18-month process and multiple meetings with local providers noted on page 77, **not a single letter from a referring physician is included in the application to support the application's market share claims**. The three "community" letters provide no information regarding the signatories, including their address or county of residence.
- The application notes that members of the applicant entity own GI endoscopy ASFs in other counties, including Johnston County. As noted above, the Johnston County facility, Clayton Endoscopy, provides a good analog for the proposed project, as it is located in a county with one hospital system and one existing GI endoscopy ASF (related to the applicant), and borders a large urban county with multiple hospital and ASF providers. As shown in the table below, although it has been open for several years, the related entity in Johnston County has yet to exceed a 20 percent market share.

	2017	***2018***	***2019***
Total Johnston County GI Endoscopy Patients	5,622	6,032	6,504
Clayton Endoscopy GI Endoscopy Patients from Johnston County	974	1,254	1,279
Clayton Endoscopy Market Share of Johnston County	17.3%	20.8%	19.7%

Source: DHSR, Healthcare Planning and Certificate of Need Section database, calculations

As shown, despite having a presence in Johnston County for a number of years, the only non-hospital GI endoscopy provider, owned by the same group that will own the proposed ASF in Granville County, is unable to achieve the market share projected in the application.

Clearly, the application's market share assumptions are unreasonable, and the proposed facility will not achieve the utilization projected in the application.

6. Unreasonable Assumptions for Virginia cases

In Step 7, page 110, the application projects volume for Dr. Allen, with the assumption that 80 percent of his current patient base will seek care at the proposed facility. The application fails to provide any support for this assumption, including even a single letter from an existing Mecklenburg County, Virginia patient with such an intention. Further, given the facts, the assumption is simply unreasonable. According to page 17 of the application, Dr. Allen is in the process of relocating his practice to Wake Forest and joining the members of Raleigh Medical Group, who are members of the applicant entity. Thus, Dr. Allen will be practicing in Wake County from 2020 through 2023, the first year of the project. Given his relocation several counties and another state away, it is unreasonable to expect that Dr. Allen will continue to maintain his Virginia patient base, particularly over the course of more than two years until the proposed facility opens. The assumptions in the application are based on the premise that patients are unable or unwilling to travel from Granville County and other parts of the service area to Wake or Durham counties; if that is true, then it is certainly unreasonable to assume that patients from an

even greater distance away in another state will travel to Wake County for care. The application provides no analysis or support for this assumption, nor is it credible. Without the projected cases from Virginia, which encompass the plurality of the expected volume, the application falls far short of the minimum required utilization.

Based on the above issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and the performance standards in the GI endoscopy room rules (10A NCAC 14C .3903).

Missing Capital Costs

The capital costs in the application appear to be understated. In particular, the cost estimate provided in Exhibit F.1.b states that it includes costs to upfit the shell building; however, it is clear from the itemized cost list on page 5 of that exhibit that a substantial portion of the costs to develop the ASF are excluded from the estimate. Specifically, the total estimate for the construction costs exceed $1.2 million, while the costs assigned to the project are less than $750,000. The line drawings in Exhibit K.2 demonstrate that the entire structure of the building will be occupied by the proposed ASF; as such, there is no basis for excluding any of the cost for the building. Moreover, the building owner and applicant share common ownership, as noted on page 10 of the application. Finally, on pages 14 and 15 the application provides a response to Policy GEN-4, which only applies for projects exceeding $2 million in capital costs; thus, the application tacitly concedes that the capital costs will be greater than those shown in Section F.2.

As a result of these issues, the application fails to demonstrate the reasonableness of the projected costs, nor does it provide documentation of financing for the capital costs necessary to develop the project.

Given this lack of transparency and understated costs of the proposed project, the application should be found non-conforming with Criteria 5 and 12.

Failure to Demonstrate Coordinated Care

The application proposes to develop an ASF in Oxford to be staffed by physicians with Raleigh Medical Group. While this physician practice has offices in Wake County, it has no offices in Granville County, nor does the application indicate any intention to develop a presence in the county. Rather, it appears that the gastroenterologists will drive to the proposed ASF, perform their cases, and drive back out of the county to their homes. The application provides no commitment to obtaining privileges at GHS to provide coverage for emergency cases or inpatient care. Without a local office to see patients outside the ASF, even patients seeking outpatient care or follow up visits would be required to travel to a Raleigh Medical Group office outside the county. Curiously, the application even references the necessity of the services provided by the physicians outside of the GI endoscopy room on page 17, such as evaluating new patients, performing consultations and follow-up visits, as well as drawing lab specimens and evaluating medication. Without a physician office in Granville County, none of these services will be provided locally. This lack of coordination certainly undermines the utilization projections, based on expected referrals from local physicians, but it also indicates that the facility will not be developed in coordination with the local healthcare system.

Given this issue, the application should be found non-conforming with Criterion 8.

Attachment 1

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)

COMBINED FINANCIAL STATEMENTS
AND SUPPLEMENTARY INFORMATION

YEARS ENDED SEPTEMBER 30, 2018 AND 2017

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
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Oxford, North Carolina

Report on the Combined Financial Statements

We have audited the accompanying combined financial statements of Granville Health System and Affiliate (the System), a component unit of Granville County, which comprise the combined statement of net position as of September 30, 2018, and the related combined statements of revenues, expenses, and changes in net position, and cash flows for the year then ended, and the related notes to the combined financial statements.

Management's Responsibility for the Combined Financial Statements

Management is responsible for the preparation and fair presentation of these combined financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of combined financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these combined financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the combined financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the combined financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the combined financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the combined financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the combined financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the combined financial statements referred to above present fairly, in all material respects, the financial position of the System as of September 30, 2018, and the changes in its financial position and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Other Matters

The 2017 combined financial statements of the System were audited by other auditors whose report dated November 2, 2018, expressed an unmodified opinion on those combined financial statements.

Required Supplementary Information

Accounting principles generally accepted in the United States of America require that the management's discussion and analysis on pages 3 through 10, the Proportionate Share of Net Pension Liability on page 39, and the Pension Contributions on page 40 be presented to supplement the basic combined financial statements. Such information, although not a part of the basic combined financial statements, is required by the Governmental Accounting Standards Board, who considers it to be an essential part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with auditing standards generally accepted in the United States of America, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic combined financial statements, and other knowledge we obtained during our audit of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

Supplementary Information

Our audit was conducted for the purpose of forming an opinion on the combined financial statements of the System as a whole. The Combined Schedule of Net Patient Service Revenue, and the Combined Schedule of Other Operating Revenue are presented for purposes of additional analysis and are not required parts of the combined financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the combined financial statements. The information has been subjected to the auditing procedures applied in the audit of the combined financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the combined financial statements or to the combined financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the combined financial statements as a whole.

CliftonLarsonAllen LLP

CliftonLarsonAllen LLP

Raleigh, North Carolina
November 25, 2019

Granville Health System (the Hospital) provides inpatient, outpatient, emergency, surgery, and behavioral health care at our 62 bed hospital facility. The Hospital also provides skilled nursing home care, on-campus adult day care, and operates a primary care practice adjacent to the hospital campus, "Granville Primary Care - Oxford," a primary care practice in South Granville, "Granville Primary Care - Butner Creedmoor," and a general surgery office practice, "Granville Surgical Associates." In addition, the Hospital provides urology, gastroenterology, heart and vascular and ear nose and throat services at its specialty clinics (collectively, the System). The System provides services for residents of Granville County (the County) and the surrounding areas. The System's financial data is incorporated into the Comprehensive Annual Financial Report of Granville County, North Carolina, as a component unit and is an integral part of the County's financial statements.

FINANCIAL HIGHLIGHTS 2018

The assets and deferred outflows of resources of the System exceeded its liabilities and deferred inflows of resources at September 30, 2018 by approximately $20,509,000 (net position). This amount may be used to meet the System's ongoing financial obligations and to finance future capital improvement and expansion of services.

The System's total net position decreased approximately $2,223,000 for the year ended September 30, 2018, consisting of a deficit of revenues under expenses of approximately $2,356,000 and capital grants and contributions of approximately $133,000. The System experienced a 7.9% increase in net patient service revenue, which is reported with the provision for bad debts deducted from gross revenue. The increase in net revenue is primarily due to an increase in both inpatient and outpatient volumes compared the prior year. The System continued to experience a high volume of uninsured patients. The volume of uninsured patients is impacted by the state of North Carolina's decision to not expand the Medicaid program. The decrease in net position was smaller in 2018 due to the growth in revenues noted above, and management's efforts to contain operating expenses.

FINANCIAL HIGHLIGHTS 2017

The assets and deferred outflows of resources of the System exceeded its liabilities and deferred inflows of resources at September 30, 2017 by approximately $22,732,000 (net position).

The System's total net position decreased approximately $5,022,000 for the year ended September 30, 2017, consisting of a deficit of revenues under expenses of approximately $5,154,000 and capital grants and contributions of approximately $133,000. The System experienced a 3.0% decrease in net patient service revenue, which is reported with the provision for bad debts deducted from gross revenue. The decrease in net revenue is primarily due to an increase in bad debt of 18% compared the prior year. The System experienced a high volume of uninsured patients in 2017 (11.3%) and 2016 (11.7%). The volume of uninsured patients is impacted by the state of North Carolina's decision to not expand the Medicaid program. The decrease in net position resulted from an increase in expenses of 6.7% due primarily to salaries, benefits, supplies, purchased services, and other expenses.

OVERVIEW OF FINANCIAL STATEMENTS

This analysis is intended to serve as an introduction to the System's combined financial statements, which are composed of two components: 1) government-wide financial statements and 2) notes to the combined financial statements.

Government-wide combined financial statements include combined statements of net position, combined statements of revenue, expenses, and changes in net position, and combined statements of cash flows for the fiscal years ended September 30, 2018 and 2017. The System operates similarly to a private business and therefore utilizes the proprietary fund method of accounting. This method provides both long-term and short-term financial information and requires that revenue and expenses are recognized on the full accrual basis.

The combined statements of net position present information on all of the System's assets, deferred outflows of resources, liabilities, and deferred inflows of resources, with the difference reported as net position. Increases or decreases in net position serve as a useful indicator of whether the financial position of the System is improving or deteriorating.

The combined statements of revenue, expenses, and changes in net position present information showing how the System's net position changed during the most recent fiscal year. All changes in net position are reported as soon as the underlying event giving rise to the change occurs, regardless of the timing of the related cash flows.

The combined statement of cash flows presents information reconciling current year operations and changes in the combined statement of net position to the net change in cash during the year.

FINANCIAL ANALYSIS

Total Assets and Deferred Outflows of Resources

Total assets and deferred outflows of resources increased approximately $6,393,000 in 2018 as compared to 2017 and decreased approximately $8,319,000 in 2017 as compared to 2016 (See Table 1).

Table 1
Summary of Assets and Deferred Outflows of Resources

	2018	2017	2016
Current and Other Assets	$ 24,721,690	$ 20,044,231	$ 24,401,762
Capital Assets	29,372,478	29,534,974	31,000,599
Deferred Outflows of Resources	4,609,912	2,732,100	5,228,372
Total Assets and Deferred Outflows	$ 58,704,080	$ 52,311,305	$ 60,630,733

FINANCIAL ANALYSIS (CONTINUED)

Total Assets and Deferred Outflows of Resources (Continued)

During fiscal year 2018, assets increased overall primarily due to the BB&T holding account for the construction of the new medical office building. Capital assets decreased approximately $162,000 due to current year depreciation in excess of capital additions. In addition, the pension related deferred outflows of resources increased to approximately $4,610,000 in 2018 from approximately $2,732,000 in 2017. This adjustment is based on actuarial calculations at the state-wide level and applies to all entities participating in the state Local Government Employees' Retirement System (LGERS) plan.

During fiscal year 2017, assets decreased overall primarily due to the reduction in cash and cash equivalents and patient accounts receivable. Assets limited to use also increased by approximately $976,000 during the fiscal year due to Medicaid DSH money received during the year to offset uncompensated care expenses. Capital assets decreased approximately $1,466,000 due to current year depreciation in excess of capital additions. The pension related deferred outflows of resources decreased to approximately $2,732,000 in 2017 from approximately $5,228,000 in 2016.

Total Liabilities, Deferred Inflows of Resources and Net Position

Total liabilities, deferred inflows of resources and net position of the System in 2018 increased approximately $6,393,000 from fiscal year 2017 primarily due to a new note payable with the county to fund the new medical office building. Total liabilities, deferred inflows of resources and net position of the System in 2017 decreased approximately $8,319,000 from fiscal year 2016 primarily due to the change in the net pension liability. A cash flow plan was developed to programmatically reduce accounts payable to lower levels while building cash reserves.

Table 2
Summary of Liabilities, Deferred Inflows of Resources and Net Position

	2018	2017	2016
Current Liabilities	$ 10,757,382	$ 9,111,597	$ 9,372,040
Long-Term Liabilities	27,089,788	20,098,893	23,062,753
Total Liabilities	37,847,170	29,210,490	32,434,793
Deferred Inflows of Resources	348,092	368,846	442,353
Net Position:			
Net Investment in Capital Assets	8,711,598	13,794,525	14,297,683
Restricted, Net Pension Asset	47,757	58,434	55,071
Unrestricted	11,749,463	8,879,010	13,400,833
Total Net Position	20,508,818	22,731,969	27,753,587
Total Liabilities and Net Position	$ 58,704,080	$ 52,311,305	$ 60,630,733

FINANCIAL ANALYSIS (CONTINUED)

Net Patient Service Revenue

Net patient revenue increased 7.9% in fiscal year 2018 over 2017 primarily due to growth in both inpatient and outpatient revenue. The System saw increased revenue deductions due to a high volume of uninsured patients. Clinic revenues increased overall across all practices due to an increase in patient volumes. Implementation of new gastroenterology practice also contributed to increase in clinic revenues during the year. These visits also drove growth in other areas such as CT, ultrasound and radiology. Revenue related to the Brantwood nursing center decreased approximately 2% in 2018. This revenue is reflected as part of the overall inpatient revenue.

Net patient revenue decreased 3.0% in fiscal year 2017 from 2016 due to an increase of approximately $2,203,000 in the provision for bad debt. Revenues were impacted by associated implant and supply charges. Increased bad debt write offs of approximately 18% also decreased net patient revenue in the fiscal year due to a high volume of uninsured patients and prior year bad debt reconciliation. Clinic revenues increased by 25% over the prior year due primarily to growth in the two primary care clinics (Granville Primary Care Oxford & South Granville Primary Care) and due to the addition of new physicians and Granville Urology as a result of higher patient volume. These visits also drove growth in other areas such as CT, ultrasound and radiology. Brantwood inpatient revenue decreased by 6.9% compared to 2016.

Table 3
Summary of Net Patient Service Revenue

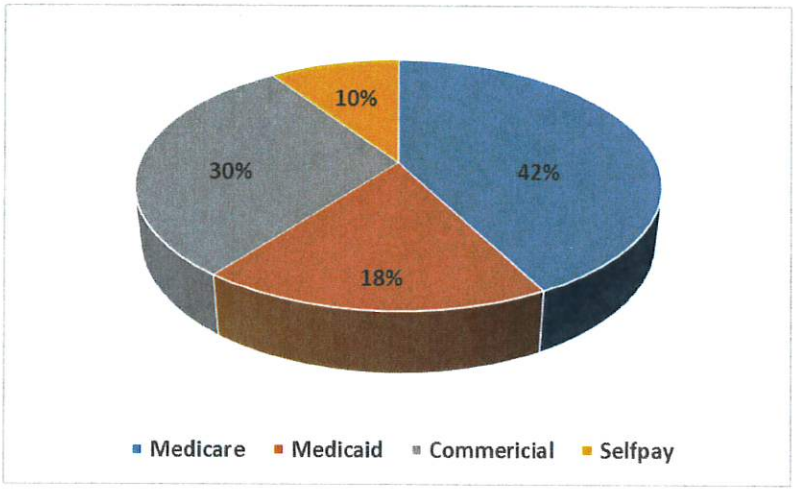
	2018	2017	2016
Inpatient Revenue	$ 43,371,356	$ 40,547,794	$ 40,244,496
Outpatient Revenue	112,548,358	108,372,498	103,774,550
Less: Charity Care	(1,857,900)	(1,986,375)	(2,121,669)
Patient Revenue	154,061,814	146,933,917	141,897,377
Contractual Adjustments	(78,402,861)	(77,245,596)	(72,551,983)
Other Adjustments	(484,567)	(471,927)	(664,036)
Provision for Bad Debts	(15,993,389)	(14,364,685)	(12,161,811)
Total Revenue Deductions	(94,880,817)	(92,082,208)	(85,377,830)
Net Patient Service Revenue	59,180,997	54,851,709	56,519,547
Other Operating Revenue	3,167,469	2,372,634	2,088,520
Total Operating Revenue	$ 62,348,466	$ 57,224,343	$ 58,608,067

FINANCIAL ANALYSIS (CONTINUED)

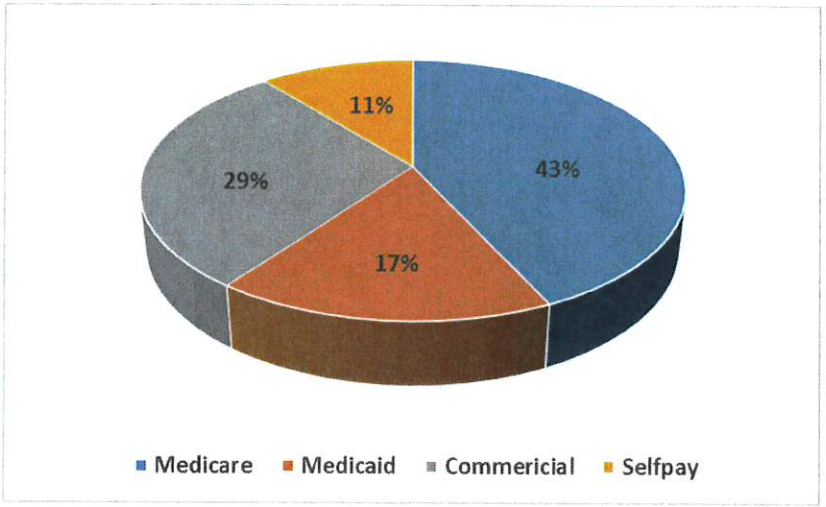
Net Patient Service Revenue (Continued)

The System has third-party payor agreements that provide reimbursement to the System. Graph 1 and 2 present gross patient revenue for the System by payor type for fiscal years 2018 and 2017.

Graph 1
2018 Patient Revenues by Payor Type



Graph 2
2017 Patient Revenues by Payor Type



FINANCIAL ANALYSIS (CONTINUED)

Net Patient Service Revenue (Continued)

During both 2018 and 2017, the largest percentage of healthcare service provided by the System was to Medicare and Medicaid beneficiaries, consuming 60% of total services each year. Commercially insured, including managed care subscribers, and uninsured patients comprise the remaining percentage of healthcare service, representing 30% and 10% in fiscal year 2018. These percentages saw a small shift from the prior year with more revenues moving to the commercial groups from uninsured patients.

The Medicare and Medicaid programs and commercial managed care programs pay healthcare organizations less than full charges. Increases in reimbursement from these payors have been less than the System's rate increases, thus requiring a constant evaluation of the types of services offered, as well as controlling expenses.

Operating Expenses

During the fiscal year ended September 30, 2018, total operating expenses were approximately $64,995,000, which equated to an increase over fiscal year ended September 30, 2017 of $1,714,000, or 2.7%. The most significant area of increase was to salaries and benefits which increased from 2017 by approximately $674,000. The increase in salaries and benefits was due to annual cost of living adjustments and higher than anticipated healthcare claims. The Hospital operates twenty-four hours a day with an array of specialized, highly skilled staff members. For fiscal year ended September 30, 2018, personnel and benefit costs accounted for approximately 56% of the System's operating expenses.

Physician fees increased by approximately $305,000 due to increased locums coverage throughout the organization. Contract labor was also increased due to the utilization of contract nursing because of position vacancies in Brantwood, and in the lab and anesthesia departments.

During fiscal year ended September 30, 2018, purchased services increased approximately $280,000 primarily due to collection agency fees and RVU fees at Granville Heart and Vascular. The System continues to partner with Professional Recovery Consultants to provide a third-party collection solution in order to decrease outstanding patient liability balances. The System also requires patients to pay the patient liability portion of their bill upfront for schedulable and nonemergent procedures. Legislative changes have resulted in insurance plans with higher deductibles and patient responsibilities. This is another step the System has taken to improve overall patient collections and remain competitive in a changing marketplace.

Other expenses increased primarily due to expenses booked for participation in the Medicaid DSH program which are offset against the recognized revenue.

CAPITAL ASSET AND DEBT ADMINISTRATION

Capital Assets

At September 30, 2018, the System had a total net investment of approximately $29,372,000 in land, buildings, equipment and furniture.

Major capital asset additions for the year ended September 30, 2018 include:

- Senoclaire LLH, DBT License
- Ambulance, 2017 Ford
- Brantwood Roof Replacement
- System 7 Saw
- Bipolar and Ultrasonic Generator
- AC Unit, Trane 15 Ton Split System

Major capital asset additions for the year ended September 30, 2017 include:

- CT Scanner Somatom Perspective 64 Slice
- CT Scanner Room Building Upfit
- Allscripts Professional PM Upgrade
- Meditech Magic ITS Conversion 2017
- Ambulance 2016 Chevrolet
- 2017 Chevrolet Tahoe EMS

The System's fiscal year 2019 capital budget projects spending $1,229,000 for equipment and renovations.

Long-Term Debt and Capital Leases

At September 30, 2018, the System had approximately $19,544,000 in long-term debt (net of current portion of approximately $918,000). This increase over prior year is due to a new note payable related to a new medical office building.

At September 30, 2017, the System had approximately $14,723,000 in long-term debt (net of current portion of approximately $604,000). This decrease over prior year is due to current debt service requirements. The System was able to reduce long-term debt (net of current portion) by approximately $0.6 million or 4%.

ECONOMIC FACTORS AND NEXT YEAR'S BUDGET

Economic Factors

The economy of Granville County overall has remained stable during this period. This is the result of the progressive community and its economic development strategy.

Next Year's Budget

For fiscal year 2019, the System has budgeted increases of 2.4% in net patient revenue due to expected volume increases driven by the addition of two general surgeons, a pediatrician, a new GI Practice and favorable impacts from renegotiated insurance contracts. The System continues to work with Wake Emergency Physicians, which provides coverage for the Emergency Department. Their physicians are board certified in emergency medicine and provide outstanding care to the community. The System has also implemented new upfront patient collection practices to help offset increasing bad debt expenses. Patients are now required to pay their responsibility upfront for schedulable and nonemergent procedures. An increase in expenses is anticipated as cost of living salary increases are planned for employees along with the addition of new physicians. We expect to continue to realize net cost savings in our drug purchasing program by continuing to carve in to the 340B program. Continual program modifications to our employee benefit programs should reduce health care expenses on a per member basis. The System has also partnered with Professional Recovery Consultants to provide a third-party extended business office solution to pursue patient liability balances and to improve patient collections. The System also participates in the NC Debt Setoff program to improve patient collections and recover outstanding patient balances based on criteria established by the state of North Carolina.

REQUESTS FOR INFORMATION

This financial report is designed to provide a general overview of the System for those interested in the System's finances. Questions concerning any of the information provided in this report or requests for additional information should be addressed to Adam McConnell, CFO at Granville Health System and Affiliate.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED STATEMENTS OF NET POSITION
SEPTEMBER 30, 2018 AND 2017

ASSETS AND DEFERRED OUTFLOWS OF RESOURCES	2018	2017
CURRENT ASSETS		
Cash and Cash Equivalents	$ 1,760,576	$ 666,792
Assets Limited as to Use, Current	9,258	3,860
Patient Accounts Receivable, Net of Allowance for Uncollectible Accounts of Approximately $19,158,000 and $16,712,000 at September 30, 2018 and 2017, Respectively	9,617,591	8,909,608
Accounts Receivable, Other	605,063	888,750
Supplies	2,061,394	1,975,750
Prepaid Expenses	256,315	416,607
Total Current Assets	14,310,197	12,861,367
ASSETS LIMITED AS TO USE		
By Board for Capital Improvements	4,398,057	6,722,055
By Third Party for Patient Personal Funds	9,258	3,860
Total Noncurrent Cash and Investments	4,407,315	6,725,915
Less: Amounts Required to Meet Current Obligations	9,258	3,860
Noncurrent Cash and Investments	4,398,057	6,722,055
CAPITAL ASSETS		
Nondepreciable Capital Assets	3,296,356	1,970,846
Depreciable Capital Assets, Net	26,076,122	27,564,128
Total Capital Assets Net of Accumulated Depreciation	29,372,478	29,534,974
GOODWILL, NET	-	5,834
PHYSICIAN RECRUITMENT RECEIVABLES, NET	755,641	454,975
DUE FROM RELATED PARTY	5,257,795	-
Total Assets	54,094,168	49,579,205
DEFERRED OUTFLOWS OF RESOURCES		
Pension Deferrals	4,609,912	2,732,100
Total Assets and Deferred Outflows of Resources	$ 58,704,080	$ 52,311,305

See accompanying Notes to Combined Financial Statements.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED STATEMENTS OF NET POSITION (CONTINUED)
SEPTEMBER 30, 2018 AND 2017

LIABILITIES, DEFERRED INFLOWS OF RESOURCES, AND NET POSITION	2018	2017
CURRENT LIABILITIES		
Current Installments of Long-Term Debt	$ 917,919	$ 604,073
Current Installments of Capital Leases	169,464	213,714
Accounts Payable and Other Fees Payable	5,800,865	4,953,449
Accrued Payroll	617,864	624,073
Accrued Vacation and Other Benefits Payable	1,992,460	1,983,195
Estimated Third-Party Payor Settlements	1,258,810	733,093
Total Current Liabilities	10,757,382	9,111,597
LONG-TERM DEBT, EXCLUDING CURRENT INSTALLMENTS	19,543,512	14,723,179
NET PENSION LIABILITY	7,516,291	5,176,231
CAPITAL LEASES, EXCLUDING CURRENT INSTALLMENTS	29,985	199,483
Total Liabilities	37,847,170	29,210,490
DEFERRED INFLOWS OF RESOURCES		
Pension Deferrals	348,092	368,846
NET POSITION		
Net Investment in Capital Assets	8,711,598	13,794,525
Restricted - Expendable for Specific Operating Activities	47,757	58,434
Unrestricted	11,749,463	8,879,010
Total Net Position	20,508,818	22,731,969
Total Liabilities, Deferred Inflows of Resources, and and Net Position	$ 58,704,080	$ 52,311,305

See accompanying Notes to Combined Financial Statements.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED STATEMENTS OF REVENUES, EXPENSES, AND CHANGES IN NET POSITION
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
OPERATING REVENUES		
Net Patient Service Revenue, Net of Provision for Bad Debts of Approximately $15,993,000 in 2018 and $14,365,000 in 2017	$ 59,180,997	$ 54,851,709
Other Operating Revenue	2,592,469	1,935,134
Payments from Granville County for EMS Services	575,000	437,500
Total Operating Revenues	62,348,466	57,224,343
OPERATING EXPENSES		
Salaries	28,185,662	28,074,606
Benefits	8,131,370	7,567,928
Physician Fees	1,156,781	852,181
Contract Labor	417,434	262,329
Professional Fees	1,272,586	1,177,995
Supplies	8,696,500	8,498,479
Purchased Services	5,064,231	4,784,012
Utilities	1,152,929	1,114,858
Leases and Rentals	738,949	789,169
Repair and Maintenance	1,806,493	1,826,909
Insurance	432,693	496,610
Interest Expense	646,970	709,773
Other Expenses	4,655,187	4,386,343
Depreciation	2,631,411	2,649,444
Impairment of Goodwill	5,834	90,000
Total Operating Expenses	64,995,030	63,280,636
LOSS FROM OPERATIONS	(2,646,564)	(6,056,293)
NONOPERATING REVENUES		
Investment Income	38,880	17,938
Other	221,659	392,445
Noncapital Grants	30,000	491,419
Net Nonoperating Revenues	290,539	901,802
DEFICIT OF REVENUES UNDER EXPENSES BEFORE CAPITAL GRANTS AND CONTRIBUTIONS	(2,356,025)	(5,154,491)
CAPITAL GRANTS AND CONTRIBUTIONS	132,874	132,873
DECREASE IN NET POSITION	(2,223,151)	(5,021,618)
Net Position - Beginning of Year	22,731,969	27,753,587
NET POSITION - END OF YEAR	$ 20,508,818	$ 22,731,969

See accompanying Notes to Combined Financial Statements.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Receipts from Patients and Third-Party Payors	$ 58,998,731	$ 57,372,542
Payments to Employees for Services	(36,080,450)	(36,229,328)
Payments to Suppliers for Goods and Services	(29,538,525)	(23,745,206)
Other Receipts from Operations	1,945,499	2,170,825
Payments from Granville County for EMS Service	575,000	437,500
Net Cash Provided (Used) by Operating Activities	(4,099,745)	6,333
CASH FLOWS FROM NONCAPITAL FINANCING ACTIVITIES		
Other Nonoperating Revenue	221,659	392,445
Noncapital Grants and Contributions	30,000	491,419
Net Cash Provided by Noncapital Financing Activities	251,659	883,864
CASH FLOWS FROM CAPITAL AND RELATED FINANCING ACTIVITES		
Proceeds from Long-Term Debt	5,800,000	-
Purchase of Capital Assets	(2,468,915)	(1,183,819)
Capital Grants and Contributions	132,874	132,873
Repayment of Long-Term Debt	(665,821)	(751,088)
Repayment of Capital Leases	(213,748)	(211,379)
Net Cash Provided (Used) by Capital and Related Activities	2,584,390	(2,013,413)
CASH FLOWS FROM INVESTING ACTIVITIES		
Investment Income	38,880	17,938
Net Change in Assets Limited as to Use	2,318,600	(976,474)
Net Cash Provided (Used) by Investing Activities	2,357,480	(958,536)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,093,784	(2,081,752)
Cash and Cash Equivalents - Beginning of Year	666,792	2,748,544
CASH AND CASH EQUIVALENTS - END OF YEAR	$ 1,760,576	$ 666,792

See accompanying Notes to Combined Financial Statements.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED STATEMENTS OF CASH FLOWS (CONTINUED)
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
RECONCILIATION OF LOSS FROM OPERATIONS TO NET CASH PROVIDED (USED) BY OPERATING ACTIVITIES		
Loss from Operations	$ (2,646,564)	$ (6,056,293)
Adjustments to Reconcile Net Loss to Net Cash Provided (Used) by Operating Activities:		
Depreciation	2,631,411	2,649,444
Pension Expense	1,967,957	1,686,185
Impairment of Goodwill	5,834	90,000
Provision for Bad Debts	15,993,389	14,364,685
Changes in Assets, Deferred Outflows, Liabilities, and Deferred Inflows:		
Patient Accounts Receivable, Net	(16,701,372)	(11,196,049)
Accounts Receivables, Other	283,687	235,691
Supplies	(85,644)	(91,119)
Prepaid Expenses	160,292	(7,168)
Physician Recruitment Receivables, Net	(300,666)	(143,787)
Accounts Payable and Other Fees Payable	754,718	399,558
Accrued Payroll	97,821	150,833
Accrued Vacation and Other Benefits Payable	(2,067)	(15,842)
Estimated Third-Party Payor Settlements	525,717	(647,803)
Due from Related Party	(5,257,795)	-
Net Deferred Outflows, Inflows, Pension Liability	(1,526,463)	(1,412,002)
Net Cash Provided (Used) by Operating Activities	$ (4,099,745)	$ 6,333

See accompanying Notes to Combined Financial Statements.

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Granville Health System (the Hospital) is a nonprofit acute care hospital and skilled nursing facility located in Oxford, North Carolina. The board of trustees (the board), appointed by the Granville County Board of Commissioners, is responsible for the operations of the Hospital, which is a component unit of Granville County (the County). The Hospital provides inpatient, outpatient, skilled nursing, and emergency care services for residents of the County and surrounding areas.

Granville Health Inc. (the Corporation), an affiliate of the Hospital, was formed in the fiscal year ended September 30, 2009 to engage in charitable efforts and to support the Hospital in providing healthcare and related services to the citizens and residents of the County and the surrounding community. The board also serves as the governing board for the Corporation. As a result, the Corporation is presented as a blended component unit of the Hospital.

The Granville Health System Foundation (the Foundation) supports the Hospital in promoting and advancing the well-being of the community by providing quality health care and health-related services. The Foundation is not included in the accompanying combined financial statements as it is not considered material to the combined financial statements as a whole.

Basis of Accounting

The accompanying combined financial statements are prepared and presented on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America.

Principles of Combination

The combined financial statements include the accounts of the Hospital and the Corporation (collectively, the System). All material intercompany accounts and transactions have been eliminated in combination.

Use of Estimates

The preparation of combined financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the combined financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

All cash and investments, except assets limited as to use, are essentially demand deposits and are considered cash and cash equivalents. The System considers demand deposits and investments purchased with an original maturity of three months or less and used for operations to be cash and cash equivalents.

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Patient Accounts Receivable

Patient accounts receivable is reported at estimated net realizable amounts from patients and responsible third-party payors. Amounts owed to the System are reported net of allowances for contractual adjustments and uncollectible accounts. The process for estimating the ultimate collection of receivables involves significant assumptions and judgments. In this regard, the System has implemented a standardized approach to estimate and review the collectability of its receivables based on patient receivable aging trends and historical collection rates.

Supplies

Supplies are stated at the lower of cost on the first-in, first-out method or market stated at net realizable value.

Assets Limited as to Use

Assets limited as to use include assets set aside by the board for future capital improvements, over which the board retains control and may at its discretion subsequently use for other purposes; assets set aside in accordance with agreements with third parties for patient personal funds; and any assets set aside by donors or grantors for specific purposes.

All deposits of the System are made in board-designated official depositories and are secured as required by North Carolina General Statue 159-31. The System may designate, as an official depository, any bank or savings association whose principal office is located in North Carolina. Also, the System may establish time deposit accounts such as NOW and SuperNOW accounts, money market accounts and certificates of deposit.

Capital Assets

Capital assets with cost exceeding $2,500 and construction projects are capitalized. Capital asset acquisitions are recorded at cost or the market value of donated items on the date of contribution.

Depreciation expense is provided over the estimated useful life of each class of depreciable asset and is computed on the straight-line method. Equipment under capital leases is amortized on the straight-line method over the shorter period of the lease term or the estimated useful life of the capital asset. Such amortization is included with depreciation in the combined financial statements.

The cost of physicians' office buildings owned by the County and maintained by the System are not included in the accompanying combined financial statements. Rental income and related maintenance expense are reported by the System as other operating revenue and operating expenses, respectively.

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Deferred Outflows/Inflows

In addition to assets, the combined statements of net position will sometimes report a separate section for deferred outflows of resources. This separate financial statement element presents a consumption of net position that applies to a future period and so will not be recognized as an expense or expenditure until then. The System has one item that meets this criteria — pension plan related items (See Note 8).

In addition to liabilities, the statement of financial position will sometimes report a separate section for deferred inflows of resources. This separate financial statement element represents an acquisition of net position that applies to a future period and so will not be recognized as revenue until then. The System has one item that meets the criteria for this category — pension plan related items (See Note 8).

Net Position

In accordance with GASB Statement No. 63, *Financial Reporting of Deferred Outflows of Resources, Deferred Inflows of Resources, and Net Position*, net position is categorized as net investment in capital assets, restricted and unrestricted. Net investment in capital assets consists of capital assets, net of accumulated depreciation, assets limited as to use held under indenture for the purchase of capital assets, and the outstanding balances of any borrowing attributable to the acquisition, construction, or improvement of capital assets. Restricted net position represents resources whose use by the System has been limited by donors (a) to later periods of time or after specified dates or (b) to specified purposes. Unrestricted net position has no third-party restrictions on its use.

Operating Revenues and Expenses

For purposes of presentation, activities deemed by management to be ongoing, major, or central to the provision of health care services are reported as operating revenues and expenses, including interest expense. Activities not directly related to the provision of healthcare services are reported as nonoperating income.

Net Patient Service Revenue

The System has agreements with third-party payors that provide for payments to the System at amounts different from its established rates. Payment arrangements include prospectively determined rates per discharge, reimbursed costs, discounted charges, and per diem payments. Net patient service revenue is reported at the estimated net realizable amounts from patients, third-party payors, and others for services rendered, including estimated retroactive adjustments due to future audits, reviews, and investigations. Retroactive adjustments are accrued on an estimated basis in the period the related services are rendered and adjusted in future periods as adjustments become known or as years are no longer subject to such audits, reviews, or investigations.

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Charity Care

The System provides care to patients who meet certain criteria under its charity care policy without charge or at amounts less than its established rates. Because the System does not pursue collection of amounts determined to qualify as charity care, they are not reported as net patient service revenue.

Meaningful Use of Electronic Health Records (EHR)

The System recognizes revenues for incentives earned under the Medicare program in the period in which it is reasonably assured that it will comply with the applicable EHR meaningful use requirements and payment has been received. Incentive payments received under the Medicare program include a discharge-related portion, which is calculated by Centers for Medicare & Medicaid Services based on the System's most recently filed cost report. Such amounts are subject to adjustment at the time of settling the 12-month cost report for the System's fiscal year that begins after the beginning of the payment year. During 2017, the System attested to Modified Stage 2 under the Medicare program and accordingly, recognized other operating revenue of approximately $65,000 in the combined statement of revenue, expenses and changes in net position for the year ended September 30, 2017. No amounts were recognized for the year ended September 30, 2018. The System does not maintain reserves related to these monies.

Grants and Contributions

From time to time, the System receives grants from the County, as well as contributions from individuals and private organizations. Revenues from grants and contributions (including contributions of capital assets) are recognized when all eligibility requirements, including time requirements, are met. Grants and contributions may be restricted for either specific operating purposes or for capital purposes. Amounts that are unrestricted or that are restricted to a specific operating purpose are reported as nonoperating income. Amounts restricted to capital acquisitions are reported after deficit of revenues under expenses, but are included in the change in net position.

Risk Management

The System is exposed to various risks of loss from torts; theft of, damage to, and destruction of assets; business interruption; errors and omissions; employee injuries and illnesses; natural disasters; medical malpractice; and employee health benefits. Commercial insurance coverage is purchased for claims arising from such matters. Settled claims have not exceeded this commercial coverage in any of the three preceding years. The System is insured for medical malpractice claims and judgments, as discussed in Note 15.

Income Taxes

The Hospital and the Corporation are exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code (IRC), accordingly, the accompanying combined financial statements do not reflect a provision or liability for federal and state income taxes. The System has determined that it does not have any material unrecognized tax benefits or obligations as of September 30, 2018.

NOTE 2 DEPOSITS

All of the System's deposits are either insured or collateralized by using one of two methods. Under the Dedicated Method, all deposits exceeding the federal depository insurance coverage are collateralized with securities held by the System's agent in the System's name. Under the Pooling Method, which is a collateral pool, all uninsured deposits are collateralized with securities held by the State Treasurer's agent in the name of the State Treasurer. Since the State Treasurer is acting in a fiduciary capacity for the System, these deposits are considered to be held by the System's agent in the System's name. The amount of the pledged collateral is based on an approved averaging method for noninterest bearing deposits and the actual current balance for interest bearing deposits. Depositories using the Pooling Method report to the State Treasurer the adequacy of their pooled collateral covering uninsured deposits. The State Treasurer does not confirm this information with the System or the escrow agent. Because of the inability to measure the exact amount of collateral pledged for the System under the Pooling Method, the potential exists for under-collateralization, and this risk may increase in periods of high cash flows. However, the State Treasurer of North Carolina enforces strict standards of financial stability for each depository that collateralizes public deposits under the Pooling Method. The System has no policy regarding custodial credit risk for deposits.

At September 30, 2018, the System's deposits had a carrying amount of approximately $6,168,000 and a bank balance of approximately $6,805,000. Of the bank balance, approximately $509,000 was covered by federal depository insurance and approximately $6,296,000 was covered by collateral held under the Pooling Method. At September 30, 2018, there were no deposits collateralized using the Dedicated Method. The System had cash on hand of approximately $3,500 included in cash and cash equivalents on the combined statement of net position. No funds were held by the County at September 30, 2018.

At September 30, 2017, the System's deposits had a carrying amount of approximately $7,393,000 and a bank balance of approximately $8,052,000. Of the bank balance, approximately $504,000 was covered by federal depository insurance and approximately $7,548,000 was covered by collateral held under the Pooling Method. At September 30, 2017, there were no deposits collateralized using the Dedicated Method. The System had cash on hand of approximately $3,200 included in cash and cash equivalents on the combined statement of net position. No funds were held by the County at September 30, 2017.

NOTE 3 ASSETS LIMITED AS TO USE

Assets limited as to use are required for obligations classified as current liabilities are reported with current assets. Assets limited as to use are stated at cost, which approximates fair value, and consist of cash, money market accounts and certificates of deposit, all with a maturity of less than one year. The composition of assets limited as to use is set forth in the following table as of September 30:

	2018	2017
By Board for Capital Improvements	$ 4,398,057	$ 6,722,055
By Third Party for Patient Personal Funds	$ 9,258	$ 3,860

Interest Rate Risk – Interest rate risk is the risk that changes in market interest rates will adversely affect the fair value of a fixed income investment. Investments are predominantly in certificates of deposit. However the System has no policy regarding limiting its exposure to losses from rising interest rates.

Credit Risk – Credit risk is the risk that an issuer or other counter-party to an investment will not fulfill their obligations as required by the investment. The System has no policy regarding credit risk.

Concentration of Credit Risk – The System places no limit on the amount that the System may invest in any one issuer.

Investment Income

Investment income on assets limited as to use totaled approximately $39,000 and $18,000 for years ended September 30, 2018 and 2017, respectively, and consists of interest income.

NOTE 4 PATIENT ACCOUNTS RECEIVABLE

Patient accounts receivable consisted of the following at September 30:

	2018	2017
Gross Patient Accounts Receivable	$ 35,944,996	$ 31,433,079
Allowance for Contractual Adjustments	(7,169,727)	(5,811,706)
Allowance for Uncollectible Accounts	(19,157,678)	(16,711,765)
Patient Accounts Receivable, Net	$ 9,617,591	$ 8,909,608

NOTE 4 PATIENT ACCOUNTS RECEIVABLE (CONTINUED)

Other receivables consisted of the following at September 30:

	2018	2017
Sales Tax	$ 115,793	$ 334,611
Proceeds from Insurance	109,914	-
Cost Report Settlements	271,440	275,621
Miscellaneous	107,916	278,518
Total Other Receivables	$ 605,063	$ 888,750

NOTE 5 CAPITAL ASSETS

Capital asset additions, retirements, and balances are as follows for the years ended September 30:

	Balance September 30, 2017	Additions	Retirements/ Transfers	Balance September 30, 2018
Nondepreciable Capital Assets:				
Land	$ 1,790,207	$ -	$ -	$ 1,790,207
CIP	180,639	1,460,949	(135,439)	1,506,149
Total Nondepreciable Capital Assets	1,970,846	1,460,949	(135,439)	3,296,356
Depreciable Capital Assets:				
Land Improvements	1,707,754	-	-	1,707,754
Buildings	31,052,048	137,956	-	31,190,004
Equipment and Fixtures	32,593,901	1,016,760	(23,627)	33,587,034
Capitalized Interest	181,828	-	-	181,828
Total Depreciable Capital Assets	65,535,531	1,154,716	(23,627)	66,666,620
Total Capital Assets at Historical Costs	67,506,377	2,615,665	(159,066)	69,962,976
Less Accumulated Depreciation:				
Land Improvements	(1,177,964)	(53,290)	-	(1,231,254)
Buildings	(14,805,782)	(831,442)	-	(15,637,224)
Equipment and Fixtures	(21,987,657)	(1,746,679)	12,316	(23,722,020)
Total Accumulated Depreciation	(37,971,403)	(2,631,411)	12,316	(40,590,498)
Capital Assets, Net	$ 29,534,974	$ (15,746)	$ (146,750)	$ 29,372,478

NOTE 5 CAPITAL ASSETS (CONTINUED)

	Balance September 30, 2016	Additions	Retirements/ Transfers	Balance September 30, 2017
Nondepreciable Capital Assets:				
Land	$ 1,790,207	$ -	$ -	$ 1,790,207
CIP	229,960	234,542	(283,863)	180,639
Total Nondepreciable Capital Assets	2,020,167	234,542	(283,863)	1,970,846
Depreciable Capital Assets:				
Land Improvements	1,707,754	-	-	1,707,754
Buildings	30,975,409	76,639	-	31,052,048
Equipment and Fixtures	32,564,081	872,638	(842,818)	32,593,901
Capitalized Interest	181,828	-	-	181,828
Total Depreciable Capital Assets	65,429,072	949,277	(842,818)	65,535,531
Total Capital Assets at Historical Costs	67,449,239	1,183,819	(1,126,681)	67,506,377
Less Accumulated Depreciation:				
Land Improvements	(1,124,674)	(53,290)	-	(1,177,964)
Buildings	(13,959,651)	(846,131)	-	(14,805,782)
Equipment and Fixtures	(21,364,315)	(1,750,023)	1,126,681	(21,987,657)
Total Accumulated Depreciation	(36,448,640)	(2,649,444)	1,126,681	(37,971,403)
Capital Assets, Net	$ 31,000,599	$ (1,465,625)	$ -	$ 29,534,974

NOTE 6 LONG-TERM DEBT

A schedule of changes in the System's long-term debt are as follows for the years ended September 30:

	Balance September 30, 2017	Additions	Payments	Balance September 30, 2018	Amounts Due Within One Year
Long-Term Debt	$ 15,327,252	$ 5,800,000	$ (665,821)	$ 20,461,431	$ 917,919

	Balance September 30, 2016	Additions	Payments	Balance September 30, 2017	Amounts Due Within One Year
Long-Term Debt	$ 16,078,340	$ -	$ (751,088)	$ 15,327,252	$ 604,073

NOTE 6 LONG-TERM DEBT (CONTINUED)

Long-term debt consists of the following at September 30:

Description	2018	2017
Note payable monthly at 3.97% interest; principal and interest of $11,073 through March 2022; guaranteed by Granville County.	$ 430,231	$ 535,321
Note payable monthly at 4.09% interest; principal and interest of $13,889 through January 2018; collateralized by real estate.	-	69,443
Note payable monthly at 3.73% interest, principal and interest payable semi-annually of $79,324 through July 2027; collateralized by real estate.	1,203,464	1,315,931
Note payable at 1.98% interest, principal and interest payable annually of $105,963 through June 2019; collateralized by equipment.	103,906	205,794
Note payable at 4.22%, principal due annually of $290,000 plus interest through May 2038; collateralized by building and guaranteed by the County.	5,800,000	-
Note payable monthly at 4.00% interest, principal and interest payable monthly of $66,920 through December 2043; collateralized by real estate; guaranteed by Granville County.	12,923,830	13,200,763
Total Long-Term Debt	20,461,431	15,327,252
Less: Current Installments of Long-Term Debt	917,919	604,073
Long-Term Debt, Excluding Current Installments	$ 19,543,512	$ 14,723,179

The future principal and interest payments on long-term debt for the years ending September 30, follows:

Year Ending September 30,	Amount
2019	$ 917,919
2020	834,972
2021	856,768
2022	809,154
2023	764,986
Thereafter	16,277,632
Total	$ 20,461,431

NOTE 7 CAPITAL LEASE OBLIGATIONS

A schedule of changes in the System's capital lease obligations are as follows for the years ended September 30:

	Balance September 30, 2017	Additions	Payments	Balance September 30, 2018	Amounts Due Within One Year
Long-Term Debt	$ 413,197	$ -	$ (213,748)	$ 199,449	$ 169,464

	Balance September 30, 2016	Additions	Payments	Balance September 30, 2017	Amounts Due Within One Year
Long-Term Debt	$ 624,576	$ -	$ (211,379)	$ 413,197	$ 213,714

Capital lease obligations consist of the following at September 30:

Description	2018	2017
Capital lease at 3.92% interest, principal and interest payable monthly of $10,070 through December 2019; collateralized by equipment.	$ 147,148	$ 259,815
Capital lease at 3.7199% interest, principal and interest payable monthly of $4,560 through April 2019; collateralized by equipment.	31,528	83,987
Capital lease at 3.55% interest, principal and interest payable monthly of $4,192 through February 2019; collateralized by equipment.	20,773	69,395
Total Capital Leases	199,449	413,197
Less: Current Installments of Capital Leases	169,464	213,714
Capital Leases, Excluding Current Installments	$ 29,985	$ 199,483

The future principal and interest payments on capital lease obligations for the years ending September 30, follows:

Year Ending September 30,	Principal	Interest
2019	$ 169,464	$ 4,257
2020	29,985	197
Total	$ 199,449	$ 4,454

NOTE 8 LOCAL GOVERNMENTAL EMPLOYEES' RETIREMENT SYSTEM — DEFINED BENEFIT PENSION PLAN

Plan Description

The System is a participating employer of the statewide Local Government Employees' Retirement System (LGERS), a cost-sharing multiple-employer defined benefit pension plan administered by the state of North Carolina. LGERS membership is comprised of general employees and local law enforcement officers (LEO) of participating local government entities. Article 3 of G.S. Chapter 128 assigns the authority to establish and amend benefit provisions to the North Carolina General Assembly. Management of the Plan is vested in the LGERS board of trustees, which consists of 13 members — nine appointed by the Governor, one appointed by the State Senate, one appointed by the State House of Representatives, and the State Treasurer and State Superintendent, who serve as ex-officio members. The LGERS is included in the CAFR for the state of North Carolina. The state's CAFR includes financial statements and required supplementary information for LGERS. That report may be obtained by writing to the Office of the State Controller, 1410 Mail Service Center, Raleigh, North Carolina 27699-1410, or by calling (919) 981-5454, or at www.osc.nc.gov.

Benefits Provided

LGERS provides retirement and survivor benefits. Retirement benefits are determined as 1.85% of the member's average final compensation times the member's years of creditable service. A member's average final compensation is calculated as the average of a member's four highest consecutive years of compensation. Plan members are eligible to retire with full retirement benefits at age 65 with five years of creditable service, at age 60 with 25 years of creditable service, or at any age with 30 years of creditable service. Plan members are eligible to retire with partial retirement benefits at age 50 with 20 years of creditable service or at age 60 with five years of creditable service (age 55 for firefighters). Survivor benefits are available to eligible beneficiaries of members who die while in active service or within 180 days of their last day of service and who have either completed 20 years of creditable service regardless of age (15 years of creditable service for firefighters and rescue squad members who are killed in the line of duty) or have completed five years of service and have reached age 60. Eligible beneficiaries may elect to receive a monthly Survivor's Alternate Benefit for life or a return of the member's contributions. The Plan does not provide for automatic post-retirement benefit increases. Increases are contingent upon actuarial gains of the Plan.

LGERS plan members who are LEOs are eligible to retire with full retirement benefits at age 55 with five years of creditable service as an officer, or at any age with 30 years of creditable service. LEO plan members are eligible to retire with partial retirement benefits at age 50 with 15 years of creditable service as an officer. Survivor benefits are available to eligible beneficiaries of LEO members who die while in active service or within 180 days of their last day of service and who also have either completed 20 years of creditable service regardless of age, or have completed 15 years of service as a LEO and have reached age 50, or have completed five years of creditable service as a LEO and have reached age 55, or have completed 15 years of creditable service as a LEO if killed in the line of duty. Eligible beneficiaries may elect to receive a monthly Survivor's Alternate Benefit for life or a return of the member's contributions. The System has no Plan members who are LEOs.

NOTE 8 LOCAL GOVERNMENTAL EMPLOYEES' RETIREMENT SYSTEM — DEFINED BENEFIT PENSION PLAN (CONTINUED)

Contributions

Contribution provisions are established by General Statute 128-30 and may be amended only by the North Carolina General Assembly. System employees are required to contribute 6.00% of their compensation. Employer contributions are actuarially determined and set annually by the LGERS board of trustees. The System's contractually required contribution rate for the year ended June 30, 2018, was 8.25% of compensation for law enforcement officers and 7.50% for general employees and firefighters, actuarially determined as an amount that, when combined with employee contributions, is expected to finance the costs of benefits earned by employees during the year. Contributions to the pension plan from the System were approximately $1,543,000 for the year ended September 30, 2018.

Refunds of Contributions

System employees who have terminated service as a contributing member of LGERS, may file an application for a refund of their contributions. By state law, refunds to members with at least five years of service include 4% interest. State law requires a 60 day waiting period after service termination before the refund may be paid. The acceptance of a refund payment cancels the individual's right to employer contributions or any other benefit provided by LGERS.

Pension Liabilities, Pension Expense, and Deferred Outflows of Resources and Deferred Inflows of Resources Related to Pensions

At September 30, 2018, the System reported a liability of approximately $7,516,000 for its proportionate share of the net pension liability. The net pension liability was measured as of June 30, 2018. The total pension liability used to calculate the net pension asset was determined by an actuarial valuation as of December 31, 2017. The total pension liability was then rolled forward to the measurement date of June 30, 2018 utilizing update procedures incorporating the actuarial assumptions. The System's proportion of the net pension asset was based on a projection of the System's long-term share of future payroll covered by the pension plan, relative to the projected future payroll covered by the pension plan of all participating LGERS employers, actuarially determined. At September 30, 2018, the System's proportion was 0.31683%, which was a decrease of 0.02199% from its proportion measured as of September 30, 2017.

For the year ended September 30, 2018, the System recognized pension expense of approximately $1,968,000.

NOTE 8 LOCAL GOVERNMENTAL EMPLOYEES' RETIREMENT SYSTEM — DEFINED BENEFIT PENSION PLAN (CONTINUED)

At September 30, 2018, the System reported deferred outflows of resources and deferred inflows of resources related to pensions from the following sources:

	Deferred Outflows of Resources	Deferred Inflows of Resources
Difference Between Expected and Actual Experience	$ 1,159,585	$ 38,910
Changes in Assumptions	1,994,534	-
Net Difference Between Projected and Actual Earnings on Pension Plan Investments	1,031,763	-
Changes in Proportion and Differences Between Hospital Contributions and Proportionate Share of Contributions	-	309,182
Hospital Contributions Subsequent to the Measurement Date	424,030	-
Total	$ 4,609,912	$ 348,092

At September 30, 2017, the System reported deferred outflows of resources and deferred inflows of resources related to pensions from the following sources:

	Deferred Outflows of Resources	Deferred Inflows of Resources
Difference Between Expected and Actual Experience	$ 298,199	$ 146,523
Changes in Assumptions	739,237	-
Net Difference Between Projected and Actual Earnings on Pension Plan Investments	1,256,796	-
Changes in Proportion and Differences Between Hospital Contributions and Proportionate Share of Contributions	14,983	222,323
Hospital Contributions Subsequent to the Measurement Date	422,885	-
Total	$ 2,732,100	$ 368,846

The amount reported in the table above as deferred outflows related to pensions resulting from System contributions subsequent to the measurement date will be recognized as a decrease of the net pension liability in the year ended September 30, 2019. Other amounts reported as deferred inflows related to pensions will be recognized in pension expense as follows:

Year Ending September 30,	Amount
2019	$ 1,883,133
2020	1,228,001
2021	170,741
2022	555,915
Total	$ 3,837,790

NOTE 8 LOCAL GOVERNMENTAL EMPLOYEES' RETIREMENT SYSTEM — DEFINED BENEFIT PENSION PLAN (CONTINUED)

Actuarial Assumptions

The total pension liability in the December 31, 2017 actuarial valuation was determined using the following actuarial assumptions, applied to all periods included in the measurement:

Inflation	3.00%
Salary Increases	3.50% to 8.10% including Inflation and Productivity Factor
Investment Rate of Return	7.00%, Net of Pension Plan Investment Expense, including Inflation

The Plan currently uses mortality tables that vary by age, gender, employee group (i.e. general, law enforcement officer) and health status (i.e. disabled and healthy). The current mortality rates are based on published tables and based on studies that cover significant portions of the U.S. population. The healthy mortality rates also contain a provision to reflect future mortality improvements.

Future ad hoc cost-of-living adjustment amounts are not considered to be substantively automatic and are therefore not included in the measurement.

The projected long-term investment returns and inflation assumptions are developed through review of current and historical capital markets data, sell-side investment research, consultant whitepapers, and historical performance of investment strategies. Fixed income return projections reflect current yields across the U.S. Treasury yield curve and market expectations of forward yields projected and interpolated for multiple tenors and over multiple year horizons. Global public equity return projections are established through analysis of the equity risk premium and the fixed income return projections. Other asset categories and strategies' return projections reflect the foregoing and historical data analysis. These projections are combined to produce the long-term expected rate of return by weighting the expected future real rates of return by the target asset allocation percentage and by adding expected inflation. The target allocation and best estimates of arithmetic real rates of return for each major asset class as of June 30, 2018 are summarized in the following table:

Asset Class	Target Allocation	Long-Term Expected Real Rate of Return
Fixed Income	36.0 %	2.2 %
Global Equity	40.5	5.8
Real Estate	8.0	5.2
Alternatives	6.5	9.8
Credit	4.5	6.8
Inflation Protection	4.5	3.4
Total	100.0	

NOTE 8 LOCAL GOVERNMENTAL EMPLOYEES' RETIREMENT SYSTEM — DEFINED BENEFIT PENSION PLAN (CONTINUED)

Actuarial Assumptions (Continued)

The information above is based on 30 year expectations developed with the consulting actuary for the 2015 asset liability and investment policy study for the North Carolina Retirement Systems, including LGERS. The long-term nominal rates of return underlying the real rates of return are arithmetic annualized figures. The real rates of return are calculated from nominal rates by multiplicatively subtracting a long-term inflation assumption of 3.19%. All rates of return and inflation are annualized.

Discount Rate

The discount rate used to measure the total pension liability was 7.00%. The projection of cash flows used to determine the discount rate assumed that contributions from Plan members will be made at the current contribution rate and that contributions from employers will be made at statutorily required rates, actuarially determined. Based on these assumptions, the pension plan's fiduciary net position was projected to be available to make all projected future benefit payments of the current Plan members. Therefore, the long-term expected rate of return on pension plan investments was applied to all periods of projected benefit payments to determine the total pension liability.

Sensitivity of the System's Proportionate Share of the Net Pension Liability to Changes in the Discount Rate

The following presents the System's proportionate share of the net pension liability calculated using the discount rate of 7.00%, as well as what the System's proportionate share of the net pension liability would be if it were calculated using a discount rate that is one percentage point lower (6.00%) or one percentage point higher (8.00%) than the current rate:

	2018		
	1% Decrease (6.00%)	Discount Rate (7.00%)	1% Increase (8.00%)
Hospital's Proportionate Share of the Net Pension Liability (Asset)	$ 18,054,782	$ 7,516,291	$ (1,289,837)

	2017		
	1% Decrease (6.20%)	Discount Rate (7.20%)	1% Increase (8.20%)
Hospital's Proportionate Share of the Net Pension Liability (Asset)	$ 15,539,163	$ 5,176,231	$ (3,473,545)

Pension Plan Fiduciary Net Position

Detailed information about the pension plan's fiduciary net position is available in the separately issued CAFR for the state of North Carolina.

NOTE 9 OPERATING LEASES

The System leases certain equipment under various lease agreements. These lease terms expire over the next 1 to 34 years, and certain leases contain renewal and/or purchase options. The leases for certain equipment are accounted for as operating leases.

The System has also entered into an operating lease agreement to lease space in a medical office building adjacent to the Hospital. Under the agreement, the System is obligated to pay 180 monthly payments with base rent of $18,866. Each year base rent is increased 3%. There are two renewal options of five years each under the agreement. Currently this space is subleased to several tenants. Rental terms include maturity dates from three to five years with each lease having renewal options to extend the original terms. Rental income under these subleases amounted to approximately $98,000 and $108,000 as of September 30, 2018 and 2017, respectively.

Total rental expense charged to operations amounted to approximately $739,000 and $789,000 for the years ended September 30, 2018 and 2017, respectively. Approximate future minimum rentals for years ending September 30 are as follows:

Year Ending September 30,	Amount
2019	$ 679,528
2020	621,075
2021	573,299
2022	555,429
2023	548,841
Total	$ 2,978,172

NOTE 10 NET PATIENT SERVICE REVENUE

The Hospital's agreements with third-party payors provide for payments to the Hospital at amounts different from its established rates. A summary of the payment arrangements with major third-party payors follows:

Medicare

Inpatient acute care services rendered to Medicare program beneficiaries are paid at prospectively determined rates per discharge. These rates vary according to a patient classification system that is based on clinical, diagnostic, and other factors. Inpatient nonacute services are paid based on a cost and/or prospective payment reimbursement methodology. Reimbursement for outpatient services is under a prospective payment system called the Ambulatory Payment Classification System. Prospective payment rates are established for each group of services provided in hospital outpatient departments for the diagnosis or treatment of beneficiaries. This system categorizes payments according to clinical diagnosis and resource use. Services covered under other Medicare fee schedules are excluded and will continue to be paid using such fee schedules.

NOTE 10 NET PATIENT SERVICE REVENUE (CONTINUED)

Medicaid

Inpatient services rendered to Medicaid program beneficiaries are paid at prospectively determined rates per discharge. These rates vary according to a patient classification system that is based on clinical, diagnostic and other factors. Outpatient services are reimbursed under a cost reimbursement methodology in which the Hospital is reimbursed at a tentative rate with final settlement determined after submission of annual cost reports and audits thereof by Medicaid.

Other

The Hospital has entered into payment agreements with certain commercial insurance carriers, health maintenance organizations, and preferred provider organizations. The basis for payment to the Hospital under these agreements includes prospectively determined rates and discounts from established charges.

Laws and regulations governing the Medicare and Medicaid programs are extremely complex and subject to interpretation. As of September 30, 2018, the Hospital believes that they are in compliance with all applicable laws and regulations and are not aware of any pending or threatened investigations involving allegations of potential wrongdoing. While no such regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation as well as significant regulatory action, including fines, penalties and exclusions from the Medicare and Medicaid programs. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term if Medicare or Medicaid interprets and enforces certain laws and regulations that are not consistent with current activities.

The Hospital is subject to various final settlements determined after submission of annual cost reports and preliminary audits by the Medicare and Medicaid fiscal intermediaries. Classification of patients under the Medicare and Medicaid programs and the appropriateness of their admissions are subject to an independent review by a peer review organization. As of September 30, 2018, audit or desk reviews of Medicare cost reports through 2015 and Medicaid cost reports through 2014 have been completed. Net patient service revenue increased approximately $57,000 and $1,380,000 for the years ended September 30, 2018 and 2017, respectively, due to prior year retroactive settlements differing from amounts previously estimated.

The Hospital participates in a voluntary Medicaid Reimbursement Initiative (the Initiative), which allows the Hospital to receive additional annual Medicaid funding. The Hospital has reserved a portion of funds received under the Initiative for the year ended September 30, 2018, as a final settlement for this year has yet to be reached. Amounts received, recognized as revenue, and reserved under the Initiative for years that are yet to be final settled are set forth in the following table. Reserved balances are included with estimated third-party payor settlements in the combined statements of net position.

NOTE 10 NET PATIENT SERVICE REVENUE (CONTINUED)

Program Year	Received/ Accrued	Amounts Recognized 2018	Amounts Recognized 2017	Amounts Reserved September 30, 2018	Amounts Reserved September 30, 2017
2011	$ 1,378,423	$ -	$ -	$ -	$ -
2012	1,105,934	-	-	-	-
2013	907,726	-	-	-	-
2014	1,154,378	-	-	-	-
2015	1,136,445	-	86,444	-	-
2016	1,719,164	-	485,347	-	-
2017	1,645,069	-	1,300,000	345,069	345,069
2018	1,807,951	1,518,798	-	634,222	-
Total	$ 10,855,090	$ 1,518,798	$ 1,871,791	$ 979,291	$ 345,069

The Initiative was amended in 2012 to provide additional funds to cover a portion of the unreimbursed costs of treating uninsured patients. This amended funding plan is referred to as the GAP Plan. The GAP Plan requires hospitals to pay assessments into a state fund as a condition to receive the additional funds. The state submitted the GAP Plan to Centers for Medicare and Medicaid Services (CMS) for approval in January 2010. It was approved in April 2012, retroactive to the submission date of January 2010.

The funds received under the GAP Plan are included in net patient service revenue, and the assessments paid are included in other operating expenses in the accompanying statements of revenues, expenses, and changes in net position.

During the years ended September 30, 2018 and 2017, the Hospital received funds under the GAP Plan totaling approximately $400,000 and $601,000, respectively, and paid assessments of approximately of $477,000 and $692,000, respectively.

NOTE 11 RELATED PARTY TRANSACTIONS

Granville County

Included in other operating revenues for years ended 2018 and 2017 are County contributions to the Hospital for operating purposes as follows:

	2018	2017
Indigent Care	$ 214,495	$ 214,495
Operations	61,800	50,000
Total	$ 276,295	$ 264,495

For both the years ended September 30, 2018 and 2017, the County contributed approximately $133,000 of capital grants and contributions to the System. These amounts are reflected in the combined statements of revenues, expenses, and changes in net position as capital grants and contributions.

NOTE 11 RELATED PARTY TRANSACTIONS (CONTINUED)

Granville County (Continued)

During the year ended September 30, 2010, Granville County transferred Granville County's Emergency Medical Services division of the Department of Emergency Services (EMS) to the System. Through the transfer, all personal property, including equipment, inventory, licenses, contracts and other assets was assumed by the System. Additionally, the County will provide annual payments to the System. For the years ended September 30, 2018 and 2017, payments from the County totaled approximately $575,000 and $437,500, respectively, and are included in operating revenues in the combined statement of revenues, expenses and changes in net position.

Granville Health System Foundation

As described in Note 1, the Hospital is the sole beneficiary of the Foundation. At September 30, 2018 and 2017, the Foundation held approximately $183,000 and $197,000, respectively, in assets. These assets are not reported in the accompanying combined financial statements of the System since they are immaterial to the System's combined financial statements. The Foundation contributed approximately $150,000 and $151,000 to the System for the years ended September 30, 2018 and 2017, respectively.

NOTE 12 OTHER EMPLOYMENT BENEFITS

The System has elected to provide death benefits to employees through the Death Benefit Plan for members of the LGERS (Death Benefit Plan), a multiple-employer, state-administered, cost-sharing plan funded on a one- year term cost basis. The beneficiaries of those employees who die in active service after one year of contributing membership in the Death Benefit Plan, or who die within 180 days after retirement or termination of service and have at least one year of contributing membership service in the Death Benefit Plan at the time of death, are eligible for death benefits. Lump sum death benefit payments to beneficiaries are equal to the employee's 12 highest months' salary in a row during the 24 months prior to the employee's death, but the benefit may not exceed $50,000 or be less than $25,000. Because all benefit payments are made by the Death Benefit Plan and not by the System, the System does not determine the number of eligible participants. The System has no liability beyond the payment of monthly contributions. The contributions to the Death Benefit Plan cannot be separated between the postemployment benefit amount and the other benefit amount. Contributions are determined as a percentage of monthly payroll based upon rates established annually by the state. The System considers these contributions to be immaterial.

Other Benefits

The System also has a retirement savings plan under Section 403(b) of the IRC which is available to employees of the Corporation. Employee contributions are made through payroll deductions authorized by the employee. The Corporation matches 50% of qualifying employees' contributions up to 6% of employee compensation. The Corporation's contributions to the 403(b) retirement savings plan for the years ended September 30, 2018 and 2017 totaled approximately $112,000 and $98,000, respectively.

NOTE 12 OTHER EMPLOYMENT BENEFITS (CONTINUED)

Other Benefits (Continued)

Employees may also make elective contributions to a 457(b) tax deferred savings plan, which are subject to governmental limitations.

NOTE 13 MANAGEMENT CONTRACTS

The System has a contract with an outside organization to manage and operate the nutrition services for the System. Management fees, staff salaries, and food costs paid for the years ended September 30, 2018 and 2017 were approximately $1,491,805, and $1,515,000, respectively. The fee for these services is adjusted annually, not to exceed the current Consumer Price Index. The agreement expires October 31, 2022.

NOTE 14 SELF-INSURANCE PROGRAM

The System provides medical benefits to its employees under a self-insurance program. Under the program, all employees who work over 30 hours per week are eligible to participate. All eligible employees have the option to elect dependent coverage. The System contracts with an outside entity to administer the program and pay related claims on behalf of the System. The System maintains aggregate and individual stop-loss coverage, which provides reimbursement of claims paid by the System in excess of specified levels. Employee health and welfare expenses for the years ended September 30, 2018 and 2017 were approximately $3,491,000, and $3,143,000, respectively, which relate to the cost of this program, including claims, administrative fees and cost of related stop-loss coverage.

At September 30, 2018 and 2017, the System had accrued liabilities of approximately $399,000 and $203,000, respectively, representing actual and estimated claims incurred, but not reported related to this program. The System also records stop-loss receivables from an outside insurance provider for claims in excess of $115,000, which is included with other receivables in the combined statements of net position. The System did not record any stop-loss receivables at September 30, 2018 and 2017.

NOTE 15 PROFESSIONAL LIABILITY COVERAGE

The System is involved in litigation in the ordinary course of business related to professional liability claims. Management believes all claims will be settled within the limits of insurance coverage. Other claims may be asserted arising from past services provided through September 30, 2018. Management believes these claims, if asserted, would be settled within the limits of insurance coverage. The System's medical malpractice coverage is on an occurrence basis with insurance limits of $1,000,000 per claim and $3,000,000 in the aggregate. The System also has an occurrence based umbrella policy of $10,000,000.

NOTE 16 CONCENTRATION OF CREDIT RISK

In the course of providing healthcare through its inpatient and outpatient care facilities, the System grants credit to patients and generally does not require collateral or other security in extending credit; however, it routinely obtains assignment of (or is otherwise entitled to receive) patient benefits under their health insurance programs, plans or policies (e.g. Medicare, Medicaid, Blue Cross, health maintenance organizations, preferred provider organizations, and commercial insurance policies). For both the years ended September 30, 2018 and 2017, approximately 60% of the System's gross patient service revenue was derived from the federal Medicare program or the North Carolina Medicaid program.

The System is located in Oxford, North Carolina. The System grants credit without collateral to its patients, most of who are local residents and are insured under third-party payor agreements. The mix of receivables from patients and third-party payors was as follows:

	2018	2017
Medicare	13 %	12 %
Medicaid	10	12
Blue Cross	6	3
Other Third-Party Payors	22	9
Patients	49	64
Total	100 %	100 %

NOTE 17 RESTRICTED NET POSITION

Restricted net position consists of grants and contributions received to fund various community projects and programs sponsored by the System. These amounts are to be released as expenses are incurred or after a pre-determined time period as set by the donor. At September 30, 2018 and 2017, the System had restricted net position of approximately $48,000 and $58,000, respectively.

NOTE 18 GOODWILL

Goodwill represents the cost of purchased healthcare entities in excess of the fair value of net position acquired. Such amounts are considered for impairment based on the expected net present value of future cash flows of the practices. In June 2008, the System entered into an agreement to purchase South Granville Primary Care, PA, which resulted in a total cost of approximately $1,000,000 and goodwill of $400,000. In August 2009, the System entered into an agreement to purchase Granville Internal Medicine and Geriatrics, which resulted in a total cost of approximately $653,000 and goodwill of $440,000. As of September 30, 2018 and 2017, total goodwill had a carrying amount of approximately $-0- and $6,000, respectively. Impairment of approximately $6,000 and $90,000 was recorded for the years ended September 30, 2018 and 2017, respectively.

NOTE 19 COMMITMENTS AND CONTINGENCIES

In November 2018, the System disclosed two circumstances under the Centers for Medicare and Medicaid Services Voluntary Self-Disclosure Protocol. Management is not yet able to estimate any potential payback related to these disclosures. As such no reserves have been recorded related to this issue as of September 30, 2018.

NOTE 20 CONDENSED COMBINING FINANCIAL INFORMATION

Following is the condensed combining statement of net position as of September 30, 2018, and the related condensed combining statements of revenues, expenses, and changes in net position, and cash flows for the material affiliates of the System as of and for the year ended September 30, 2018:

	Granville Health System	Granville Health, Inc.	Eliminations	Total
Total Current Assets	$ 51,764,187	$ 3,982	$ (37,457,972)	$ 14,310,197
Assets Limited as to Use:				
By Board for Capital Improvements	4,398,057	-	-	4,398,057
Total Capital Assets, Net of Accumulated Depreciation	29,372,478	-	-	29,372,478
Other Assets, Net	6,013,436	-	-	6,013,436
Deferred Outflow of Resources	4,609,912	-	-	4,609,912
Total Assets and Deferred Outflows	$ 96,158,070	$ 3,982	$ (37,457,972)	$ 58,704,080
Total Current Liabilities	$ 10,608,025	$ 37,607,329	$ (37,457,972)	$ 10,757,382
Long-Term Debt, Excluding Current Portion	19,543,512	-	-	19,543,512
Net Pension Liability	7,516,291	-	-	7,516,291
Capital Lease Obligations, Less Current Maturities	29,985	-	-	29,985
Pension Deferrals	348,092	-	-	348,092
Total Liabilities and Deferred Inflows	38,045,905	37,607,329	(37,457,972)	38,195,262
Total Net Position	58,112,165	(37,603,347)	-	20,508,818
Total Liabilities, Deferred Inflows, and Net Position	$ 96,158,070	$ 3,982	$ (37,457,972)	$ 58,704,080

NOTE 20 CONDENSED COMBINING FINANCIAL INFORMATION (CONTINUED)

	Granville Health System	Granville Health, Inc.	Eliminations	Total
Total Operating Revenues	$ 62,348,466	$ -	$ -	$ 62,348,466
Operating Expenses:				
Depreciation	2,631,411	-	-	2,631,411
Other Operating Expenses	56,629,793	5,733,826	-	62,363,619
Total Operating Expenses	59,261,204	5,733,826	-	64,995,030
Income (Loss) from Operations	3,087,262	(5,733,826)	-	(2,646,564)
Nonoperating Revenue	290,539	-	-	290,539
Excess (Deficit) of Revenues over Expenses before Capital Grants and Contributions	3,377,801	(5,733,826)	-	(2,356,025)
Capital Grants and Contributions	132,874	-	-	132,874
Increase (Decrease) in Net Position	$ 3,510,675	$ (5,733,826)	$ -	$ (2,223,151)

	Granville Health System	Granville Health, Inc.	Eliminations	Total
Cash Flows:				
Operating Activities	$ (4,099,552)	$ (193)	$ -	$ (4,099,745)
Noncapital Financing Activities	251,659	-	-	251,659
Capital and Related Financing Activities	2,584,390	-	-	2,584,390
Investing Activities	2,357,480	-	-	2,357,480
Change in Cash and Cash Equivalents	1,093,977	(193)	-	1,093,784
Cash and Cash Equivalents - Beginning of Year	662,617	4,175	-	666,792
Cash and Cash Equivalents - End of Year	$ 1,756,594	$ 3,982	$ -	$ 1,760,576

REQUIRED SUPPLEMENTARY INFORMATION

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
PROPORTIONATE SHARE OF NET PENSION LIABAILITY
LAST THREE FISCAL YEARS*

	2018	2017	2016
Hospital's Proportion of Net Pension Liability (%)	0.32 %	0.34 %	0.35 %
Hospital's Proportion of Net Pension Liability ($)	$ 7,516,291	$ 5,176,231	$ 7,324,813
Hospital's Covered Payroll	$ 20,440,428	$ 20,785,497	$ 21,123,955
Hospital's Proportion of Net Pension Liability (%) as a Percentage of Covered Payroll	36.77 %	24.90 %	34.68 %
Plan Fiduciary Net Position as a Percentage of the Total Pension Liability **	91.63 %	94.18 %	91.47 %

* Amounts presented for each fiscal year were determined as of the state fiscal year ending June 30.

** This will be the same percentage for all participant employers in the LGERS plan.

Additional years will be accumulated as the data becomes available.

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
PENSION CONTRIBUTIONS
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017	2016
Contractually Required Contribution	$ 1,542,748	$ 1,503,395	$ 1,473,222
Contributions in Relation to Contractually Required Contribution	1,542,748	1,503,395	1,473,222
Contribution Deficiency (Excess)	$ -	$ -	$ -
Hospital's Covered Payroll	$ 20,440,428	$ 20,785,497	$ 21,123,955
Contributions as a Percentage of Covered Payroll	7.55 %	7.23 %	6.97 %

Additional years will be accumulated as the data becomes available.

SUPPLEMENTARY INFORMATION

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED SCHEDULES OF NET PATIENT SERVICE REVENUE
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
INPATIENT SERVICE REVENUE		
Daily Patient Services, Room, and General:		
Routine Services	$ 3,643,381	$ 3,449,678
Emergency Services	2,616,630	2,511,052
Brantwood Nursing Care	5,344,803	5,481,716
Subtotal	11,604,814	11,442,446
Special Medical Services:		
Hospitalist	1,520,874	1,457,694
CT Scanner	2,609,794	2,402,654
Medical and Surgical Supply	6,371,736	5,803,998
Operating and Recovery Room	3,895,025	3,144,706
Delivery Room	596,773	595,474
Radiology	583,571	453,742
MRI	2,614,913	261,546
Anesthesiology	398,209	2,046,321
Laboratory	3,660,177	3,414,566
Pharmacy	6,101,874	6,163,943
Intravenous Therapy	707,689	639,605
Physical, Occupational, and Speech Therapy	437,336	366,575
Inhalation Therapy	724,792	757,629
Electrocardiology	108,287	105,809
Nuclear Medicine	36,854	77,525
Blood Bank	339,625	456,885
Ultrasound	794,226	725,136
Oncology	264,787	231,540
Subtotal	31,766,542	29,105,348
Total Gross Inpatient Service Revenue	43,371,356	40,547,794

GRANVILLE HEALTH SYSTEM AND AFFILIATE AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED SCHEDULES OF NET PATIENT SERVICE REVENUE (CONTINUED)
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
OUTPATIENT SERVICE REVENUE		
Daily Patient Services, Room, and General:		
Emergency Services	$ 27,483,091	$ 28,389,763
Granville Surgical Associates	2,179,522	1,894,795
South Granville Medical Center	325,448	469,757
South Granville Primary Care	2,526,236	2,098,732
Granville Internal Medicine	2,750,156	2,577,479
Granville Urology	1,886,334	2,168,588
Gastroenterology	189,154	-
Subtotal	37,339,941	37,599,114
Special Medical Services:		
CT Scanner	15,347,216	14,762,933
Medical and Surgical Supply	7,370,488	7,239,311
Operating and Recovery Room	10,043,290	8,848,401
Delivery Room	326,574	321,992
Radiology	3,900,843	3,679,962
MRI	1,986,428	2,203,825
Anesthesiology	5,547,585	4,743,741
Laboratory	12,211,633	11,450,781
Sleep Lab	323,588	362,936
Pharmacy	7,328,615	6,942,876
Intravenous Therapy	712,787	707,883
Physical, Occupational, and Speech Therapy	375,963	109,614
Inhalation Therapy	153,656	193,822
Electrocardiology	744,516	774,348
Nuclear Medicine	892,234	989,239
Blood Bank	182,455	210,794
Ultrasound	3,598,088	3,485,949
CAP	131,790	167,160
Cardiology	1,672,062	1,683,302
Behavioral Health	2,165,184	1,715,272
Other	193,422	179,243
Subtotal	75,208,417	70,773,384
Total Gross Outpatient Service Revenue	112,548,358	108,372,498
Total Gross Patient Service Revenue	155,919,714	148,920,292
Less: Charity Care	1,857,900	1,986,375
GROSS PATIENT SERVICE REVENUE	154,061,814	146,933,917

GRANVILLE HEALTH SYSTEM AND AFFILIATE AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED SCHEDULES OF NET PATIENT SERVICE REVENUE (CONTINUED)
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
Less: Contractual Adjustments		
Hospital:		
Medicare	$ 41,173,739	$ 43,079,739
Medicaid	18,868,636	16,257,127
Other	18,360,486	17,908,730
Subtotal	78,402,861	77,245,596
Nursing Home:		
Medicare	267,683	197,503
Medicaid	216,884	274,424
Subtotal	484,567	471,927
Total Contractual Adjustments	78,887,428	77,717,523
Less: Provision for Bad Debt	15,993,389	14,364,685
NET PATIENT SERVICE REVENUE	$ 59,180,997	$ 54,851,709

GRANVILLE HEALTH SYSTEM AND AFFILIATE
(A COMPONENT UNIT OF GRANVILLE COUNTY)
COMBINED SCHEDULES OF OTHER OPERATING REVENUE
YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
OTHER OPERATING REVENUE		
Sale of Drugs and Supplies to Employees	$ -	$ 12,470
Other Rental Income	40,637	36,343
Management Fees	8,621	8,249
Physician Office Rental Income	57,606	71,746
Contributions from Granville County	276,295	264,495
Pharmacy Management	1,625,512	1,399,249
Miscellaneous, Net	583,798	142,582
Total	$ 2,592,469	$ 1,935,134

Attachment 2

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: April 13, 2007
PROJECT ANALYST: Helen E. Alexander
SECTION CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: L-7771-06 Halifax Gastroenterology, P.C. d/b/a Prashanti Endoscopy Center / Develop a new ambulatory surgical facility with two gastrointestinal endoscopy rooms / Halifax 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

There are no policies or need determinations in the 2006 State Medical Facilities Plan applicable to the review of applications for gastrointestinal endoscopy rooms. Therefore, this criterion is not applicable in this review.

(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.

NC

Halifax Gastroenterology, P.C. d/b/a Prashanti Endoscopy Center (PEC) proposes development of a new ambulatory surgical facility with two gastrointestinal ("GI")

endoscopy rooms for a single specialty gastroenterology practice in Roanoke Rapids. Prashanti, L.L.C. owns the land and building that will house the proposed ambulatory surgical facility and the physician practice. PEC proposes to lease approximately 3,444 square feet of space from Prashanti, L.L.C. for the new ambulatory surgical facility, which will be located at 1007 Gregory Drive, Roanoke Rapids. The sole owner of Halifax Gastroenterology, P.C. is Dr. Nagarjuna Yerra. Prashanti, LLC is owned equally by Dr. Nagarjuna Yerra and Padma Yerra.

In Section I., page 3, the applicant stated "*The proposed GI endoscopy facility will begin operation in November 2006."* Therefore, construction on the building and the two gastrointestinal endoscopy rooms was almost complete at the time the application was submitted. In Section II., page 9, the applicant states:

> *"At the* present *time, Dr. Yerra only performs GI endoscopy procedures at Halifax Regional Medical, the area hospital and licensed facility."*

Population to be served

In Section III. 6, the applicant identifies Halifax and Northampton Counties as its primary service area and Warren County, Hertford County, Greenville County, Virginia, and Brunswick County, Virginia as the secondary service area. On page 13, the applicant states the number of patients to be served in the GI endoscopy room as follows:

> "*The number of patients projected to be served in the first three (3) years of the proposed project is approximately 15% less than the number of procedures to be performed:*
>
> *Year #1: 1,530*
> *Year #2: 1,785*
> *Year #3: 2,040"*

In Section III.7, page 43 of the application, the applicant identified the population to be served by the proposed facility in the first three years of operation following completion of the project as shown in the following table:

County	Projected Number of *Patients [sic] YR 1 (6/07-5/08)	Projected Number of *Patients [sic] YR 2 (6/08-5/09)	Projected Number of *Patients [sic] YR 3 (6/09-5/10)	Percent of Total *Patients [sic]
Halifax	1,156	1,348	1,541	64.2%
Northampton	472	550	629	26.2%
Warren	41	48	55	2.3%
Hertford	38	44	50	2.1%
Greensville, VA	34	40	46	1.9%
Brunswick, VA	31	36	41	1.7%
Other	29	34	38	1.6%
Total	**1,800**	**2,100**	**2,400**	**100%**

*These numbers are the applicant's projections of procedures to be performed as stated In Section IV and the rest of the application.

In the above table the applicant incorrectly refers to its projections of the number of procedures to be performed, as patients. In the rest of the application the applicant

correctly refers to these numbers as projected procedures. Regardless, the applicant adequately identified the population proposed to be served.

Need for the Proposed Service

In Section IV.2, pages 46-47 of the application, the applicant provides three tables showing the projected number of GI endoscopy procedures to be performed in the proposed facility in the first three years of operation following completion of the project, which is summarized below.

Project Year	Procedures
YR 1 (6/07-5/08)	1,800
YR 2 (6/08-5/09)	2,100
YR 3 (6/09-5/10)	2,400

In Section II., page 29, the applicant provided the following assumptions for the stated projections:

1. *"The average number of GI endoscopy cases performed per hour by a gastroenterologist is 2. The actual performance is likely to be in excess of 2.50.*
2. *The proposed GI endoscopy facility will have two (2) procedure schedules. One schedule will have one (1) gastroenterologist working out of one (1) procedure room. The other schedule will have one (1) gastroenterologist working out of two (2) procedure rooms. It is assumed that Halifax Gastroenterology, P. C. will recruit a second gastroenterologist to join the practice within the next year to meet patient demand and unmet medical need.*
3. *The GI endoscopy facility will operate at least eight (8) hours per day with procedures being performed within six (6) hour periods.*
4. *Depending on the physician schedule used (as outlined in point #2 above), the number of procedures performed per room per year will have a minimum level of 1,500 GI endoscopy procedures per procedure room (250 days x 6 hours per day x 2.5 procedures per hour = 3,750 procedures) when a second gastroenterologist is recruited by Halifax Gastroenterology, P.C. The six (6) hour assumption for procedure performance in an eight (8) hour work day takes into (1) account facility set-up and maintenance time required to support safe and high quality patient care and (2) a solo gastroenterologist at this time must also make time for hospital-based procedures, outpatient office visits, and inpatient consultations. . .*
5. *The actual projected volume for the proposed GI endoscopy facility is . . . [1,800 in Year 1, 2,100 in Year 2, and 2,400 in Year 3]. Given unmet patient demand and medical need, it is likely that the proposed GI endoscopy facility will exceed these projected volume estimates."*

Thus, the applicant based its projections on the number of procedures a gastroenterologist is capable of performing, rather than on the number of procedures needed by the population proposed to be served. Further, the applicant states there is "*unmet patient demand and medical need*" but does provide adequate documentation to support the population's need for the number of endoscopy procedures it proposes to provide. Therefore, the applicant does not demonstrate that the projected number of persons to be served is reasonable.

The applicant's reasons for development of the facility are discussed below. In Section III.1 of the application, pages 37-40 of the application, the applicant states the need for the gastrointestinal endoscopy facility in Halifax County as follows:

> *"With proper and timely screening via GI endoscopy, the mortality rate from colo-rectal and other GI related cancers can be greatly reduced.*
>
> *As further background, colo-rectal cancer is the most preventable cancer in America. It is the second highest cancer killer in America, and currently only 30-40% of North Carolina citizens appropriate for colo-rectal cancer screening undergo any type of screening including colonoscopy and fecal occult blood tests. . .*
>
> *We expect demand to increase to at least 50% of the population choosing screening colonoscopy within the next few years based upon similar experience in states like Virginia, where public and physician awareness increased significantly due to publicity campaigns begun in 2000. . .*
>
> *Given the low GI physician to population ratio in our region, we feel that a physician office-based GI endoscopy facility is critical to future GI physician recruiting success."*

In Section III. 1. (b), pages 38-40 and Section II. pages 22-26, the applicant discusses the following factors to substantiate the need for the facility:

- Population and Gastroenterologist Ratios;
- Colo-Rectal Cancer Endoscopy Screening Demand/Need Analysis;
- Migration of GI Endoscopy Procedures Out of Hospital Facility Setting; and
- Population and Gastroenterologist Ratios.

In Exhibit 17, PEC provided Blue Cross Blue Shield's handouts for Office Endoscopy presented to the Endoscopy Workgroup on January 28, 2005. This presentation compared the member cost sharing for Upper and Lower GI Endoscopies performed in office surgery, freestanding ambulatory surgical facilities, and hospitals (outpatients only). The report shows costs for hospital outpatient for

Upper and Lower GI Endoscopy procedures were higher than the costs for these procedures in freestanding ambulatory surgical facilities. The applicant stated:

> *"A number of private health insurance plans, including the majority of health plans administered by Blue Cross Blue Shield of North Carolina ("BCBSNC"), treat GI endoscopy procedures performed within a physician office as a part of a physician office visit.*
>
> *The resulting cost to patients under most BCBSNC health plan benefits is a specialty physician office co-payment. This specialty physician office co-payment may be as low as $30. Therefore, the total out-of pocket cost to a patient is limited to this co-payment amount. If the same GI endoscopy procedure is performed in a hospital or free standing ASC facility setting, the patient's out-of-pocket cost is calculated as the deductible plus co-insurance. For patients with high deductible health plan policies, the out-of-pocket cost to patients can be well over $1,000 for GI endoscopy procedures performed in hospital and free standing ASC facility settings."*

The CON Section is aware that some existing licensed ambulatory surgical facilities have negotiated with BCBS to bill their endoscopy procedures as being performed in a physician office in order for patients to pay a lower co-payment. However, the applicant did not provide any evidence in its application that BCBS would approve its proposed licensed ambulatory surgical facility to bill its procedures in this manner. Therefore, the applicant failed to adequately demonstrate in its application that the out-of-pocket costs to the patient served in its proposed ambulatory surgical facility will be the same amount as the patient pays in an unlicensed physician's office.

In Section III. 9., page 44, the applicant states the following reasons for constructing a GI endoscopy facility:

> *"1. Need to provide more affordable GI endoscopy procedures to patients;*
>
> *2. Need to protect the economic viability and financial interest of the practice given expanded competition from other newly developed physician office based GI endoscopy facilities being promoted by insurance payers such as BCBSNC;*
>
> *3. Need to increase procedure volume through increased operational efficiency; and*
>
> *4. Support of gastroenterologist physician recruitment to better meet the medical service needs of the region."*

In Section III., page 39, PEC provided the information in the following table as a reason for development of the proposed facility.

County	GI Physicians	2005 Population	Est. Over 50 population	Est. Current Endo Screening	Patients Needing Endo Screening
Halifax	1	56,023	20,729	15%	17,619
Northampton	0	21,483	7,949	15%	6,756
Warren	0	19,729	7,300	15%	6,205
Hertford	0	23,574	8,722	15%	7,414
Brunswick, VA	0	17,920	6,630	15%	5,636
Greensville, VA	1	11,088	4,103	15%	3,487
Total	**2**	**149,817***	**55,433***		**47,117**

*Mathematical calculation corrected by Project Analyst

However, PEC did not identify the source of the population data used in the above statements or provide the specific population data obtained from this source to substantiate its assumptions. Specifically, the population data is not consistent with the North Carolina Demographic Office's projected July 1, 2006 County Total Age Groups-Standard, updated of June 12, 2006. According to the Demographic Office's projections the 2006 projected population over 50 in Halifax County is 19,268, which is 7.6% less than the applicant's projection of 20,729 Halifax residents.

Additionally, no source is cited for the applicant's statement in Section III., page 38 that

> "*The current colo-rectal cancer screening level (rate attained) via endoscopy is estimated to be 15% of the over fifty (50) population in Halifax Gastroenterology, P.C.'s primary and secondary patient service areas."*

Specifically, the applicant failed to document or provide any data in the application to support the assertion that only 15% of the population over 50 in the proposed service area is screened for colo-rectal cancer via endoscopy at the present time. Further, the applicant offers no evidence to support its resulting conclusion that 85% of the over 50 population need an endoscopy procedure as opposed to one of the other available types of screening tests for colo-rectal cancer, such as a fecal occult blood stool test. Also, on page 38, the applicant states the clinical objective for endoscopy screening is 75%. However, its calculations in the table on page 39 show its demand analysis is based on 100% (15% plus 85%) of the over 50 population receiving an endoscopy procedure. In comparison, the American Cancer Society goal is that 75% of adults older than age 50 will have had a recent colo-rectal cancer screening test by 2015, which includes any of the types of screening tests, not just endoscopy. Additionally, materials published by the American Cancer Society indicate, if a colonoscopy is the type of screening test selected by the

patient as opposed to one of the other types of screening tests, then an average risk individual, 50 years of age or older, should receive a colonoscopy only every ten years unless they have a positive test result.

In addition, Exhibit 18 includes a publication which states,

"The colorectal cancer screening measure, new for HEDIS 2004, estimates the percentage of adults 50-80 years of age who have had appropriate screening for colorectal cancer. The screening criteria can be met with anyone of four tests: a fecal occult blood test (FOST) during the measurement year; a flexible sigmoidoscopy within the last five years; a double contrast barium enema within the last five years; or a colonoscopy within the last ten years."

Thus, the applicant's analysis and projections regarding endoscopy services artificially inflate demand for the proposed services and are unsupported and unreliable.

Further, in the applicant's defined North Carolina service area, there are two existing facilities with GI endoscopy rooms, Halifax Regional Medical Center in Halifax County and Roanoke-Chowan Hospital in Hertford County. The following table demonstrates the historical GI endoscopy procedures performed at these facilities as reported on the hospital license renewal applications:

Halifax Regional Medical Center					
Year	**# GI Endoscopy Rooms**	**Inpatient procedures**	**Outpatient procedures**	**Total procedures**	**Procedure/Room**
FY 2003	1	584	1,352	1,936	1,936
FY 2004	1	614	1,233	1,847	1,847
FY 2005	1	469	1,208	1,677	1,677
FY 2006	1	588	1,714	2,302	2,302
Roanoke-Chowan Hospital					
FY 2003	1	335	893	1,228	1,228
FY 2004	1	374	1,034	1,408	1,408
FY 2005	1	409	1,126	1,535	1,535
FY 2006	1	366	806	1,172*	1,172

*2007 License Renewal Application records 1,366 total procedures.

As shown above, the historical number of procedures reported by Halifax Regional Medical Center does not demonstrate a growth trend in demand for the procedures given that the number of procedures increased in only one of the last four years. It should be noted that Dr. Yerra and Halifax Regional Medical Center disagree on the number of procedures performed at the hospital. In Section II., pages 19-20, the applicant states it performed 2,425 GI endoscopy procedures at Halifax Regional Medical Center from October 1, 2005 to September 30, 2006 and did not perform GI endoscopy procedures in any other existing health service facility in the last 12 months. However, the applicant states on page 21 of the application that it performed 2,346 procedures in the last year. Thus, the applicant made inconsistent

statements about the number of procedures it performed. However, the number of procedures performed at the hospital is not the basis on which the following conclusions regarding the application were made.

In particular, the applicant failed to demonstrate in its application that the development of an ambulatory surgical facility for the performance of GI endoscopy procedures would significantly increase the number of endoscopy procedures performed. For example, the applicant projects an increase of approximately 17% from Year 1 to Year 2 (*1,800 procedures x 1.17 = 2,106 procedures*) and 14% from Year 2 to Year 3 (*2,100 procedures x 1.14 = 2,394 procedures*), but does not provide the statistical assumptions on which this projected growth is based. Specifically, in Section IV. 2 (b) of the application, the applicant is required to "*Provide all assumptions made and the methodology used for the projection."* However, the applicant provided no response to this question. Therefore, the applicant failed to provide the information necessary to demonstrate that the assumptions and methodology used to project utilization were reasonable.

Also, if the majority of the projected number of outpatients receive services at the proposed facility rather than the hospital, the GI endoscopy procedures performed at the hospital are likely to be less than 1,500 GI endoscopy procedures per room. The applicant did not adequately demonstrate the need for two GI endoscopy rooms in addition to the one existing GI endoscopy room at Halifax Regional Medical Center.

In Section II., page 28, in response to 10A NCAC 14C .3903(b), the applicant states

> *"The proposed GI endoscopy facility will have two (2) procedure rooms. The proposed GI endoscopy facility projects to perform the following number of procedures in the next three (3) years as calculated by CPT code:*
>
> *Year #1: 1,800*
> *Year #2: 2,100*
> *Year #3: 2,400"*

However, in accordance with 10A NCAC 14C .3903(b), the applicant must project to perform 1,500 GI endoscopy procedures **per proposed room** in the **second operating year** of the project. This rule requires the applicant to project performance of 3,000 procedures in the second operating year if the applicant proposes to develop two GI endoscopy rooms. However, in the second operating year of the project, the applicant estimates it will perform only 2,100 GI endoscopy procedures in the two rooms, which is less than 1,500 procedures per room (*2,100 procedures / 2 rooms =1,050 per room).* Consequently, based on the applicant's own projections, the application on its face does not adequately demonstrate the need for two GI endoscopy rooms.

In summary, the applicant did not adequately demonstrate the need the population to be served has for the proposed endoscopy rooms. Therefore, the application is nonconforming 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.

NC

In Section III. 9., pages 44-45, PEC discusses the alternatives that were considered in development of the proposed facility. However, the application is not conforming to all applicable statutory and regulatory review criteria. See discussion in Criteria 3, 5, 6, 7, 8, 12, 18a and "*Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities*." The applicant failed to adequately demonstrate that its proposal is an effective alternative and, therefore, is nonconforming with this criterion. Consequently, the application is disapproved.

(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.

NC

In Section VIII., the applicant provides the capital costs for Prashanti, LLC (Lessor) and Halifax Gastroenterology, P.C. (Lessee). The following table summarizes the capital cost allocated to the two entities.

Category	**Prashanti, LLC (Lessor)**	**Halifax Gastroenterology, P.C. (Lessee)**
Land purchase	$132,000	
Legal fees and closing cost	$7,111	
Survey & Subsoil Investigation	$2,500	
Site preparation costs	$161,000	
Construction Contract	$934,777	
Equipment/Furniture		$361,000
Landscaping	$20,000	
Architect and Engineering Fees	$74,782	
Consultant Fees		$24,000

Financing Costs	$5,000	$1,000
Interest During Construction	$10,405	
Total	**$1,347,575**	**$386,000**

The following table shows the amount and source of funds for each entity as stated by the applicant on pages 72-74, 78-79, and 83:

	Prashanti, LLC	**Halifax Gastroenterology, P.C.**
Stated Capital Need	$1,347,575	$386,000
Bank Loan	$1,000,000*	$361,000
Owner's Reserves	$347,575*	
Cash Reserves		$25,000
Total Capital Cost	**$1,347,575**	**$386,000**
Start-up capital		$15,000
Initial Operating Expense		$60,436
Total Working Capital		**$75,436**
Documentation		
Exhibit 34 First Citizen Loan	$1,000,000	
Exhibit 35-Capital Reserve for Dr. and Mrs. Yerra	$347,575	
Exhibit 40-Line of Credit for equipment		$450,000
Exhibit 42-Cash Reserves of Halifax Gastroenterology, P.C.		$25,000 and $75,436

*Application page 74

In Section IX.1., page 83 of the application, the applicant projects that there will be start-up expenses of $15,000 and initial operating expenses of $60,436, for total working capital requirements of $75,436. In Section IX. 2., page 83, the applicant states the working capital requirements will be financed by "*Unrestricted Cash of proponent"* ($75,436)."

Exhibit 42 includes a letter dated November 14, 2006 from Qimal R. Goyal, Accountant, which states

> *"We have reviewed the financials of Halifax Gastroenterology, P.C. Please be advised that Halifax Gastroenterology P.C. has sufficient cash flow and borrowing capacity to meet the start-up expense and working capital requirements associated with the development of the proposed gastrointestinal ("GI") endoscopy facility. As background, we have reviewed the financial pro formas and certificate of need ("CON") application of the new GI endoscopy center, as well as the new physician office."*

Additionally, Exhibit 43 contains a letter dated November 13, 2006 from Clark Young, Senior Vice President of First Citizens Bank regarding start up and initial operating expenses which states

> *"First Citizens Bank has approved and will be issuing a line of credit in the amount of $100,00 to Halifax Gastroenterology, P.C."*

Exhibit 34 contains an executed loan commitment letter dated September 13, 2006 between Prashanti, LLC and First Citizens Bank for the principal sum of $1,000,000 with an interest rate of 7.10% per annum for the sole purpose of constructing a medical office building. The loan origination fee is $5,000. Exhibit 39 contains an amortization schedule for this loan. The applicant states the additional $347,575 capital needs will be provided by owners' equity of Dr. and Mrs. Yerra. Exhibit 35 contains a letter dated November 14, 2006 from Qimat R Goyal that states

> *"Please be advised that Prashanti, LLC is a new estate management corporation that has been formed by Dr. and Mrs. Nagarjuna Yerra. As the sole owners of Prashanti, LLC, Dr. and Mrs. Yerra use their own personal net worth and borrowing capacity to support Prashanti, LLC's operations and activities.*
>
> *. . . Dr. and Mrs. Yerra have sufficient net worth and borrowing capacity to meet all capital requirements associated with the project as outlined in the financial pro formas and the CON application."*

In Section VIII. Page 79, the applicant states that the anticipated source of funding for the capital costs to be incurred by Halifax Gastroenterology, P.C. is a bank loan/line of credit for $361,000 and owner's equity of $25,000. Exhibit 35 contains a letter dated November 14, 2006 from Qimal R. Goyal, Accountant that states

"We confirm that Halifax Gastroenterology P.C. and Dr. and Mrs. Yerra have sufficient net worth and borrowing capacity to meet all the capital requirements associated with the project as outlined in the financial pro formas and the CON application."

Exhibit 40 contains an executed loan commitment letter dated September 13, 2006 between Halifax Gastroenterology, PC and First Citizens Bank for the principal sum of $450,000 with an interest rate of 7.10% per annum for the sole purpose of purchasing equipment and furniture for a medical office building. Exhibit 40, also contains a copy of a Promissory Note for the loan. Exhibit 41 contains an amortization schedule for this loan.

However, in Section VIII. 1. of the application, the applicant understated its capital costs for the proposed facility. See discussion in Criterion (12) of construction costs. Consequently, the applicant did not identify the source of funds to be used for the additional capital expenses to be incurred for the project, which are described in Criterion (12).

Further, Proforma Statements of Operating Revenue and Retained Earnings do not include adequate interest expense for the utilization of the $100,000 line of credit for start-up and initial operating expenses or the $450,000 loan for the equipment and furniture. The amortization table provided in Exhibit 41 for the $450,000 loan states that annual interest and principal payments for this loan are $82,026. This loan payment includes $30,723, $26,906, and $22,804 interest for Year 1, Year 2, and Year 3 respectively, but only $15,747 is budgeted for the annual interest payment. Further, the Proforma Statement of operating expenses does not contain any repayment of debt, although principal payments for the $450,000 loan alone are $52,303 in the first year. There are also no expenses included in the Proforma Statements for the $100,000 line of credit. Thus, the applicant does not budget adequate expenses for repayment of the loan and line of credit.

In Section X. 1., page 84, the applicant states

". . . the charge for all GI endoscopy procedures will be $675. With certain private and government insurance payers, however, facility charges are bundled with professional service charges to form a 'global' charge."

On page 15, the applicant shows a facility charge of $675 for each procedure in addition to the professional charge. However, in all three operating years the applicant projects average gross revenue per procedure will be $374.74 excluding physician fees, as shown in the Proforma Statements of Operating Results and Retained Earnings. The applicant's gross revenue per procedure is calculated as follows:

	Year 1	Year 2	Year 3
Gross Patient Revenue	$625,938	$730,261	$834,584
Number of procedures	1,800	2,100	2,400
Gross revenue per procedure	**$347.74**	**$347.74**	**$347.74**

On page 17, the applicant projects average reimbursement per procedure to range from $275 to $450. Therefore, it appears the applicant's projections of gross revenue in its proforma statements are incorrectly based on average reimbursement, rather than charges.

Further, in Section II., page 15, the applicant states that

> "*A 'global' fee includes both professional and facility reimbursement. The 'global' charge will be submitted to Medicare and other government payers that will reimburse physician office based GI endoscopy procedures using a higher facility site of service ('SOS') professional fee schedule reimbursement."*

Therefore, if the global fee is collected by the facility, then the facility must pay a professional fee to the physician's office practice. In Section II., page 15, the applicant provides the following information regarding the professional fees:

Proposed Charge Schedule

Description	Professional Charge	Facility Charge	Global Charge
Diagnostic colonoscopy	$900	$675	$1,575
Upper GI endoscopy	$650	$675	$1,325
Lesion removal colonoscopy	$1,100	$675	$1,775
Lesion removal colonoscopy	$1,100	$675	$1,775
Colon Screening Low Risk	$900	$675	$1,575
Colon Screening High Risk	$900	$675	$1,575
Upper GI, biopsy	$710	$675	$1,385
Colonoscopy & biopsy	$950	$675	$1,625
Flexible Sigmoidoscopy	$275	$675	$950
Upper GI, guide wire	$1,100	$675	$1,775

However, the Proforma Statements of Operating Results and Retained Earnings do not include either the total global charges or the expenses for payment of the professional services. Furthermore, the Proforma operating expense statements do not include sufficient expenses for all necessary staff salaries and benefits. See Criterion (7) for detailed discussion. Additionally, the applicant's projections of the number of endoscopy procedures to be performed are unsupported and unreliable. Consequently, the costs and revenues that are based on these projections are also unsupported and unreliable. See Criterion (3) for discussion.

In summary, the applicant failed to adequately demonstrate that the financial feasibility of the proposed project is based on reasonable projections of costs and charges and that sufficient funds are available for the additional capital costs. Consequently, the application is not conforming to 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.

NC

The applicant failed to adequately demonstrate the need for the proposed gastrointestinal endoscopy rooms in Halifax County. See Criterion (3) for discussion. Consequently, the applicant failed to adequately demonstrate that its proposed project would not result in unnecessary duplication of existing or approved health service capabilities and facilities. Therefore, the application is nonconforming to 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.

NC

In Section VII. 2., page 65 of the application, the applicant provides the following table showing the projected full-time equivalent (FTE) staffing for the proposed ambulatory surgical facility which will have two gastrointestinal endoscopy rooms:

Employee Category	**FTE**
Registered Nurse (RN)	2.0
Licensed Practical Nurse (LPN)	1.0
Nursing Aides, Orderlies, or Attendants	2.0
Non-Health and Technical Personnel	0.0
Total FTE Positions	**5.0**

In Section II. page 32, PEC states the staffing requirements for the facility as follows:

(1) "Administration;
Administration-0 (lead nurse will handle administration duties with practice administrator)
(2) pre-operative;
Pre-Operative-1
(3) post-operative;
Post-Operative-1
(4) procedure rooms;

Procedure Rooms--2 personnel depending on gastroenterologist room schedule; the schedule may be one (1) gastroenterologist per two (2) procedure rooms or one (1) gastroenterologist per one (1) procedure room
(5) equipment cleaning, safety, and maintenance; and
Equipment Cleaning, Safety, and Maintenance-1
(6) other
Other-none"

Further, in Section II., page 34, the applicant states

"At least one registered nurse ("R.N.") will be present during the performance of GI endoscopy procedures to manage conscious sedation and other clinical requirements."

However, the applicant failed to project adequate FTE Registered Nurses to staff two endoscopy procedure rooms in compliance with its stated policies for sedation. In Exhibit 20, Sedation Administration and Policy, page 189, the applicant states

"The RN managing the sedation of the patient may not leave the patient unattended or engage in tasks that would compromise monitoring. Immediate access to oxygen and emergency equipment must be available, including the ability to provide positive pressure ventilation."

Also, American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) Standard 310-030 states

"A physician, C.R.N.A., or R.N. with Advanced Cardiac Life Support (ACLS) certification or who is otherwise qualified in resuscitation is immediately available until all patients have met the criteria for discharge from the surgical facility."

Consequently, if the applicant proposes two endoscopy procedure rooms, the facility would need a minimum of three RNs to meet both accreditation standards and the applicant's stated policies (two RNs for the two procedure rooms and one RN for pre-operative/post operative patients). However, the applicant proposes to employ only two RNs.

Additionally, in Section II., page 34, the applicant stated *"Generally at all times two (2) clinical staff, including an R.N., will assist gastroenterologists in the performance of GI endoscopy procedures."* Thus, the required staff at this stated level is 4 FTE positions to provide assistance in the two proposed procedure rooms (2RNs and 2LPNs). However, the applicant projects in Table VII.7 Staffing by Area of Operation a total of only two staff assisting in the two procedure rooms (one RN and one LPN). See Criterion 7 and 10A NCAC 14C .3905 (d) (5) for additional discussion. Therefore, the applicant also did not propose a sufficient number of LPNs for operation of two GI endoscopy rooms.

Further, the applicant does not include in Section VII.2 or the budgeted operating expenses, staff to be used for the reception area or staff that will perform billing and collection for the ambulatory surgical facility. In Section II., page 9, the applicant states

> *"Separate financial, accounting, and other business records will be maintained for the GI endoscopy facility. Dedicated medical, professional, and administrative staff will manage the GI endoscopy facility, so that there is clear separation of the GI endoscopy facility form the physician office."*

However, the proposed staff in Section VIII. does not include any administrative personnel, except one RN manager who also has clinical responsibilities. Further, the applicant did not budget any expenses for the salaries and benefits of the additional staff discussed above or the Medical Director.

In summary, the applicant failed to adequately demonstrate the availability of sufficient resources, including health manpower and management personnel, for the provision of the proposed services. Therefore, the applicant is not 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.

NC

Exhibit 19 contains a copy of the proposed pathology provider service agreement with CBLPath. Exhibit 29 contains letters from local physicians supporting the applicant's proposal to develop an outpatient endoscopy facility and stating their intent to refer patients to the proposed facility. Exhibit 29, also, contains a letter from the Halifax County Health Department supporting the project. In Section V.2.(a), the applicant identifies Halifax Regional Medical Center as the facility with which the ambulatory surgical facility will have an agreement for patient transfer if additional medical support is needed. However, a copy of the agreement is not provided as required in 10A NCAC 14C .3904 (d) (3). In Section II., page 31 of the application, the applicant states

> *"A transfer agreement with a local hospital is not required since the gastroenterologists will use their own hospital admitting privileges in the event of an emergency transfer or other type of patient referral."*

However, because the proposed facility will be licensed as an ambulatory surgical facility, transfer agreements are required. Consequently, the applicant failed to adequately demonstrate that all necessary ancillary and support services will be available and is not conforming to 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

NA

(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.

NC

In Section XI. 5. (d), page 91, the applicant states there will be a total of 8,312 square feet in the entire building plus an additonal 1,086 square feet of attic storage, for a total of 9,348 square feet. Of this amount, the applicant states 3,444 will be used for the ambulatory surgical facility. In Section VIII.1, pages 72-73, the applicant projects the total cost for construction, land purchase and site preparation costs for the entire building will be $1,237,388. Additional costs for the building include $20,000 for landscaping, $74,782 for Architect and Engineering Fees, $5,000 for financing costs, and $10,405 for a total capital cost of $1,347,575. ($1,237,388 + $110,187). In Section VIII. 1, page 73, the applicant states

> "*This facility includes both the proposed GI endoscopy facility and the physician office of Halifax Gastroenterology, P.C. The portion of the proposed facility dedicated to GI endoscopy is 3,444 sq. ft. divided by the total 9,398 sq. ft. or 36.65%. Therefore, the capital cost attributed to the proposed GI endoscopy facility is $1,347,575 X .3665 = $493,836."*

However, the executed proposal between Halifax Gastroenterology, PC and Turn-Contractors, Inc. states the following items are not included in the pricing:

> *"1. Plan preparation cost*
> *2. Unsuitable soil removal and replacement*
> *3. Rock removal*
> *4. Electrical utility fees*
> *5. Water and sewer availability fees*
> *6. Yard sprinkler system*
> *7. Phone and data wiring*
> *8. Road sign*
> *9. Building exterior signs*
> *10. Interior door signs*
> *11. All equipment*
> *12. All furniture*
> *13. Security system*
> *14. Gas tap fees"*

Thus, the projected costs of $1,347,575 provided in Section VIII for Prashanti, LLC do not include costs for all non-equipment/furniture items in the above list. For example, costs are not included for utility tap-on fees, the security system, and signage. Consequently, the construction costs provided by the applicant in Section VIII are understated.

Exhibit 25 contains a line drawing for the proposed building with highlighted areas for the proposed GI endoscopy ambulatory surgical facility. The

highlighted areas include two GI endoscopy rooms, six pre-operative/post-operative recovery rooms, a nursing area and a scope washing area. However, not included in the proposed square footage are a receiving/registering area and a separate waiting area from the physician office. Furthermore, the applicant's line drawing of the proposed facility is unreadable and consequently it is not possible to determine whether all other required spaces are included in the design of the facility. Therefore, it appears the square footage necessary to establish a licensed ambulatory surgical facility is understated. As a result, the construction costs are understated.

In summary, the applicant failed to adequately demonstrate that the cost and design of the proposed construction represent the most reasonable alternative. Therefore, the application is non-conforming to this criterion.

(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;

NA

(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;

NA

(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

C

The following table from Section VI.13, shows the percentage of total cases for PEC by payer category for its proposed endoscopy services for the second year of operation.

Cases by Payer Category	Percent of Total

Private Pay	6.16%
Commercial Insurance	32.17%
Medicare	48.77%
Medicaid	10.32%
Charity/indigent	2.58%
Total	**100%**

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and 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. 8 (a), page 60, the applicant stated

"Patients have access to the facility's services via several options, including physician referral, self-referral, and referrals from local organizations such as the Halifax County Health Department."

The applicant demonstrated that a range of means will be offered by which a person will have access to its services, and thus, the application is conforming 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

See Section V.1 of the application and the letters in Exhibit 27. The applicant is conforming 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.

NC

The applicant failed to adequately demonstrate that its proposal will have a positive impact upon the cost effectiveness and quality of the proposed services. Therefore, the applicant is nonconforming to this criterion. See Criteria (3), (5), (7), (8) and (12) for discussion.

(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.

NA

(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.

NC

The proposal submitted by Halifax Gastroenterology, P.C. is not conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as required by 10A NCAC 14C .3900, as indicated below.

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

10A NCAC 14C .3902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information:

(1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906;

-C- The applicant identified the service area as Halifax, Northampton, Warren and Hertford Counties in North Carolina and Greensville and Brunswick Counties in Virginia. Therefore, the applicant is conforming to this rule.

(2) with regard to services provided in the applicant's GI endoscopy rooms, identify:

(A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located;

-C- The applicant does not currently operate any GI endoscopy rooms in a licensed facility. However, the proposed facility will have two GI endoscopy rooms. See Exhibit 25 for the floor plan.

(B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area;

-NA- The applicant does not have an existing licensed health service facility and no related entity to the applicant has a licensed health service facility in the proposed service area.

(C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months;

-NA- The applicant did not have any licensed or non-licensed GI endoscopy rooms in the last 12 months before the application was filed.

(D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project;

-C- In Section II., page 12, the applicant provided the projected number of procedures by CPT Code for the first three years of operation of the proposed facility.

Therefore, the application is conforming to this rule. See Criterion (3) for discussion regarding the reasonableness of the projections.

(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months;

-NA- The facility is new and was not operational in the last 12 months.

(F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project;

-NA- The applicant states that PEC will perform only gastroenterology endoscopy procedures in the proposed GI endoscopy rooms.

(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months; and,

-NA- The facility is new and was not operational in the last 12 months.

(H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project;

-C- On page 13 of the application, the applicant projects 1,530 patients will be served in the first year, 1,785 in the second year and 2040 in the third year. See Criterion (3) for discussion of the reasonableness of the projections.

(3) with regard to services provided in the applicant's operating rooms identify:

(A) the number of existing operating rooms in the facility;

(B) the number of procedures by type performed in the operating rooms in the last 12 months; and

(C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project;

-NA- The applicant does not have any operating rooms.

(4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located;

-C- On page 14 of the application, the applicant states that the facility will be operated Monday through Friday from 7:30 AM to 5 PM, 52 weeks per year, except for holidays.

(5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months;

-NA- The applicant is not an existing facility that provides endoscopy services.

(6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility;

-C- On page 15 of the application, the applicant provides the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility.

(7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge;

-C- On page 16 of the application, the applicant states that facility charge "*includes all services and items to be billed to patients. The projected average facility charge ($675) is set at approximately 156% of Medicare allowable ambulatory surgery center ("ASC") reimbursement ($433).* On page 15, the applicant states *"Some private insurance payers reimburse physician office based GI endoscopy procedures on a "global" fee basis. A 'global' fee includes both professional and facility reimbursement. The 'global' charge will be submitted to Medicare and other government payers that will reimburse physician office based GI endoscopy procedures using a higher facility site of service ('SOS') professional fee schedule for reimbursement."*

(8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges;

-C- On page 16 of the application, the applicant states that "*No other services or items will be billed to patients in excess of the facility charge for facility related services, except for pathology services or professional services under the submission of 'global' charges. If a health plan payer reimburses on a 'global' basis (professional and facility payments combined into a single reimbursement), then the charge structure will be based on a 'global' charge with professional and facility charges combined together. Pathology services will be billed on a separate basis for non-government health plan players."*

(9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months; and

-NA- The applicant is not an existing facility that provides endoscopy services.

(10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.

-C- On page 17 of the application, the applicant listed the average facility reimbursement by CPT Code projected to be received for the facility fee for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:

(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;

-NC- The applicant states on page 17

"Please find below a copy of the administrative policy that will be adopted by the proposed GI endoscopy facility:

Halifax Gastroenterology, PC is a provider of specialty care physician services. Our gastroenterologists and endoscopy center serve the needs of patients in the region, regardless of ability to pay, ethnicity, age, gender, financial status or insurance coverage, who are in need of appropriate and necessary medical care."

However, the above policy does not explicitly state "the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay" will be prohibited by the new endoscopy center. Therefore, the application is not conforming to this rule.

(2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;

-C- In Section II., page 18, the applicant stated *"It is the intent of Halifax Gastroenterology, P.C. to pursue state licensure and certification of the facility for the Medicare and Medicaid program once a CON is granted."*

(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;

-NC- In Section II., page 18, the applicant stated

"Halifax Gastroenterology, P.C. currently has a very high percentage of uncompensated care when compared to other gastroenterology practices in North Carolina. It is estimated that the amount of uncompensated care (charity/indigent care and bad debt combined) provided by Halifax Gastroenterology P.C. each year exceeds 7% of its collected revenues. Due to cash accounting, uncompensated care is not reported as accounts receivable and is generally understated. Please refer to Exhibit 29 for copies of letter of support from the Rural Health Group, Inc., which

operates a number of Community Health Centers in Halifax and surrounding counties and communities."

However, the application does not contain *"a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services wilt be accessible by indigent patients."* In other words, the applicant does not address strategies for access to the proposed services to be provided in the new facility. Therefore, the application is not conforming to this rule.

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

-C- In Exhibit 15 of the application, the applicant provides a written description of patient selection criteria including referral arrangements for high-risk patients.

(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;

-NC- In Section II., pages 19-20, the applicant states it performed 2,425 GI endoscopy procedures at Halifax Regional Medical Center from October 1, 2005 to September 30, 2006 and did not perform GI endoscopy procedures in any other existing health service facility in the last 12 months. However, the applicant states on page 21 of the application that it performed 2,346 procedures in the last year. Thus, the applicant made inconsistent statements about the number of procedures it performed. Therefore, the applicant is not conforming to this criterion.

(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.

-C- In Section II., page 21, the applicant states

"The construction of his own physician office based GI endoscopy facility combined with other practice changes, including the addition of a mid-level practitioner, however will permit Dr. Yerra to increase the number of GI endoscopy procedures he performs each year. Through a combination of (1) efficiency gains, (2) scheduling improvements, and (3) increased procedure schedule time, it is expected that Dr. Yerra will increase his annual GI procedure count from 2,346 to over 3,000. There will always remain inpatient and a fair amount of outpatient GI endoscopy procedures that will continue to be performed in Halifax Regional Medical Center due to clinical and other consideration."

The applicant states that market forces are causing the migration of GI endoscopy procedures out of hospitals. Market forces include consumer

demand for lower out-of-pocket costs, accessibility, advanced technology, and increased privacy.

10A NCAC 14C .3903 PERFORMANCE STANDARDS

(a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.

-NA- The applicant does not have an operating room.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

-NC- The applicant projects to perform an average of only 1,050 GI endoscopy procedures per room in the second operating year (*2,100 procedures / 2 procedure rooms = 1,050 procedures per room).* Therefore, the application is not conforming to this rule. Also, the applicant did not adequately demonstrate that the number of GI endoscopy procedures it projects to perform during the second operating year is reasonable. See Criterion (3) for a detailed discussion of the analysis of the projections.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.

-C- On page 29 of the application, the applicant states that it will provide the following types of GI endoscopy procedures: upper endoscopy, esophagoscopy and colonoscopy procedures.

(d) If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:

(1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or

(2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.

-NA- The applicant nor any related entity does not have and does not propose to have any operating rooms in the proposed service area.

(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.

-NC- The applicant failed to adequately describe all assumptions and the methodology used for each projection in this Rule. See Criterion 3 for discussion. In fact, the applicant did not respond to Section IV. 2 (b) of the application. Therefore, the application is not conforming to this rule.

10A NCAC 14C .3904 SUPPORT SERVICES

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.

-C- The applicant provides a copy of an agreement with the pathologist in Exhibit 19 of the application.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.

-C- The applicant provides a copy of its Anesthesia Policies in administration of conscious sedation and anesthesia, including procedures for tracking and responding to adverse reactions and unexpected outcomes, in Exhibit 20 of the application.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.

-C- The applicant provides a copy of its policies and procedures for cleaning and maintaining the cleanliness of scopes, other equipment, and the procedure room between cases in Exhibit 21 of the application.

(d) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:

(1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county;

-C- In Exhibit 22 of the application, the applicant provides evidence that Dr. Yerra who will utilize the proposed facility will have practice privileges at Halifax Regional Medical Center.

(2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges; and

-NC- The application did not contain a copy of an agreement to transfer and accept referrals of GI endoscopy patients <u>from</u> Halifax Regional Medical Center. Therefore, the application is not conforming to this rule.

(3) documentation of a transfer agreement with a hospital in case of an emergency.

-NC- The application did not contain documentation of a transfer agreement with a hospital in case of an emergency. Therefore, the application is not conforming to this rule.

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas:

(1) administration;
(2) pre-operative;
(3 post-operative;
(4 procedure rooms;
(5) equipment cleaning, safety, and maintenance; and
(6) other.

-C- The applicant identified the number of staff it proposed to utilize in each of the above areas on page 32, page 68 and Exhibit 36, 37 and 38 of the application. See Criterion (7) and 10A NCAC 14C .3905(d) for discussion of the reasonableness of the proposed number of staff for operation of two procedure rooms.

(b) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.

-C- The applicant identified one physician who is a board certified gastroenterologist and is projected to utilize the facility at this time. The applicant plans to extend privileges to others.

(c) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility.

-NC- The applicant refers to Exhibit 23. However, the applicant provided Dr. Verra's reappointment application to the medical staff of Halifax Regional Medical Center in Exhibit 23. The applicant did not provide the criteria to be used by the new ambulatory surgical facility in extending privileges to medical personnel that will provide services in the new facility.

(d) If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:

(1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;

-C- On page 33 of the application, the applicant identified Nagarjuna Yerra M.D., a board certified gastroenterologist, as the medical director. Exhibit 28 contains the Curriculum Vitae of Dr. Yerra, which states he is a Board Certified Gastroenterologist and is licensed to practice medicine in North Carolina.

(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;

-C- On page 33 the applicant states *"All gastroenterologists performing GI endoscopy procedures in the proposed facility are board certified and fellowship trained."*

(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;

-C- In Section II., page 34, the applicant states "*All gastroenterologists performing GI endoscopy procedures in the proposed facility have admitting privileges at Halifax Regional Medical Center."*

(4) at least one registered nurse shall be employed per procedure room;

-NC In Section VII., Table VII.7 Staffing by Area of Operation, page 68, the applicant lists only one RN for the two GI procedure rooms. The second RN listed as staff is assigned to the preoperative and postoperative care. In Section II., page 34, the applicant stated *"Generally at all times two (2) clinical staff, including an R.N., will assist gastroenterologists in the performance of GI endoscopy procedures."* Because two GI endoscopy rooms are proposed, another RN is needed for the second endoscopy room in order to have one RN per procedure room. See Criterion 7 and 10A NCAC 14C .3905 (d) (5) for additional discussion. Therefore, the applicant is not conforming with this criterion.

(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,

-NC- In Section II., page 34, the applicant stated *"Generally at all times two (2) clinical staff, including an R.N., will assist gastroenterologists in the performance of GI endoscopy procedures."* Thus, the required staff at this stated level is 4 FTE positions to provide assistance in the two proposed procedure rooms (2RNs and 2LPNs). However, the applicant projects in Table VII.7 Staffing by Area of Operation only two staff for the two procedure rooms (one RN and one LPN). See Criterion 7 and 10A NCAC 14C .3905(d)(5) for additional discussion. Therefore, the applicant did not propose a sufficient number of LPNs for operation of two GI endoscopy rooms, and is not conforming to this criterion.

(6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.

-C- On page 34 of the application, the applicant states that "*At least one (1) staff member will be ACLS certified, and at least one (1) other staff member will be BCLS certified. The proposed GI endoscopy facility will likely exceed these minimum requirements."*

10A NCAC 14C .3906 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NC- On page 34 of the application, the applicant states *"Halifax Gastroenterology, P.C. confirms that the proposed GI endoscopy facility will be separately identifiable from administrative, financial, and physical plant perspectives within the physician office facility to meet CFR 416 rules and state licensure and legal requirements."* The above information is not sufficient to demonstrate that the proposed new ambulatory surgical facility will be a separately identifiable entity administratively and will be financially independent and distinct from the rest of the operations of the facility. In particular, the applicant is Halifax Gastroenterology, P.C., which is the same entity that will occupy the rest of the building. Further, certain positions/functions necessary for the separate operation of the proposed new ambulatory surgical facility from the physician office were not listed in Section VII.2. of the application. Also, because professional fees were not listed as an expense to be paid by the facility to the physicians, it was not clear that the applicant considered the professional practice to be administrated as a separate entity from the ambulatory surgical facility. Therefore, it is not apparent that the new ambulatory surgical facility will be administratively and financially independent and distinct from the other operations of Halifax Gastroenterology, P.C., in the building. See Criterion (7) for discussion of staff issues. In summary, the applicant did not adequately demonstrate conformance to this rule.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project.

-C- On page 35 of the application, the applicant states it is committed to obtaining accreditation from the Accreditation Association for Ambulatory Health Care and projects to be accredited in the Spring of 2007.

(c) If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall:

(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

-NC- On page 35 of the application, the applicant states the proposed physical plant will conform to the requirements of federal, state, and local regulatory bodies. However, the room labels on the floor plan provided in Exhibit 25 are not readable. Therefore, it is not possible to determine if all required space is included in the design of the facility. Also, the applicant did not identify a receiving/registering area on the drawing, and did not document a waiting area for the ambulatory surgical facility that is separate from the waiting area for the physician office. Consequently, the application is not conforming to this rule.

(2) provide a floor plan of the proposed facility identifying the following areas:
(A) receiving/registering area;
(B) waiting area;
(C) pre-operative area;
(D procedure room by type; and
(E) recovery area.

-NC Exhibit 25 of the application contains a copy of the facility's floor plan. However, the floor plan for the space to be licensed as the ambulatory surgical facility does not include a receiving/registering area or a separate waiting area from the physician office. Therefore, the application is not conforming to this rule.

(3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,

-C- On page 35, the applicant states *"The proposed GI endoscopy suite is physically separated by a separate fire and smoke compartment from the physician office to meet Life Safety Code/NFPA 101 fire safety requirements."*

(4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.

-C- Prashanti LLC, a related entity owns the site. Exhibit 7 contains a copy of the lease agreement for the portion of the building to be used for the GI Suite. The owner of the building is Prashanti, LLC which is Dr. and Mrs. Yerra and the tenant is Halifax Gastroenterologists P.C. which is solely owned by Dr. Yerra.

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: September 5, 2007

PROJECT ANALYST: Michael J. McKillip
SECTION CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: #J-7847-07/Kurt G. Vernon, M.D., P.A./Develop two gastrointestinal endoscopy rooms in a licensed ambulatory surgical facility/Wake 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

There are no policies or need determinations in the 2007 State Medical Facilities Plan applicable to the review of applications for gastrointestinal endoscopy rooms. Therefore, this criterion is not applicable in this review.

(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.

NC

The applicant, Kurt G. Vernon, M.D., P.A. **(Dr. Vernon)**, is a gastroenterologist with an office located at 1004 Procure Street in Fuquay-Varina (Wake County). Dr. Vernon proposes development of a new ambulatory surgical facility with two gastrointestinal ("GI") endoscopy rooms for a single specialty gastroenterology practice in leased medical office space located adjacent to his medical office. It should be noted that the applicant makes inconsisten statements regarding the number of GI endoscopy rooms proposed. In Section II.3, page 9 of the application, the applicant states, *"The proposed GI endoscopy facility will have two (2) procedure rooms, but only one (1) procedure room may be operational upon opening of the facility in May 2007."* In Section II.6, page 10 of the application, the applicant states, *"A second procedure room is available in the current design, but it will not become operational upon opening of the facility."* In Section II.12, page 12 of the application, the applicant states, *"A second procedure room will become operational as part of Dr. Vernon's new office facility in Fuquay-Varina when required."* In Section III.1, page 40 of the application, the applicant states, *"The proposed facility will have one (1) GI endoscopy procedure room."* And in Section IV.3, page 59 of the application, the applicant states, *"Please note that total procedure volume performed by Dr. Vernon is projected to exceed 1,500 per year in the proposed one (1) procedure room GI endoscopy facility."* However, Exhibit 32 of the application contains the applicant's proposed floor plan for the facility which shows two procedure rooms. Therefore, based on all of the above information, the proposal constitutes the development of two GI endoscopy rooms.

Population to be Served

In Section III.7, page 53 of the application, the applicant provides projected patient origin for the proposed ambulatory surgery facility based upon its current patient origin, as shown in the table below.

County	**Percentage of Patients**
Harnett	75.87%
Johnston	8.03%
Cumberland	6.59%
Sampson	4.56%
Wake	2.77%
Other NC Counties	2.07%
Out of State	0.12%
Total	**100%**

The applicant adequately identified the population proposed to be served.

Need for the Proposed Service

In Section III. 1., page 40, the applicant states the following factors support the need for additional gastrointestinal endoscopy rooms.

> *"The vast majority of GI endoscopy procedures are preformed for purposes of cancer screening. GI endoscopy is considered to be the best method to detect pre-cancerous polyps, Barrett's Esophagus, and other medical conditions that are precursors to cancer, as documented in current medical research. ... As further background, colorectal cancer is the most preventable cancer in America. It is the second highest cancer killer in America, and currently only 30-40% of North Carolina citizens appropriate for colo-rectal cancer screening undergo any type of screening, including colonoscopy and fecal occult blood tests. This screening level is up from 15% in the 1990's. ... We expect demand to increase to at least 50% of the population choosing screening colonoscopy within the next few years based upon similar experience in states like Virginia, where public and physician awareness increased significantly due to publicity campaigns begun in 2000. This increase in demand has been so great as to overwhelm gastroenterologist capacity and hospital procedure room supply and has led to prolonged scheduling delays for patients. ... The education campaigns nationally funded by several physician and lay organizations, including the American College of Gastroenterology, The American Gastroenterology Association, and The American Society of Gastrointestinal Endoscopy, as well as local physicians in private practice educating their peers and local citizen groups, are expected to help gain improved screening levels of the target population. ... There exists significant unmet patient demand and medical "need" for cancer screening via GI endoscopy procedures. The current colo-rectal cancer screening level (rate attained) via endoscopy is estimated to be 55% to 60% of the over age fifty (50) population in Kurt G. Vernon, M.D., P.A.'s primary and secondary patient service areas. The clinical objective is 75%. Colo-rectal cancer remains the second leading cancer death rate in the United States. ... Upper GI endoscopy screening for Barrett's Esophagus is another endoscopy demand that is now emerging at an unprecedented rate. Recent medical research literature indicates a rise in this medical condition among the patient population that leads to esophageal cancer. The best way to diagnose this medical condition is via upper GI endoscopy."*

In Section III.1(b), pages 48-49 of the application, the applicant states

> *"The degree of patient demand and medical need being unmet or unserved*

can be documented for Kurt G. Vernon, M.D., P.A.'s primary and secondary patient service areas. Please review the two charts below to evaluate patient demand and need for GI endoscopy services in Kurt G. Vernon, M.D., P.A.'s primary and secondary patient service areas as well as other counties from which patients originate.

Population and Gastroenterologist Ratios

Primary and Secondary Patient Service Area Counties

County	Total Procedures	GI Physicians	2005 Population	GI Ratio	Population Growth	2010 Est Population	GI Ratio
Harnett	1,946	3	101,608	33,869	11.6%	112,581	37 527
Johnston	206	2	146312	73,156	20.0%	169,143	84,572
Cumberland	169	13	305 173	23.475	0.7%	312,107	24,008
SamDson	117	0	63,566	0	5.7%	68,764	0
Wake	71	30	755,034	25,168	20.3%	876,643	29,221
Other NC Counties	53						
Out of State	3						
Total	2,565	48	1,371 693	28,577		1,539,238	32,067
North Carolina			8,682,066		7.89%	9,349,175	

Sources: United States Census Bureau and United States Department of Health and Human Services

Colo-Rectal Endoscopy Screening Demand/Need Analysis

County	GI Physicians	2005 Population	Est. Over 50 Population	Est. Current Endo Screenlng	Patients Needing Endo Screen
Harnett	3	101,608	25,038	57.37%	10,674
Johnston	2	146,312	36,210	59.46%	14,680
Cumberland	13	305,173	66 618	60.81%	26 108
Sampson	0	63,566	18,409	57.34%	7853
Wake	30	755,034	166 738	58.96%	68,429
Other NC Counties					
Out of State					
Total	48	1,371,693			
North Carolina		8,682,066			

Sources: United States Census Bureau and United States Department of Health and Human Services

Patients in the primary and secondary patient service areas of Kurt G. Vernon, M.D., P.A. are clearly underserved. Depending on the research criteria, the desired gastroenterologist to population ratio ranges from

> *one (1) gastroenterologist per 15,000 to 25,000 people. Some private insurance health plans want one (1) gastroenterologist per every 7,500 members. ... The primary and secondary patient service areas of Kurt G. Vernon, M.D., P.A. have an estimated one (1) gastroenterologist to 28,577 population ratio, which does not meet current patient demand and medical needs, especially given a projected population growth rate of 20% every 2 to 3 years in Wake County. ... It is estimated in the Colo-Rectal Cancer Endoscopy Screening Demand/Need Analysis chart/table above that there is unmet need for colo-rectal cancer via endoscopy of 127,744 in Kurt G. Vernon, M.D, P.A.'s primary and secondary service areas for colo-rectal cancer alone. Regardless of the screening rate, the unmet demand/need is significant and would take more than the current number of gastroenterologists and other physicians performing GI endoscopy procedures to meet this screening demand. The result is that there is an acute shortage of physicians performing GI endoscopy procedures in surrounding service region of Fuquay-Varina, including Harnett County and Southeastern Wake County."*

However, there is no information in the application that identifies the source of the statistical information used to estimate the current percentage of the over 50 population receiving endoscopy screening in the defined service area. Additionally, the applicant does not adequately demonstrate the relationship between the number of gastroenterologists in the service area and the number of patients who need gastroenterology procedures. Further, the applicant offers no data or statistical information to substantiate its claim on page 49 that *"Some private insurance health plans want one (1) gastroenterologist per every 7,500 members."*

The applicant fails to take into account that not all people over the age of 50 need endoscopy screening on an annual basis. In fact, in Exhibit 23 of the application, the applicant provided a document titled, *"NCQA* [National Committee for Quality Assurance] *Colo-Rectal Cancer Screening Measurement"*, which states

> "*The* [colo-rectal cancer] *screening criteria can be met with any one of four tests: a fecal occult blood test (FOBT) during the measurement year; a flexible sigmoidoscopy within the last five years; a double contrast barium enema within the last five years; or a colonoscopy within the last ten years."*

As shown in the applicant's table identified as *"Colo-Rectal Cancer Endoscopy Screening Demand/Need Analysis,"* (page 49 of the application) the applicant fails to reduce the over age 50 population in 2005 by the number of people receiving one of the four types of screening tests. On page 41 of the application, the applicant states the clinical objective for endoscopy screening is 75%. However, the calculations in

the table on page 49 show the applicant's demand analysis is based on 100% of the over 50 population receiving an endoscopy procedure. However, the American Cancer Society goal is 75% of adults older than age 50 will have a recent colo-rectal cancer screening test by 2015, which includes any of the types of screening tests, not just endoscopy. Additionally, materials published by the American Cancer Society indicates that if a colonoscopy is the type of screening test selected by the patient as opposed to one of the other types of screening tests, then an average risk individual, 50 years of age or older, should receive a colonoscopy only every ten years. The American Cancer Society also recommends that a positive test result from an alternative screening test should be followed up with a colonoscopy. Thus, the applicant's analysis and projections artificially inflate demand for the proposed services because average risk individuals need an endoscopy procedure only once in ten years, and the applicant failed to adjust "need" for this factor. Thus, the estimates of the need on page 49 of the application are unsupported and unreliable.

In Section IV. 2. (b), pages 58-59, the applicant provides projected utilization for the facility in the first three years of operation following completion of the project, which is summarized below.

Project Year	Total Endoscopy Cases	GI Endoscopy Rooms	Cases Per Endoscopy Room
YR 1 (FY2008)	1,800	2	900
YR 2 (FY2009)	2,000	2	1,000
YR 3 (FY2010)	2,200	2	1,100

In Section IV.2, page 57 of the application, with regard to the applicant's assumptions and methodology for projecting utilization of the proposed GI endoscopy rooms, the applicant states, *"The primary assumptions are that the patient referral letters found in Exhibits 19 and 39 more than support year 1 through year 3 procedure volume forecasts."* Exhibit 39 contains letters from physicians stating their intention to refer patients to Dr. Vernon's proposed facility. The following table summarizes the number of patients the physicians estimate they will refer to Dr. Vernon's proposed endoscopy facility for GI endoscopy procedures on a per month and annualized basis:

Physician or Medical Group	Estimated Endoscopy Referrals Per Month	Estimated Endoscopy Referrals Per Year
TriCounty Community Health Center	10-20	120-240
Premier Surgical Associates	3	36
Sessoms Medical Practice, P.A.	3-5	36-60
Barbara Lowe Bethea, M.D.	15	180
Professional Women's Healthcare, P.A.	5	60
Western Medical Group	35	420
Dunn OB-Gyn Associates, P.C.	10	120
Dunn-Erwin Medical Center	15-20	180-240
Village Surgical Associates, P.A.	4-8	48-96
Mind, Body, Spirit Women's Health	10	120
Orthopedic Solutions & Sports Medicine, P.A.	15-20	180-240
Cardinal Medical Specialists, P.A.	10	120
Southeastern Medical Center, P.C.	10-15	120-180
Maria Medical Center	83	996
Village Surgical Associates of Harnett County	15	180
Totals	**243-274**	**2,916-3,288**

Based on the above numbers of estimated referrals, the applicant projects to perform a total of 2,000 GI endoscopy procedures in the two proposed GI endoscopy rooms in the second year of operation following completion of the project, which is an average of 1,000 procedures per room (*2,000 procedures/2 rooms = 1,000 procedures per room).* Thus, the applicant did not demonstrate that it will perform at least 1,500 GI endoscopy procedures in each of the two proposed rooms as required in 10A NCAC 14C .3903(b).

In summary, the applicant did not adequately demonstrate the need the population proposed to be served has for the two proposed GI endoscopy rooms. Consequently, the application is not 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.

NC

In Section III. 9, page 55 of the application, the applicant discusses the alternatives it considered prior to submission of this application and the basis for selection of the proposed project. However, the application is not conforming with all applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (7), (8), (12), (18a), and "*Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities*" in 10A NCAC 14C .3900. Therefore, the applicant did not adequately demonstrate that the proposed project is an effective alternative and the application is not conforming to this criterion. Consequently, the application is disapproved.

(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.

NC

In Section I.10, page 4 of the application, the applicant states, *"The proposed GI endoscopy facility is located in a property that is leased from Jayku, LLC ("lessor") by Kurt G. Vernon, M.D., P.A."* In Exhibit 3 of the application, the applicant identifies the sole members of Jayku, LLC as Kurt G. Vernon, M.D. (60%) and Jay Parikh, M.D. (40%). In Section VIII.1, page 84, the applicant states the projected capital cost to be incurred by the Jayku, LLC (lessor) is $820,638, including $86,838 for site costs, $672,300 for construction costs, and $61,500 for miscellaneous project costs.

In Section VIII.2, page 84 of the application, the applicant states the lessor, Jayku, LLC, will fund its capital costs with a bank loan in the amount of $672,300 and *"reserves/savings"* of $148,338. Exhibit 44 contains a loan commitment letter dated March 5, 2007 from Billy F. Sutton, Senior Vice President, First Citizens Bank, which stipulates the terms and condition under which the bank will make a loan to Jayku, LLC in an amount up to $600,000 *"for the purpose of completing upfits and improvements (medical office building)."* Also in Exhibit 44 of the application is a loan commitment letter dated January 26, 2007 from Billy F. Sutton, Senior Vice President, First Citizens Bank, which stipulates the terms and condition under which the bank will make a loan to Jayku, LLC in an amount up to $1,200,000 *"for the*

purpose of purchasing the property and improvements (medical office building)." In Section VIII.4, page 86 of the application, the applicant states,

> *"The total loan amounts* [of $1.8 million] *are for the entire* [medical office] *building. The GI endoscopy facility portion of the loan is approximately 37.35% (calculated as 2,988 of the total 8,000 sq. ft.).*

Therefore, based on the applicant's statement, the portion of the bank loans allocated to the development of the proposed GI endoscopy facility is $672,300 [37.35% X $1.8 million = $672,300]. However, the applicant did not identify the source of funds for the *"reserves/savings"* of $148,338.

On page 88 of the application, the applicant states the projected capital cost to be incurred by the Kurt D. Vernon, M.D., P.A. (lessee) is $333,690, including $303,690 for equipment costs and $30,000 for miscellaneous project costs. Exhibit 47 of the application contains an unaudited balance sheet for Kurt. D.Vernon, M.D. dated December 31, 2006, which indicates the applicant had $183,903 in current assets. In Section VIII.7, page 90 of the application, the applicant states

> *"The financing is anticipated to be provided through Dr. Vernon's personal reserves and the cash flow of the practice. The vast majority of the equipment costs is related to endoscopy equipment, which can be financed on a per procedure basis over five (5) years. If necessary, a line of credit has been secured with BB&T Bank."*

However, the applicant did not document sufficient funds to the meet the need for $333,690 in capital project costs to be incurred by Kurt D. Vernon, M.D., P.A. (lessee).

In Section IX.1, page 93 of the application, the applicant states that there will be $10,000 in start-up expenses and $71,143 in initial operating expenses, for total working capital required of $81,143. Exhibit 46 of the application contains a revolving secured line of credit commitment letter addressed to Kurt D. Vernon M.D. and dated April 12, 2007, from Larry R. Byrd, Senior Vice President, Branch Banking & Trust Co., which stipulates the terms and condition under which the bank will extend a line of credit to Kurt D. Vernon, M.D., P.A. in an amount up to $250,000 *"to fund start up expenses and working capital for the new medical facility located in Fuquay-Varina."*

On page 16 of the application, the applicant states the proposed average facility charge will be $675 per procedure in each of the first three years of the project. However, in the *"Pro Forma Statement of Operating Results and Retained Earnings"* at the end of the application, the applicant indicates the gross revenue per

procedure will be $411.83 in Year 1 and $386.38 in Years 2 and 3. The applicant's gross revenue per procedure is calculated as follows:

	PROJECT YEAR 1	PROJECT YEAR 2	PROJECT YEAR 3
Gross Patient Revenue	$680,544	$705,262	$775,788
Other Revenue Sources*	$60,750	$67,500	$74,250
Gross Procedure Revenue	$741,294	$772,762	$850,038
Number of Procedures	1,800	2,000	2,200
Gross Revenue Per Procedure	$411.83	$386.38	$386.38

*Pathology services

On page 18 of the application, the applicant projects average reimbursement for the facility will range from $350 to $400 per procedure. Therefore, it appears the applicant's projections of gross revenue in its pro forma financial statements are not calculated based on the charge per procedure, which the applicant states will average $675 per procedure. In fact, Exhibits 15, 16, and 17 detail the calculations for Years 1, 2, and 3, respectively. The following table summarizes Exhibit 15 and Exhibit 16 for Years 1 and Year 2:

	Year 1			Year 2		
Payor	Number	Reimbursement	Total	Number	Reimbursement	Total
Medicare -Colon	176	$433	$76,208	195	$303	$59,085
Medicare-EGD	95	$385	$36,575	105	$270	$28,350
Medicaid-Colon	70	$390	$27,300	78	$273	$21,294
Medicaid-EGD	38	$347	$13,186	42	$243	$10,206
Insurance-Colon	878	$400	$351,200	975	$400	$390,000
Insurance-EGD	473	$350	$165,550	525	$350	$183,750
Self Pay-Colon	47	$175	$8,225	52	$175	$9,100
Self Pay EGD	25	$125	$3,125	28	$125	$3,500
Total	1,800		$681,369	2,000		$705,285

Thus, the applicant's gross procedure revenue from the pro forma financial statements in both Year 1 and Year 2 is essentially the same as the reimbursement calculated by procedure type above. Therefore, it appears the pro forma financial statements are incorrectly based on average reimbursements by payer type rather than gross patient charges.

On page 16, the applicant states

> *"Some private insurance payers reimburse physician office based GI endoscopy procedures on a 'global' fee basis. A 'global' fee includes both professional and facility reimbursement. The 'global' charge will be submitted to Medicare and other government payers that will reimburse physician office based GI endoscopy procedures using a*

higher facility site of service ('SOS') professional fee schedule for reimbursement."

However, based on the pro forma financial statements of revenue and expenses, the applicant did not include professional fees collected under the "global charge" as revenues or expenses. Therefore, the *"ProForma Statements of Operating Results and Retained Earnings"* for the proposed project do not project reliable revenues and expenses for the facility given its intent to file global charges with certain payers.

Additionally, the applicant did not include all expenses in the *"ProForma Statements of Operating Results and Retained Earnings."* No interest expense is stated for the use of a line of credit for the working capital. In fact, there is no interest expense listed for all three years.

Furthermore, Exhibits 15, 16, and 17 state the total cost of equipment as $242,190. In the assumptions and notes for Form B (assumption #14), on page 112 of the application, the applicant states, *"Depreciation expense is five (5) year straight line."* Consequently, the depreciation for the equipment listed in Exhibits 15, 16, and 17 is $48,438 *($242,190/5 years = $48,438 per year).* However, the pro forma financial statements include only $32,178 depreciation expense for each year.

Furthermore, in the *"ProForma Statement of Operating Results and Retained Earnings,"* the applicant projects costs for plant operation and maintenance of only $47,620, $50,001 and $52,501 in Years 1, 2, and 3 respectively. However, in addition to plant operation and maintenance, the applicant states it will also have equipment maintenance expenses. Exhibits 15, 16, and 17 list $113,612 as the cost of total equipment and maintenance expenses alone. Also, there is an unspecified listing of *"Other Property, Ownership and Use Expenses"* of $54,249 per year. However, neither the projected *"plant operation and maintenance"* or the *"Other Property, Ownership and Use Expenses"* included in the pro forma financial statements of operating expenses are sufficient for the equipment maintenance expenses listed in the Exhibits 15-17.

Exhibits 15, 16, and 17 contain the assumptions and calculations for revenue, personnel, facility costs, equipment costs and administration/operations for Year 1, Year 2, and Year 3 respectively. The following table compares the total expenses from the Exhibits to the total expenses in the applicant's *"ProForma Statement of Operating Results and Retained Earnings"* for the each year:

Year 1	
Exhibit 15 Total Expenses	$569,141
Pro Forma Form B Total Expenses	$554,423
Difference	$14,718
Year 2	
Exhibit 16 Total Expenses	$573,141
Pro Forma Form B Total Expenses	$570,831
Difference	$2,310
Year 3	
Exhibit 17 Total Expenses	$577,141
Pro Forma Form B Total Expenses	$587,685
Difference	-$10,544

As demonstrated above, the projected operating expenses from Exhibits 15-17 for the facility, equipment, and administration do not match or explain the amounts in the applicant's pro forma financial statements. Therefore, the applicant makes inconsistent statements concerning the projected operating expenses for the proposed facility. Consequently, the expense projections are unreliable.

Additionally, the pro forma financial operating statements do not include sufficient expenses for all necessary staff salaries and benefits. See Criterion (7) for discussion.

In summary, the applicant failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Further, the applicant did not adequately demonstrate the availability of sufficient funds for the capital needs of the project. Therefore, the application is not conforming to 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.

NC

The applicant failed to adequately demonstrate the need for the two proposed gastrointestinal endoscopy rooms in Fuquay-Varina (Wake County). See Criterion (3) for discussion. Consequently, the applicant failed to adequately demonstrate that its proposed project would not result in unnecessary duplication of existing or approved health service capabilities and facilities. Therefore, the application is nonconforming to 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.

NC

In Section II.8, page 36 of the application, the applicant identifies Kurt G. Vernon, M.D., a board-certified gastroenterologist, as the medical director for the proposed project. In Sections VII.7, page 79, the applicant provided a table showing the projected full-time equivalent (FTE) staffing for the proposed ambulatory surgical facility, which is summarized below:

EMPLOYEE CATEGORY	FTE
Registered Nurse (RN) 1.0 post-operative, 1.0 GI procedure room	2.0
Licensed Practical Nurse 1.0 pre-operative, 1.0 GI procedure room	2.0
Nursing Aides, Orderlies, or Attendants 1.0 "Other"*	1.0
All "non-health professionals" and "technical" personnel (Administration)	1.0
Total FTE Positions	**6.0**

*Applicant identifies 1.0 FTE *"Other" as "equipment cleaning, safety, and maintenance"* on page 35 of the application.

The applicant proposes only one FTE registered nurse (RN) and one FTE licensed practical nurse (LPN) to be assigned to the two GI endoscopy rooms. No other positions are designated as assisting in the GI endoscopy rooms. Based on these projections, the applicant failed to propose adequate staff for operation of two GI endoscopy rooms. Specifically, the applicant does not show it will comply with its policies for sedation as stated in Exhibit 26, Sedation Administration and Policy, page 228 of the Exhibit, which is quoted below,

> *"The RN managing the sedation of the patient may not leave the patient unattended or engage in tasks that would compromise monitoring. Immediate access to oxygen and emergency equipment must be available, including the ability to provide positive pressure ventilation."*

Also, American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) Standard 310-030 states

> *"A physician, C.R.N.A., or R.N. with Advanced Cardiac Life Support (ACLS) certification or who is otherwise qualified in resuscitation is immediately available until all patients have met the criteria for discharge from the surgical facility."*

Consequently, for operation of two GI endoscopy procedure rooms, the facility would need a minimum of three RNs to meet both accreditation standards and the applicant's stated policies (two RNs for the two procedure rooms and one RN for post-operative patients). In other words, the applicant does not propose sufficient staff for the two procedure rooms because each procedure room would require an RN based on the applicant's policies. Also, the applicant proposes a total of two LPNs, one of which will assist in the procedure rooms and one assigned to the pre-operative patients. However, the applicant does not propose adequate LPN staffing to assure a second clinical personnel is assisting in each procedure room at all times, in accordance with the applicant's stated policy contained in Exhibit 26. Thus, two FTE LPNs would be needed to assist in two procedure rooms. This would mean a total of four FTE staff assisting in the two procedure rooms (2 RNs and 2 LPNs). However, the applicant projects in *"Table VII.7 Staffing by Area of Operation"* a total of only two staff assigned to the procedure rooms for the entire facility (one RN and one LPN). See 10A NCAC 14C .3905 (d) (5) for additional discussion. Therefore, the applicant did not propose sufficient staff for operation of two GI endoscopy rooms.

Further, the applicant does not include in Section VII.2 or in the budgeted operating expenses, adequate staff for the reception area, administration area or staff to perform billing and collection for the new ambulatory surgical facility. In Section II.3, page 9 of the application, the applicant states

> *"Separate financial, accounting, and other business records will be maintained for the GI endoscopy facility. Dedicated medical, professional, and administrative staff will manage the endoscopy facility, so that there is clear separation of the GI endoscopy facility from the physician office."*

However, the only non-clinical personnel included in Section VII are two 0.5 FTEs listed as "non-health professional" and "technical" personnel. In Exhibits 15, 16, and 17, the two positions are listed as 0.5 FTE *"reception"* and 0.5 FTE *"billing."* In Exhibit 42, the applicant provides the following job descriptions for the proposed endoscopy facility:

- Endoscopy Medical Assistant;
- Endoscopy Nurse;
- Equipment Processing Technician;
- Laboratory Technician;
- Medical Director;
- Nurse Manager;
- Nursing Assistant;

- Practice Administrator; and
- Licensed Practical Nurse.

Thus, the applicant makes inconsistent statements about the personnel to be employed in the ambulatory surgical facility.

In summary, the applicant failed to adequately document the availability of sufficient health manpower and management personnel to provide the proposed GI endoscopy services. Therefore, the application is not 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.

NC

Exhibit 25 contains a copy of letter from a pathology services provider, CBLPath, Inc., addressed to Kurt G. Vernon, M.D. regarding the provision of pathology services to the proposed endoscopy facility. Exhibit 39 contains letters from physicians stating their support for the proposed project and their intent to refer patients to the facility. However, the application did not contain a copy of a transfer agreement with a hospital regarding transfer of the applicant's patients to the hospital in the case of an emergency, as required in 10A NCAC 14C .3904(d)(3). Consequently, the applicant did not adequately demonstrate that all necessary ancillary and support services will be available and that the service will be coordinated with the existing health care system. Therefore, the application is not conforming to 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

NA

(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.

NC

In Section VIII, the applicant states the construction costs for Jayku, LLC (lessor) for the proposed ambulatory surgical facility is $672,300. In Exhibit 43, the applicant provides a letter dated April 16, 2007 from Floyd L. Taylor of Progressive Builders of NC, Inc. addressed to Jayku, LLC, which states the cost of the medical office building project will be $1.8 million. In Section VIII.1, page 84 of the application, the applicant states,

"The construction and related costs described herein are for the proposed GI endoscopy facility and the new physician office for Kurt Vernon, M.D., P.A. that are co-located in the same building. ... 2,988 of the total 8,000 square footage is dedicated for the GI endoscopy facility. Total construction costs are estimated to be $1,800,000."

Therefore, the applicant projected $672,300 in construction costs for the endoscopy facility [2,988/8,000 = 37.35%; 37.35% X $1.8 million = $672,300]. In Section XI. 8., page 103, the applicant stated the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. Exhibit 31 of the application contains a letter dated April 9, 2007 from Bruce Cantrell, AIA, J. Hyatt Hammond Associates, which states

> *"The design and construction of the proposed GI endoscopy facility at 1004 Procure St, Fuquay-Varina, North Carolina should meet all state licensure and Medicare certification requirements, including Life Safety Code 2006 and NFPA 101 regulations, upon subsequent survey of the facility for its intended use."*

The applicant also provides a line drawing of the facility in Exhibit 32 of the application. However, the applicant's line drawing of the proposed ambulatory surgery facility does not identify a receiving/registering area on the drawing as required in 10A NCAC 14C .3906(c)(2). Therefore, the applicant failed to demonstrate that the cost, design, and means of construction represent the most reasonable alternative. See Criterion (5) for discussion of costs and charges. Therefore, the application is not conforming to this criterion.

(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;

NA

(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;

NA

(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

C

The following table from Section VI.13, page 74, shows the projected percentage of total cases by payer category for the second year of operation (FY2009).

PAYOR CATEGORY	PERCENT OF TOTAL REVENUE
Private Pay	1.63%
Commercial Insurance	82.98%
Medicare	11.31%
Medicaid	4.08%
Total	100.0%

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and 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

See Section VI. 2, page 69 of the application, and Section VI.8, page 72 of the application. The applicant demonstrated that a range of means will be offered by which a person will have access to its services, and thus, the application is conforming 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. (a), page 61, the applicant states, *"Kurt G. Vernon, M.D., P.A. is willing to develop new affiliations and relationships with medical schools in the*

state." Exhibit 38 contains letters from the applicant to area health professional training programs expressing his willingness to offer the proposed endoscopy facility as a training site. The applicant adequately demonstrated that the facility will accommodate the clinical training needs of the area's health professional training programs and, therefore, the application is conforming 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 failed to adequately demonstrate that its proposal will have a positive impact upon the cost effectiveness and quality of the proposed services. Therefore, the application is nonconforming to this criterion. See Criteria (3), (5), (7), (8), and (12) for discussion.

(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.

NA

(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.

NC

The proposal submitted by Kurt G. Vernon, M.D., P.A. is not conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as required by 10A NCAC 14C .3900, as indicated below.

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

10A NCAC 14C .3902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information:

(1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906;

-C- The applicant identified its service area as Harnett, Johnston, Cumberland, Sampson, and Wake counties. Therefore, the applicant is conforming to this rule.

(2) with regard to services provided in the applicant's GI endoscopy rooms, identify:

(A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located;

-NC- The applicant does not currently operate any GI endoscopy rooms. The applicant provides inconsistent statements about the number of proposed GI endoscopy procedure rooms. However, the drawing of the floor plan contained in the application shows two procedure rooms. See Criterion (3) for discussion and Exhibit 32 for a copy of the floor plan for the proposed endoscopy facility.

(B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area;

-NA- Neither the applicant nor a related entity has another licensed health service facility in the proposed service area.

(C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months;

-NA- The applicant states it does not operate any licensed or non-licensed GI endoscopy rooms.

(D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project;

-C- In Section II.8, page 13 the applicant provided the number of GI endoscopy procedures, identified by CPT code projected to be performed in the applicant's licensed endoscopy rooms in each of the first three operating years of the project. Therefore, the application is conforming to this rule. See Criterion (3) for discussion of reasonableness of projections.

(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months;

-NA- The applicant states it does not operate any licensed or non-licensed GI endoscopy rooms.

(F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project;

-NA- The applicant states that only gastroenterology endoscopy procedures will be performed in the proposed GI endoscopy room.

(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months; and,

-NA- The applicant states it does not operate any licensed or non-licensed GI endoscopy rooms.

(H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project;

-C- On page 14 of the application, the applicant projects 1,620 patients will be served in the first year, 1,800 patients in the second year, and 1,980 patients in the third year.

(3) with regard to services provided in the applicant's operating rooms identify:

(A) the number of existing operating rooms in the facility;

(B) the number of procedures by type performed in the operating rooms in the last 12 months; and

(C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project;

-NA- The applicant does not currently have any operating rooms and does not project to develop any operating rooms, as that term is defined in N.C.G.S. Section 131E-176(18c).

(4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located;

-C- On page 16 of the application, the applicant states that the facility will be operated Monday through Friday from 7:30 AM to 5:00 PM.

(5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months;

-NA- The applicant is not an existing facility.

(6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility;

-C- On page 16 of the application, the applicant provides the type and projected average facility charge for the GI endoscopy procedures which the applicant projects will be performed most often in the facility for the first three years following completion of the project.

(7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge;

-C- On page 17 of the application, the applicant provides a list of the services and items included in the facility charge, and a description of the bases for the charges.

(8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges;

-C- On page 17 of the application, the applicant identifies anesthesia and pathology services as excluded from the facility's charges.

(9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months; and

-NA- The applicant is not an existing facility.

(10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.

-C- On page 18 of the application, the applicant listed the average reimbursement from all payors projected to be received for each of the GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first years following completion of the project.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:

(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;

-NC- The applicant states on page 19 of the application,

> *"Please find below a copy of the administrative policy that will be adopted by the proposed GI endoscopy facility:*
>
> *Kurt G. Vernon, M.D., P.A., is a provider of gastroenterology endoscopy services. Our physicians and endoscopy center serve the needs of patients in the region who are in need of appropriate and necessary medical care, regardless of ability to pay, ethnicity, age, gender, financial status or insurance coverage."*

Further, in Section VI. 2., page 69, the applicant states

> *"The existing and proposed GI endoscopy facility provides access to cancer screening and other GI endoscopy procedures to all patients regardless of ability to pay, insurance coverage, racial/ethnic background, and gender."*

However, the above policy does not explicitly state "the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay" will be prohibited. Therefore, the application is not conforming to this rule.

(2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;

-C- In Section II.8, page 19 of the application, the applicant provides a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility.

(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;

-C- In Section II.8, page 19 of the application, the applicant provides a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay.

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

-C- In Exhibit 20 of the application, the applicant provides a written description of patient selection criteria including referral arrangements for high-risk patients.

(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;

-C- In Section II.8, page 21 of the application, the applicant states that Dr. Vernon performed 2,565 GI endoscopy procedures at Betsy Johnson Regional Hospital and WakeMed from January 1, 2006 to December 31, 2006.

(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.

-NC- The applicant states that it does not propose to reduce the number of GI endoscopy procedures it performs in existing facilities. In Section II.8, page 21 of the application, the applicant states, *"Given the development of the proposed physician office based GI endoscopy facility in southeastern Wake County, there will not likely be a reduction in the number of GI endoscopy procedures being performed by Dr. Kurt G. Vernon at Betsy Johnson Regional Hospital."* However, in Section II.8, page 21 of the application, the applicant states that Dr. Vernon performed a total of 2,565 GI endoscopy procedures at Betsy Johnson Regional Hospital and WakeMed during the one-year period from January 1, 2006 through December 31, 2006. The applicant did not adequately explain how it is possible that Dr. Vernon will perform an additional 1,800, 2,000, and 2,200 GI endoscopy procedures in the proposed facility in Project Years one, two, and three, respectively, without reducing the number of procedures he performs at Betsy Johnson Regional Hospital and WakeMed. Therefore, the applicant is not conforming with this rule.

10A NCAC 14C .3903 PERFORMANCE STANDARDS

(a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.

-NA- The applicant does not have and is not proposing an operating room.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

-NC- The proposed project results in the development of two GI endoscopy procedure rooms. The applicant projects to perform an average of only 1,000 GI endoscopy procedures per room in the second operating year (2,000 procedures/2 procedure rooms = 1,000 procedures per room). See Criterion (3) for discussion. Therefore, the application is not conforming to this rule.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.

-C- On page 32 of the application, the applicant states that it will provide the following types of GI endoscopy procedures: upper endoscopy, esophagoscopy and colonoscopy procedures.

(d) If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:

(1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or

(2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.

-NA- The applicant nor any related entity owns any operating rooms in the proposed service area.

(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.

-NC- The applicant failed to adequately describe the assumptions and methodology used for each projection in this Rule. See Criterion 3 for discussion. Therefore, the application is not conforming to this rule.

10A NCAC 14C .3904 SUPPORT SERVICES

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.

-C- Exhibit 25 of the application contains a copy of a signed agreement between the applicant and a provider of pathology services, CBLPath, Inc.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.

-C- The applicant provides a copy of its conscious sedation policy in Exhibit 26 of the application.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.

-C- The applicant provides a copy of its policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases in Exhibit 27 of the application.

(d) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:

(1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county;

-C- Exhibit 28 of the application contains documentation that Dr. Vernon has practice privileges at Betsy Johnson Regional Hospital, which is located in a contiguous county (Harnett County).

(2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges; and

-NC- The rule requires the application contain documentation of an agreement by which the applicant will accept patients transferred from the hospital with which it has privileges. The application did not contain a copy of an agreement to transfer and accept referrals of GI endoscopy patients from Betsy Johnson Regional Hospital, which is the facility with which Dr. Vernon has practice privileges. Therefore, the application is not conforming to this rule.

(3) documentation of a transfer agreement with a hospital in case of an emergency.

-NC- The rule requires that the application contain documentation of a transfer agreement. The application did not contain documentation of a transfer agreement with a hospital in case of an emergency. Therefore, the application is not conforming to this rule.

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas:

(1) administration;
(2) pre-operative;
(3 post-operative;
(4 procedure rooms;
(5) equipment cleaning, safety, and maintenance; and
(6) other.

-C In Section II.8, page 35 of the application, the applicant identified the number of staff by area as follows:

Administration:	3.0 FTEs
Pre-operative	1.0 FTE
Post-op:	1.0 FTE
Procedure Rooms:	2.0 FTEs
Equipment cleaning, safety & maintenance:	1.00 FTE
Other:	0.00 FTE

(b) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.

-C- In Section II.8, page 36 of the application, the applicant states one physician who is a board certified gastroenterologist will utilize the proposed facility.

(c) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility.

-NC- The applicant provided in Exhibit 29 a copy of the "Medical Staff Application for Privileges" and "Recommendation Approval Sheet." However, the applicant did not provide the criteria to be used by the facility to determine which physicians would be extended privileges.

(d) If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:

(1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;

-C- On page 36 of the application, the applicant identified Kurt G. Vernon, M.D., a board certified gastroenterologist, as the medical director. Exhibit 40 contains the Curriculum Vitae of Dr. Vernon, which states he is a Board Certified Gastroenterologist and is licensed to practice medicine in North Carolina.

(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;

-C- On page 37 the applicant states *"All gastroenterologists performing GI endoscopy procedures in the proposed facility are board certified and fellowship trained."*

(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;

-C- In Section II.8, page 37, the applicant states "*All gastroenterologists performing GI endoscopy procedures in the proposed facility have admitting privileges at Betsy Johnson Regional Hospital.*" Exhibit 28 contains a letter documenting Dr. Vernon's medical staff membership at Betsy Johnson Regional Hospital.

(4) at least one registered nurse shall be employed per procedure room;

-NC- In Section VII, *"Table VII.7 Staffing by Area of Operation"*, page 79 of the application, the applicant lists only one registered nurse (RN) for the two GI procedure rooms. Therefore, the applicant is not conforming to this criterion.

(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,

-NC- In Section II.8, page 37 of the application, the applicant states at least one or two clinical staff, including a registered nurse, shall be employed per procedure room. However, based on the staff listed in the applicant's *"Table VII.7 Staffing by Area of Operation,"* there are not enough additional staff or patient care technicians to provide assistance in two procedure rooms. See Criterion (7) for additional discussion. Therefore, the applicant is not conforming to this criterion.

(6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.

-C- On page 37 of the application, the applicant states, "*At least one (1) staff member will be ACLS certified, and at least one (1) other staff member will be BCLS certified. The proposed GI endoscopy facility will likely exceed these minimum requirements.*"

10A NCAC 14C .3906 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NC- On page 38 of the application, the applicant states, *"Kurt G. Vernon, M.D., P.A.. confirms that the proposed GI endoscopy facility will be separately identifiable from administrative, financial, and physical plant perspectives within the physician office facility to meet CFR 416 rules and state licensure and legal requirements."* However, this statement is not sufficient to demonstrate

that the proposed new ambulatory surgical facility will be a separately identifiable entity administratively and will be financially independent and distinct from the rest of the operations of the facility. Specifically, Kurt G. Vernon, M.D. will occupy space in the same building adjacent to the proposed ambulatory surgical facility. However, the application lacks evidence of adequate administrative staff for the proposed ambulatory surgical facility that is separate from the staff of the physician office practice. See Criterion (7) for discussion. Also, because professional fees were not listed as an expense to be paid by the facility to the physicians, it was not clear that the applicant considered the professional practice to be administrated as a separate entity from the ambulatory surgical facility. Therefore, it is not apparent that the new ambulatory surgical facility will be administratively and financially independent and distinct from the other operations of Dr. Vernon. In summary, the applicant did not adequately demonstrate conformance to this rule.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project.

-C- On page 38 of the application, the applicant states it is committed to obtaining accreditation from the Accreditation Association for Ambulatory Health Care and projects to be surveyed for accreditation in June 2007.

(c) If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall:

(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

-C- On page 38 the applicant states, "*The facility is designed to meet all federal, state, and local regulatory body requirements, including the requirements for state licensure and Medicare certification of the proposed GI endoscopy facility.*"

(2) provide a floor plan of the proposed facility identifying the following areas:

(A) receiving/registering area;
(B) waiting area;
(C) pre-operative area;
(D procedure room by type; and
(D) recovery area

-NC Exhibit 32 of the application contains a copy of the facility's floor plan. However, the floor plan for the space to be licensed as the ambulatory surgical facility does

not include a receiving/registering area. Therefore, the application is not conforming to this rule.

(2) *demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,*

-C- On page 39, the applicant states, *"The proposed GI endoscopy suite is physically separated by a separate fire and smoke compartment from the physician office as well as a 2 hour fire and smoke barrier in the ceiling to separate tenants to meet Life Safety Code 2006 and NFPA 101 fire safety requirements."*

(4) *document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.*

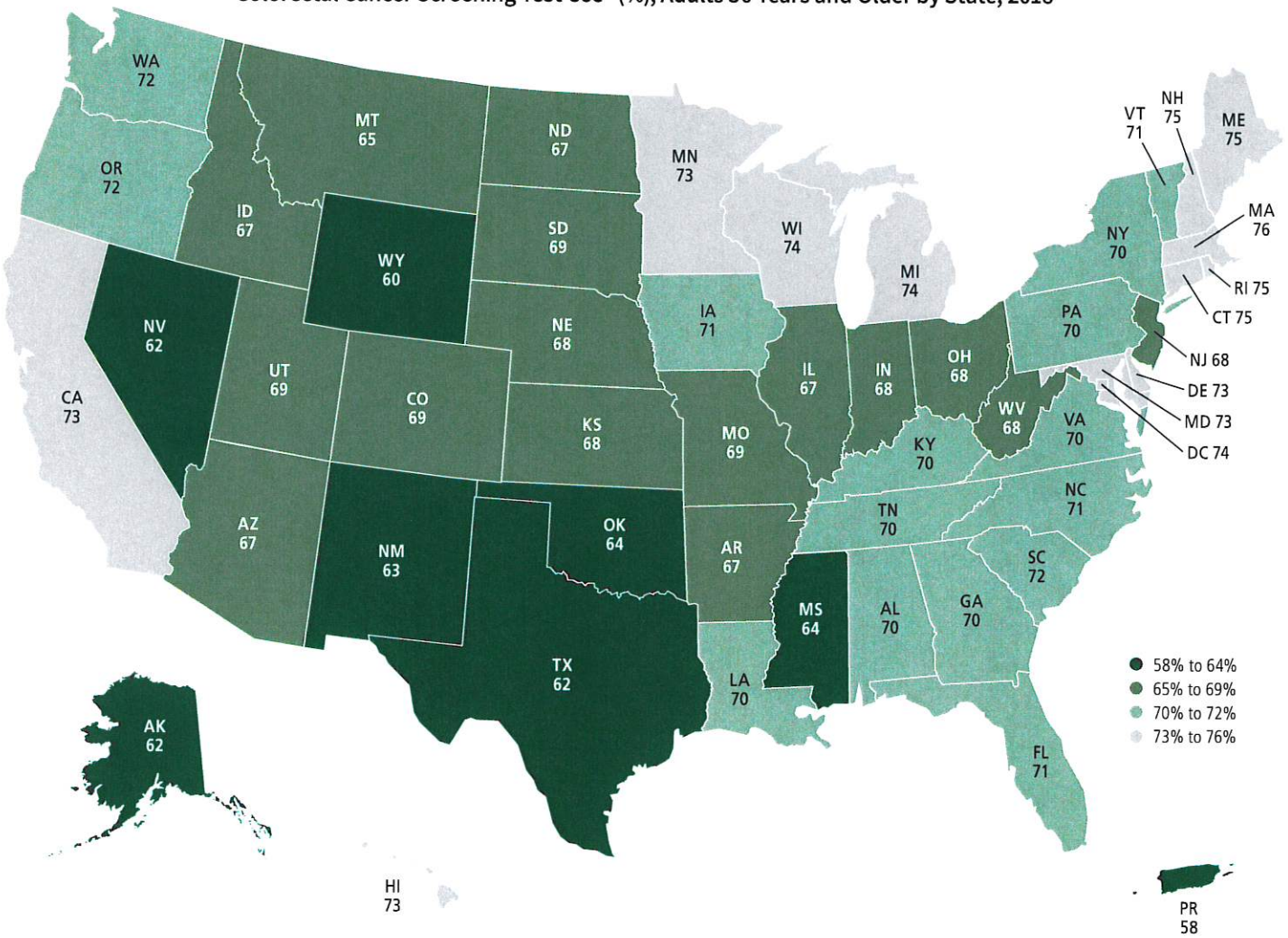
-C- Exhibit 1 of the application contains a copy of the lease agreement between Kurt D. Vernon, M.D., P.A. and Jayku, LLC for the portion of the building to be used for the GI endoscopy facility.

Attachment 3

American Cancer Society®

Colorectal Cancer
Facts & Figures 2020-2022

Colorectal Cancer Screening Test Use* (%), Adults 50 Years and Older by State, 2018



*Blood stool test, sigmoidoscopy, or colonoscopy in the past 1, 5, and 10 years, respectively.
Note: Estimates are age adjusted to the 2000 US standard population and do not distinguish between examinations for screening and diagnosis.
Source: Behavioral Risk Factors Surveillance System, 2018. See Sources of Statistics (page 32) for complete citation and more information.

Contents

This publication ottempts to summarize current scientific information about colorectal cancer. Except when specified, it does not represent the official policy of the American Cancer Society.

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Global Headquarters: American Cancer Society Inc.
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404-320-3333

Colorectal Cancer Basic Facts

What is colorectal cancer?

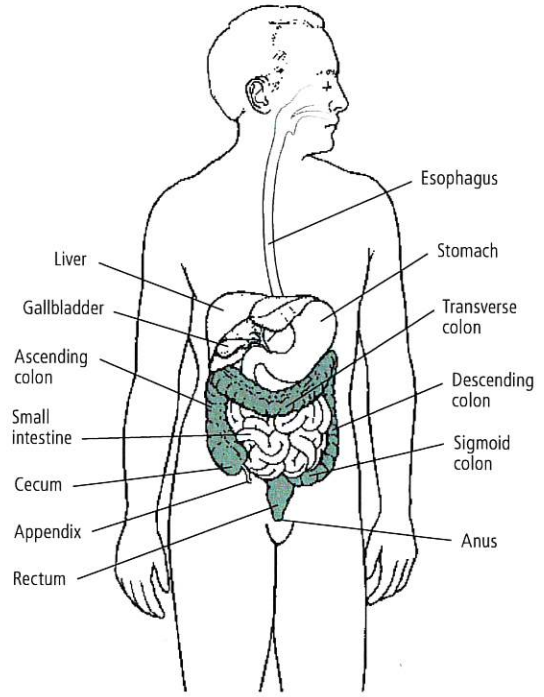
Cancer is a disease characterized by the unchecked division of abnormal cells. When this type of growth occurs in the colon or rectum, it is called colorectal cancer (CRC). The colon and rectum (colorectum), along with the anus, make up the large intestine, the final segment of the gastrointestinal (GI) system. The large intestine is sometimes called the large bowel, which is why CRC is sometimes referred to as bowel cancer. The function of the large intestine is to absorb water and electrolytes from food matter and eliminate feces. As depicted in Figure 1, the first part of the large intestine is the colon, a muscular tube about 1.5 meters (5 feet) long and 5 centimeters (2 inches) in diameter that is divided into 4 sections:

- The *ascending colon* begins with the cecum (a pouch where undigested food is received from the small intestine) and extends upward on the right side of the abdomen.
- The *transverse colon* crosses the body from right to left, and is referred to collectively with the ascending colon as the proximal, or right, colon.
- The *descending colon* descends on the left side.
- The *sigmoid colon*, named for its "S" shape, is the final portion of the colon and is referred to collectively with the descending colon as the distal, or left, colon.

Waste passes from the sigmoid colon into the rectum – the final 15 centimeters (6 inches) of the large intestine – and is then expelled through the anus (2-3 centimeters or 1 inch). Despite their anatomic proximity, cancers in the anus are classified separately from those in the rectum because they usually originate from different cell types, and thus have different characteristics.

However, tumors within the colorectum also vary in their molecular, biological, and clinical features, and in their association with risk factors.[1,2] For example, physical

Figure 1. Anatomy of the Gastrointestinal System



inactivity is associated with increased risk of cancer in the colon, but not in the rectum. In addition, patients are more likely to be diagnosed with tumors in the proximal colon if they are older (versus younger), black (versus white), or female (versus male).[3,4]

What is a colorectal polyp?

CRC almost always begins as a polyp, which is a noncancerous growth that develops in the mucosal layer (inner lining) of the colon or rectum. Polyps are common, detected in about half (including serrated polyps) of average-risk individuals 50 years of age or older undergoing colonoscopy, with higher prevalence in older age groups and among men compared to women.[5] However, fewer than 10% of polyps are estimated to progress to invasive cancer,[6,7] a process that usually occurs slowly over 10 to 20 years and is more likely as polyps increase in size.[8-10]

Polyps are classified based on their growth pattern as adenomatous (i.e., adenoma), which is the most common cancer precursor, or serrated, so-called because of its saw-toothed appearance under a microscope.[11] Serrated

polyps are further subdivided based on biological characteristics into sessile serrated polyps (SSPs), traditional serrated adenomas (TSAs), and hyperplastic polyps (HPs). Similar to adenomas, SSPs, TSAs, and large HPs are associated with an increased risk for CRC. SSPs are the most difficult to detect during colonoscopy because they are usually flat, covered with a mucous cap, and colored like the surrounding tissue. These features likely contribute to their role as precursors for a large proportion of cancers diagnosed prior to the next recommended colonoscopy (interval or post colonoscopy cancers).[12]

What are the stages of colorectal cancer?

Once a polyp progresses to cancer, it can grow into the wall of the colon or rectum where it may invade blood or lymph vessels that carry away cellular waste and fluid (Figure 2). Cancer cells typically spread first into nearby lymph nodes, which are bean-shaped structures that help fight infections. They can also be carried via blood vessels to other organs and tissues, such as the liver or lungs,[13] or be shed directly into the peritoneum (membrane lining the abdomen).[14] The spread of cancer cells to parts of the body distant from where the tumor started is called metastasis.

The extent to which cancer has spread at the time of diagnosis is described as its stage. Staging is essential for determining treatment choices and assessing prognosis (prediction of disease outcome). The two most common cancer staging systems are the American Joint Committee on Cancer (AJCC) tumor, node, and metastasis (TNM) system, typically used in clinical settings, and the Surveillance, Epidemiology, and End Results (SEER) summary staging system, used for descriptive and statistical analysis of tumor registry data. In this document, we will describe CRC stages using the SEER summary staging system:

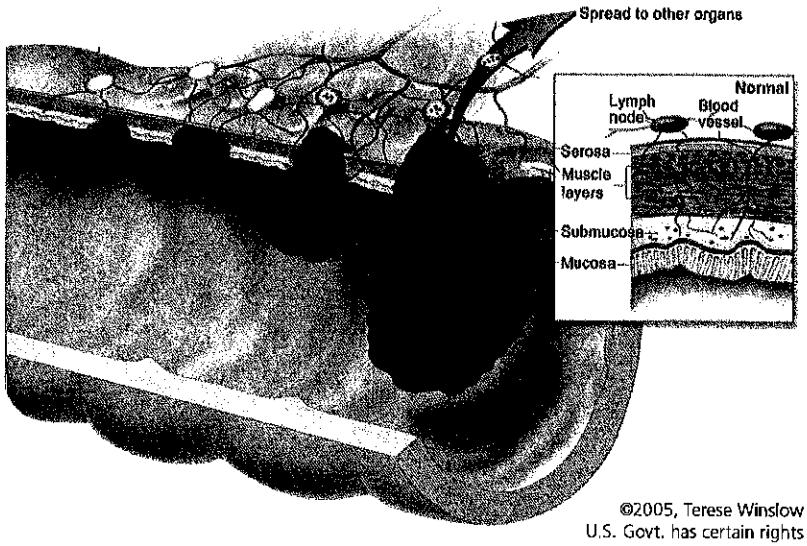
- **In situ:** Cancers that have not yet begun to invade the wall of the colon or rectum; these preinvasive lesions are not included in the cancer statistics provided in this report
- **Local:** Cancers that have grown into the wall of the colon or rectum, but have not extended through the wall into nearby tissues
- **Regional:** Cancers that have spread through the wall of the colon or rectum and have invaded nearby tissue, or that have spread to nearby lymph nodes
- **Distant:** Cancers that have spread to other parts of the body, such as the liver or lung

What are the symptoms of colorectal cancer?

Early CRC often has no symptoms, which is one of the reasons screening is so important. As a tumor grows, it may bleed or block the intestine. The most common symptoms are:

- Bleeding from the rectum
- Blood in the stool or in the toilet after having a howel movement
- Dark or black stools

Figure 2. Stages of Colorectal Cancer Growth



- A change in bowel habits or the shape of the stool (e.g., more narrow than usual)
- Cramping, pain, or discomfort in the lower abdomen
- An urge to have a bowel movement when the bowel is empty
- Constipation or diarrhea that lasts for more than a few days
- Decreased appetite
- Unintentional weight loss

In some cases, blood loss from the cancer leads to anemia (low number of red blood cells), causing symptoms such as weakness, excessive fatigue, and sometimes shortness of breath. Timely evaluation of symptoms consistent with CRC is essential for all individuals, regardless of age, given the increasing incidence in young adults (see page 6).

Colorectal Cancer Occurrence

How many new cases and deaths are estimated to occur in 2020?

In 2020, there will be an estimated 104,610 new cases of colon cancer and 43,340 cases of rectal cancer diagnosed in the US (Table 1). Although the majority of CRCs are in adults ages 50 and older, 17,930 (12%) will be diagnosed in individuals younger than age 50, the equivalent of 49 new cases per day.

An estimated 53,200 people will die from CRC in 2020, including 3,640 men and women younger than age 50. Unfortunately, reliable statistics on deaths from colon and rectal cancers separately are not available because almost 40% of deaths from rectal cancer are misclassified as colon cancer on death certificates.[15] The high level of misclassification is partly attributed to the misconception among some that the terms colon cancer and colorectal cancer are synonymous because of the widespread use of "colon cancer" to refer to both colon and rectal cancers in educational messaging. To help mitigate the issue and be more explicitly inclusive of rectal cancer patients, several organizations have publicly ended this practice.[16] The ability to study these deaths separately is increasingly important given the steep rise in rectal cancer incidence among younger adults.[17]

Table 1. Estimated Number of Colorectal Cancer Cases and Deaths in the US in 2020 by Age

	Cases			Deaths*
Age	Colorectum	Colon	Rectum	Colorectum
0-49 years	17,930	11,540	6,390	3,640
50-64 years	50,010	32,290	17,720	13,380
65+ years	80,010	60,780	19,230	36,180
All ages	147,950	104,610	43,340	53,200

Estimates are rounded to the nearest 10 and exclude in situ carcinoma.
*Deaths for colon and rectal cancers are combined because a large number of rectal cancer deaths are misclassified as colon.

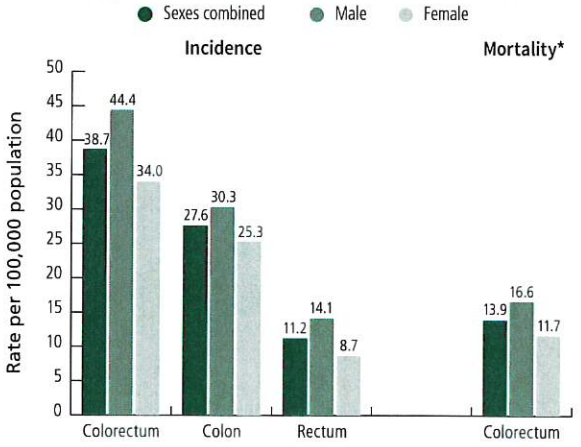
How many people who have been diagnosed with colorectal cancer are alive today?

As of January 1, 2019, there were 776,120 men and 768,650 women alive in the US with a history of CRC.[18] About one-third (35%) of these individuals were diagnosed within the preceding 5 years, and more than half (56%) were ages 65-84 years. Some of these people were cancer-free, while others still had evidence of cancer and may have been undergoing treatment.

What is the risk of developing colorectal cancer?

Approximately 4.4% of men (1 in 23) and 4.1% of women (1 in 25) will be diagnosed with CRC in their lifetime.[19] Lifetime risk is similar in men and women despite higher incidence rates in men because women have longer life expectancy. In addition to sex, age and race/ethnicity also have a large influence on risk.

Figure 3. Colorectal Cancer Incidence (2012-2016) and Mortality (2013-2017) Rates by Subsite and Sex, US



Rates are age adjusted to the 2000 US standard population. *Mortality rates by anatomic subsite are not available because a large number of rectal cancer deaths are misclassified as colon.

Sources: Inicdence – North American Association of Central Cancer Registries (NAACCR), 2019. Mortality – National Center for Health Statistics (NCHS), 2019.

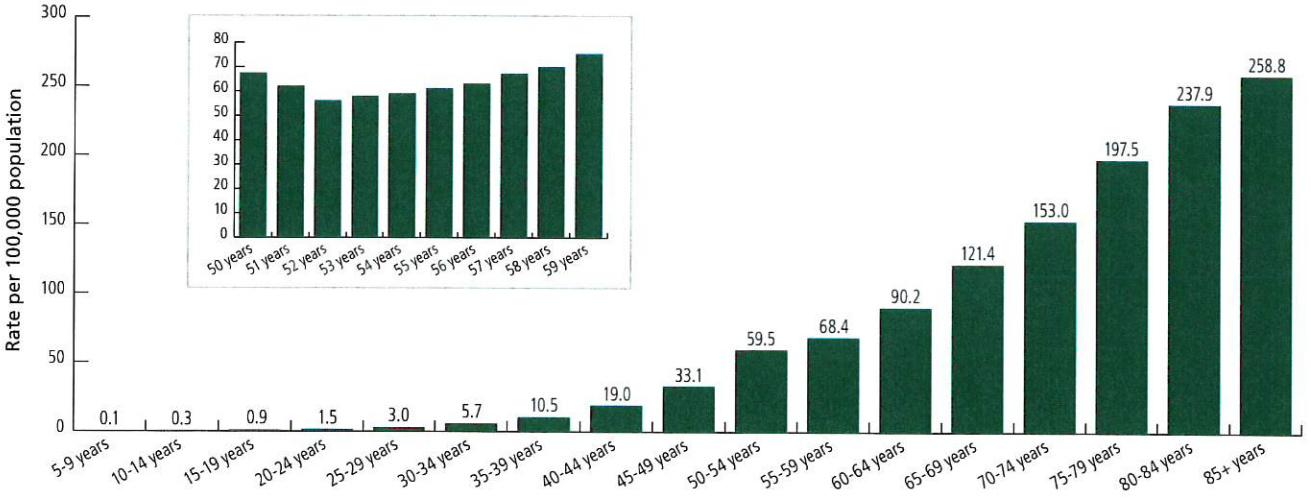
Sex

CRC incidence rates are 30% higher in men than in women, with a larger disparity for rectal cancer (60% higher) than for colon cancer (20% higher; Figure 3). As expected, women also have a lower prevalence of both adenomas overall and of advanced adenomas.[20, 21] However, among individuals 50 and older, women are more likely than men to develop adenomas in the proximal colon,[20] which are less efficiently detected through screening.[22] Gender disparities likely reflect differences in exposures to risk factors (e.g., cigarette smoking) and sex hormones, as well as complex interactions between these influences.[23] Notably, CRC incidence rates in men and women younger than 45 years are comparable.

Age

Like most types of cancer, the risk of CRC increases with age. For every subsequent 5-year age group, the incidence rate approximately doubles until age 50, and thereafter increases by about 30% (Figure 4). The exception is ages 50-54 years versus ages 55-59 years, for which there is only a 15% difference (60 versus 68 per 100,000, respectively), partly because the natural age-associated influence on risk is disrupted by first-time CRC screening in the younger age group. The screening effect is magnified in current rates by single year of age (Figure 4), which are actually higher in individuals ages 50-51 years than in those ages 52-55 years. This phenomenon is absent in incidence rates during the 1970s, prior to the uptake of screening.

Figure 4. Age-specific Colorectal Cancer Incidence Rates, US, 2012-2016



Source: Main figure: NAACCR, 2019. Inset: Surveillance, Epidemiology, and End Results (SEER) Program, 2019.

The median age at CRC diagnosis is 66 years in men and 69 years in women, but is younger for rectal cancer (age 62 and 63, respectively) than for colon cancer (age 67 and 71, respectively).[24] CRC patients overall are increasingly younger, shifting from a median age of 72 years for diagnoses in the early 2000s to 66 years today.[25] This is because incidence is increasing in younger adults and declining in older age groups.[17]

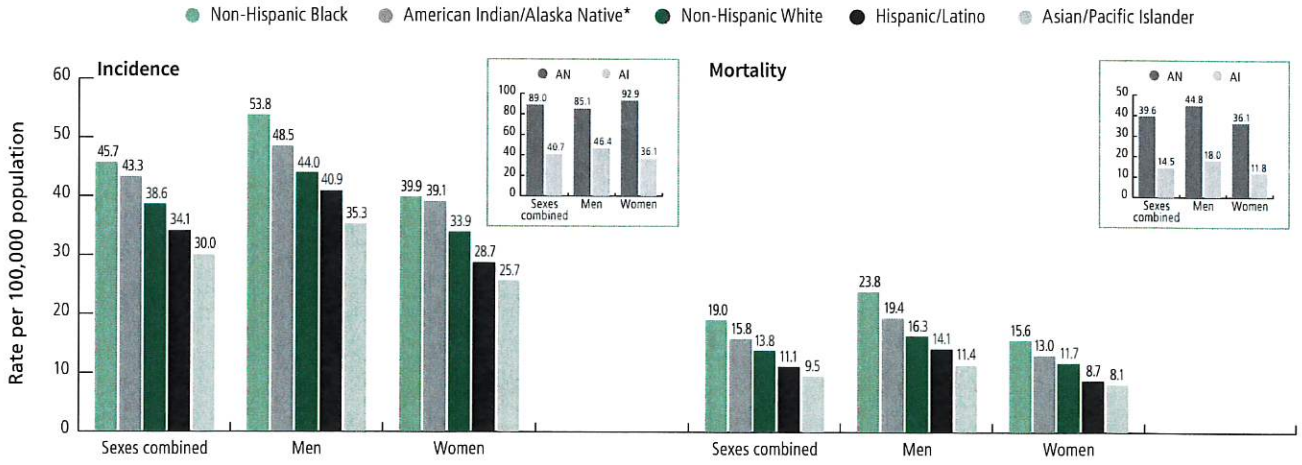
Race/ethnicity

Among broadly defined racial and ethnic groups, CRC incidence and mortality are highest in non-Hispanic blacks (hereafter, blacks), followed closely by American Indians and Alaska Natives (AIANs), and lowest in Asians/Pacific Islanders (APIs; Figure 5). During 2012-2016, CRC incidence rates in blacks were about 20% higher than those in non-Hispanic whites (NHWs) and 50% higher than those in APIs. The disparity for mortality is twice that for incidence; CRC death rates in blacks are almost 40% higher than those in NHWs and double those in APIs.

Reasons for racial/ethnic disparities in CRC are complex, but largely reflect differences in risk factor prevalence and health care access, both of which are related to socioeconomic status.[26] In 2018, the median family income was $41,361 among blacks compared to $70,642 among NHWs, with 21% and 8%, respectively, living in poverty.[27] People with the lowest socioeconomic status are 40% more likely to be diagnosed with CRC than those with the highest socioeconomic status.[28] Close to half (44%) of this disparity is attributed to differences in the prevalence of risk factors associated with CRC (e.g., smoking, obesity)[29] and a similar proportion is due to differences in CRC screening.[30] After controlling for differences in risk factors, black individuals are no more likely than whites to develop adenomas or CRC, but are less likely to receive timely follow-up of a positive screening test and/or high-quality colonoscopy.[31,32] Higher CRC mortality among blacks may also reflect a larger proportion of tumors in the proximal colon.[3]

Importantly, the broad racial and ethnic groups to which cancer statistics are generally limited mask striking differences within these heterogeneous populations. For example, although CRC incidence in API men overall is 25% lower than in NHW men, rates in Japanese men are 23% higher.[33] Even more alarming is the burden among Alaska Natives, who have the highest CRC incidence (89 per 100,000) and mortality (40 per 100,000) rates in the US, double those in blacks (46 and 19, respectively). CRC

Figure 5. Colorectal Cancer Incidence (2012-2016) and Mortality (2013-2017) Rates by Race/Ethnicity and Sex, US



AI: American Indian, excluding Alaska; AN: Alaska Native. Rates are age adjusted to the 2000 US standard population. *Statistics based on data from Purchased/Referred Care Delivery Area (PRCDA) counties. AI/AN incidence rates exclude data from Kansas and Minnesota. Incidence rates for Alaska Native men and women are not statistically significantly different.

Source: Incidence – NAACCR, 2019. Mortality – NCHS, 2019.

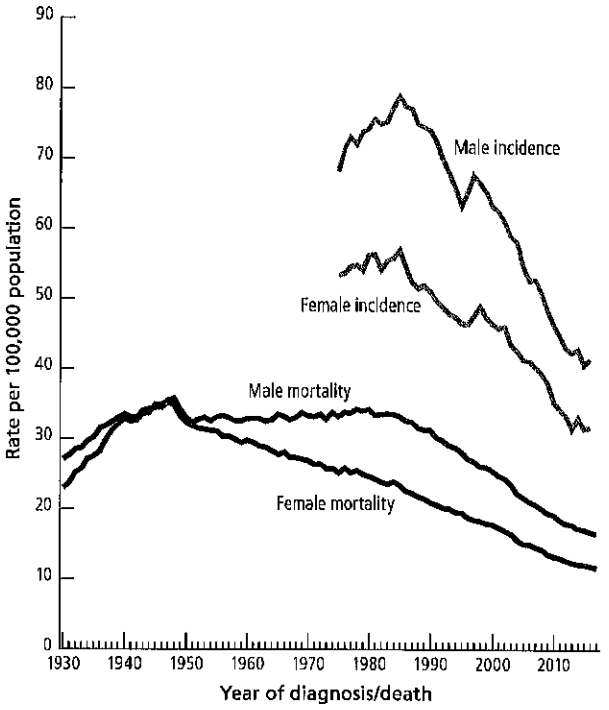
has been the most commonly diagnosed cancer in Alaska Natives since the early 1970s for reasons that are unknown, but may include a higher prevalence of CRC risk factors, such as a diet high in animal fat and low in fruits and vegetables, vitamin D deficiency, smoking, obesity, and diabetes.[34,35] In addition, Alaska Natives, particularly rural residents, have a high prevalence of *Helicobacter pylori* (*H. pylori*),[36] a bacteria associated with inflammation and cancer of the stomach that may also be associated with CRC risk.[37,38] Despite a disproportionately high burden of advanced adenomas among Alaska Natives,[39] the availability of endoscopic services in much of Alaska is inadequate.[40,41] A recent study found that Alaska had the lowest county-level CRC screening prevalence in the nation.[42] In addition, the primary mode of screening at Indian Health Service facilities is stool testing, which has a limited capacity for cancer prevention and requires timely follow-up with colonoscopy for positive tests. Notably, AIANs are the only racial and ethnic group for which CRC mortality rates are not declining (see page 8).

How has colorectal cancer occurrence changed over time?

Incidence

Despite higher incidence in men than in women, trends over time are very similar by sex (Figure 6). CRC incidence rates increased from 1975 through the mid-1980s, but since have generally decreased. The decline prior to 2000 is attributed equally to changing patterns in risk factors (e.g., reductions in smoking) and the uptake of CRC screening.[43] However, the accelerated decline that began during the late 2000s is thought to predominantly reflect widespread uptake of CRC screening with colonoscopy, which increased among adults ≥50 years of age from 20% in 2000 to 61% in 2018.[44] There is about a decade of lag time between the detection and removal of precancerous polyps through screening and its reflection on CRC incidence rates.[9,45] Notably, however, declines in CRC incidence have decelerated in the most recent 5 data years (2012-2016), perhaps reflecting a slowing in first-time screening,[46] changing risk factors exposures, such as obesity, or a combination thereof.

Figure 6. Trends in Colorectal Cancer Incidence (1975-2016) and Mortality (1930-2017) Rates by Sex, US



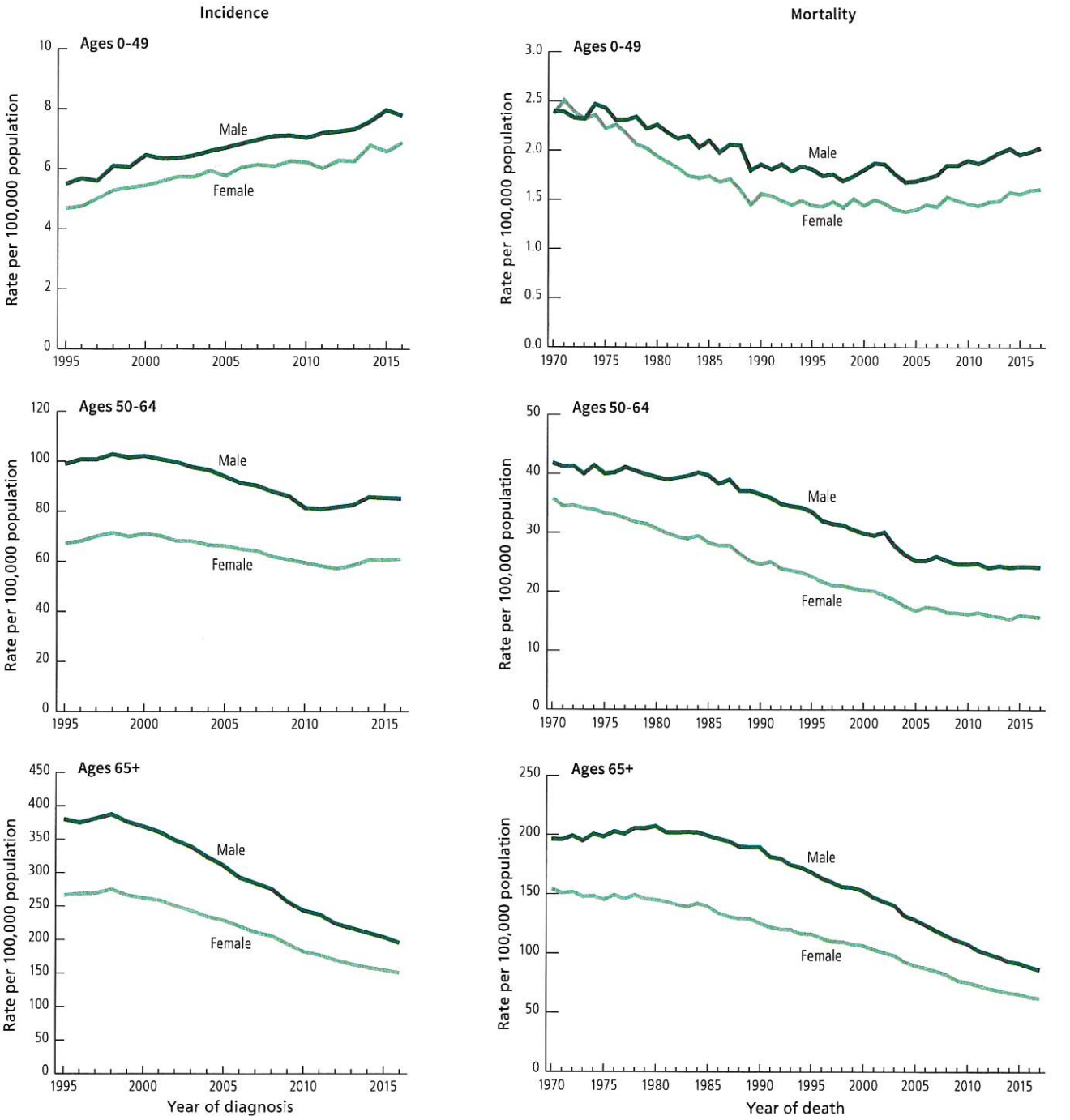
Rates are age adjusted to the 2000 US standard population. Incidence rates are adjusted for delays in reporting and exclude appendix. Due to changes in International Classification of Diseases (ICD) coding, numerator information for mortality has changed over time.

Source: Incidence – Surveillance, Epidemiology, and End Results (SEER) Program, 2019. Mortality – US Mortality Volumes 1930 to 1959, US; Mortality Data 1960-2017, NCHS, 2019.

Age-specific incidence trends

CRC trends overall reflect the majority of cases that occur in older age groups, masking trends in young adults. CRC incidence rates have been increasing since the mid-1980s in adults ages 20-39 years and since the mid-1990s in adults ages 40-54 years, with younger age groups experiencing the steepest increase.[17] This pattern is called a *birth cohort effect* because generations of individuals with higher incidence carry the elevated risk with them as they age. Indeed, after decades of decline, incidence rates have also begun to increase in ages 50-64 years. During the most recent five data years (2012-2016), incidence rates increased by 2.2% annually in individuals younger than 50 years and by 1% annually in those ages 50-64 years, a sharp contrast to declines of 3.3% per year in adults ages 65 and older (Figure 7). Although a similar incidence pattern

Figure 7. Trends in Colorectal Cancer Incidence (1995-2016) and Mortality (1970-2017) Rates by Age and Sex, US



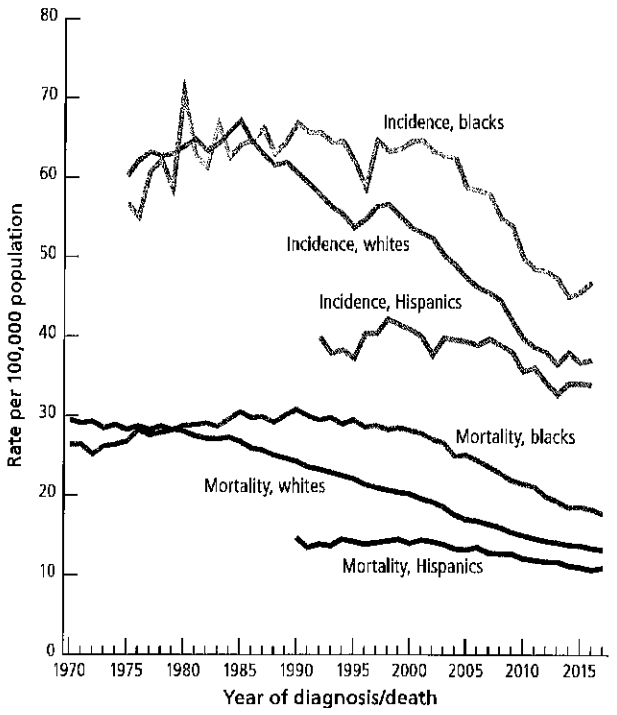
Rates are age adjusted to the 2000 US standard population. Incidence rates are adjusted for reporting delays and exclude appendix.
Source: Incidence – NAACCR, 2019. Mortality – NCHS, 2019.

has been reported in many other high-income countries,[47] reasons for the increasing trend in younger age groups are unknown. It may reflect changes in established risk factors, such as a more sedentary lifestyle and/or unfavorable dietary patterns, or other exposures whose association with CRC risk is yet unknown.

Racial/ethnic incidence trends

Historical cancer incidence data in the US are available only for the categories white, black, and other race. CRC incidence was similar in whites and blacks until the mid-1980s, when rates began declining in whites while remaining stable in blacks (Figure 8). These trends created a widening racial gap until the mid-2000s and likely reflect a combination of earlier access to and more rapid uptake of CRC screening tests among whites, as well as changing patterns in the prevalence of CRC risk factors.[48] Since the mid-2000s, CRC incidence rates decreased by about 1%-3% per year in all broadly defined racial/ethnic groups, although the pace appears to be slowing in recent years.[24] Notably, the steepest increase in early-onset CRC is among NHWs and AIANs.[49] As a result, incidence rates in NHWs ages 20-49 years are now equivalent to those in blacks (14.1 per 100,000 during 2015-2016), despite being 40% higher in blacks during 1995-1996.[50]

Figure 8. Trends in Colorectal Cancer Incidence (1975-2016) and Mortality (1970-2017) Rates by Race, US



Rates are age adjusted to the 2000 US standard population. Incidence rates are adjusted for reporting delays and exclude appendix. White and black race are not mutually exclusive from Hispanic ethnicity.

Source: Incidence – SEER program, 2019. Mortality – NCHS, 2019.

Mortality

CRC death rates have been decreasing since 1947 in women, but only since 1980 in men (Figure 6). This inconsistency likely reflects sex differences in incidence trends because of variable patterns in CRC risk factors, although population-based incidence data are not available prior to 1975. Trends over the past three decades are very similar by sex. Declines in mortality through 2000 are attributed to improvements in treatment (12%), changing patterns in CRC risk factors (35%), and screening (53%).[43] However, screening likely played an even larger role in more recent trends given its steep increase since 2000.[52] Rapid declines in CRC death rates of about 3% per year from 2002 to 2012 slowed to 2% per year from 2012 to 2017.

Age-specific mortality trends

Like incidence, CRC mortality trends vary by age (Figure 7). Among older adults, decades of rapid declines have slowed, from 1% annually during 2004-2013 to 0.6% during 2013-2017 in those ages 50-64 years and from 3.3% to 2.6%, respectively, in those ages 65 and older. In contrast, CRC death rates have increased in individuals younger than 50 years of age by 1.3% per year since 2004.

Racial/ethnic mortality trends

CRC death rates in whites began a slow decline in the early 1970s that accelerated over time. In contrast, death rates in blacks increased from the early 1970s until 1990, then decreased sluggishly during the 1990s before matching the decline in whites in the early 2000s (Figure 8). As a result of these divergent trends, although CRC death rates in blacks were 10% lower than those in whites in the early 1970s, they were almost 50% higher in 2005. The widening racial disparity was largely driven by trends for distant-stage disease, which declined in whites while remaining stable in blacks through the mid-2000s.[53] About half of the racial disparity in mortality is attributed to a combination of less screening and lower stage-specific survival rates among blacks.[30] Since the early 2000s, CRC death rates have declined consistently by 1.8% per year in Hispanics and APIs and by 2.8% per year in blacks; however, rates were stable in AIANs during this time, and in whites declines slowed from 2.5% per year during

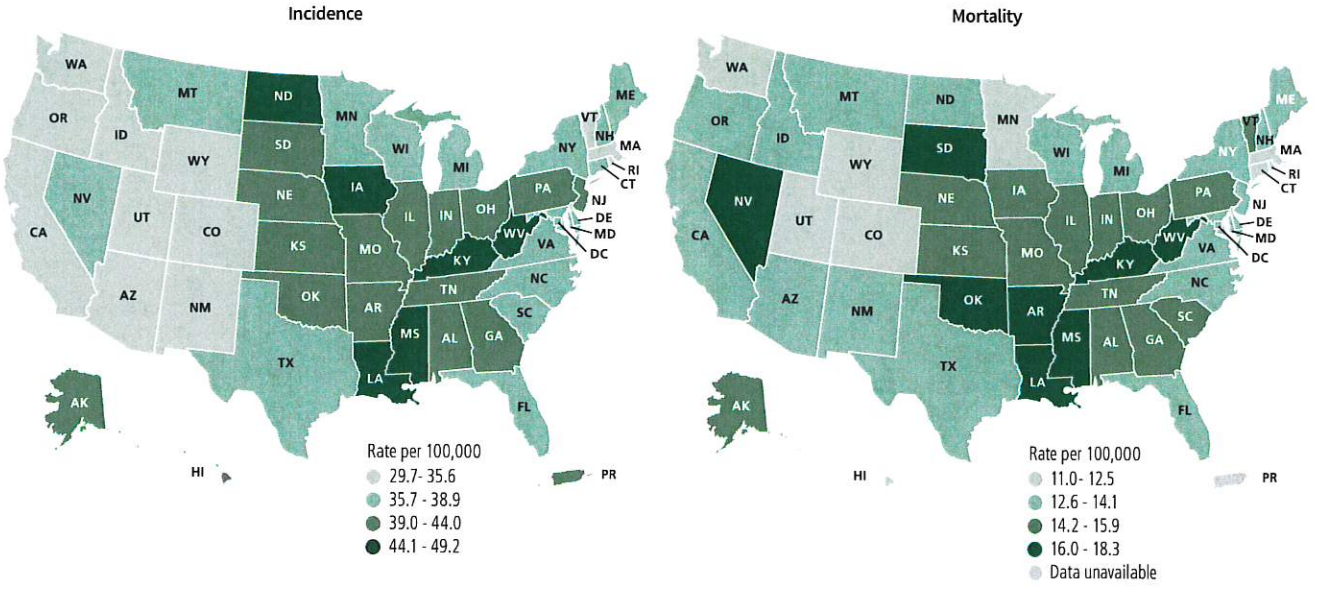
2005-2012 to 1.6% per year during 2012-2017. As a result, the black-white gap has slowly begun to narrow.

How does colorectal cancer occurrence vary by state?

The geographic pattern of CRC has changed dramatically over the past several decades. In contrast to the 1970s and 1980s, when the burden was highest across the Northeast and lowest in the South,[54] today it is highest in parts of the South, Midwest, and Appalachia and lowest in the West and Northeast. Current incidence rates range from 49 (per 100,000) in Kentucky to 30 in Utah, while death rates range from 18 in Mississippi and West Virginia to 11 in Connecticut and Utah (Figure 9). This shift is consistent with the racial and socioeconomic crossover in disease burden that occurred during the latter half of the 20th century because of changes in dietary and smoking patterns, as well as differences in access to early detection and high-quality treatment.[55] For example, CRC mortality among residents of poor counties was 20% lower than that among residents of affluent counties in the early 1970s, but is currently 30% to 40% higher.[54, 56] Geographic patterns are generally similar for blacks and whites, particularly for mortality, highlighting the importance of socioeconomic status over race in cancer disparities.[57]

Table 2 shows state-level incidence and death rates by race/ethnicity. Consistent with overall incidence, rates in NHWs and blacks are lowest in the West and highest in the South and Midwest. However, among Hispanics there is no clear pattern, perhaps reflecting geographic heterogeneity within this population in terms of place of birth and duration of residence, both of which influence CRC risk. Although data for AIANs are too sparse to provide by state, a recent study found that incidence rates for those living in Alaska (approximately 95 per 100,000) were more than two-fold higher than those living in the East and Southwest regions (30 to 40 per 100,000) of the US during 2010-2015.[58] Factors that may contribute to this disparity include differences in diet and the prevalence of obesity and smoking, as well as access to medical services, including screening. Among some more isolated groups (e.g., Alaska Natives), genetic differences may also play a role. (See page 5 and page 6 for more information about CRC in Alaska Natives.)

Figure 9. Colorectal Cancer Incidence (2012-2016) and Mortality (2013-2017) Rates by State, US



Nevada and the District of Columbia did not meet NAACCR high-quality incidence data standards for one or more years during 2012-2016. Incidence rates for the District of Columbia are based on data years 2012-2014. Rates are age adjusted to the 2000 standard population.

Sources: Incidence – NAACCR, 2019. Mortality – NCHS, 2019.

Table 2. Colorectal Cancer Incidence (2012-2016) and Mortality (2013-2017) Rates* by Race/Ethnicity and State, US

	Incidence						Mortality					
	Men			Women			Men			Women		
State	Non-Hispanic white	Non-Hispanic black	Hispanic	Non-Hispanic white	Non-Hispanic black	Hispanic	Non-Hispanic white	Non-Hispanic black	Hispanic	Non-Hispanic white	Non-Hispanic black	Hispanic
Alabama	49.4	58.9	27.6	36.3	44.6	25.5	18.5	26.4	†	12.0	17.7	†
Alaska	37.0	†	†	33.1	†	†	13.3	†	†	11.5	†	†
Arizona	37.8	33.5	41.9	29.2	33.1	26.2	15.3	18.2	15.3	10.9	16.4	8.8
Arkansas	50.1	58.2	29.4	36.5	45.8	32.0	19.4	26.0	†	13.0	19.5	†
California	40.4	48.5	38.4	32.4	39.4	27.7	14.9	21.9	13.9	11.7	16.0	8.8
Colorado	35.5	48.8	44.7	29.5	34.6	33.5	13.4	19.5	16.8	10.4	11.5	11.3
Connecticut	40.8	46.1	49.4	31.5	36.1	32.9	13.0	16.7	12.8	9.5	10.9	7.1
Delaware	42.8	51.0	34.9	32.2	38.4	42.8	17.5	17.1	†	10.2	15.7	†
Dist. Of Columbia‡,§	29.2	61.7	†	27.8	44.6	†	7.9	26.9	†	7.3	17.8	†
Florida	41.3	48.9	43.5	31.3	36.7	31.6	15.5	20.6	14.6	10.9	14.0	9.6
Georgia	47.8	57.3	37.3	34.5	41.4	30.9	17.6	25.7	10.4	11.5	15.1	5.6
Hawaii	42.2	44.5	46.5	37.3	†	42.5	12.3	†	19.7	13.0	†	†
Idaho	39.4	†	31.4	32.3	†	24.0	15.4	†	11.9	11.4	†	†
Illinois	50.3	64.4	37.5	36.8	45.9	28.5	17.5	29.1	12.4	12.4	19.0	6.8
Indiana	48.7	52.6	35.7	38.0	41.4	31.1	18.0	24.4	10.5	12.9	17.0	6.3
Iowa	50.5	57.8	36.2	39.7	37.5	19.1	17.3	18.0	†	12.7	16.2	†
Kansas	45.2	56.6	44.8	34.9	38.5	24.7	17.8	25.3	16.8	12.2	16.4	8.9
Kentucky	57.8	59.4	32.8	42.4	45.0	21.5	20.2	24.6	†	13.9	16.7	†
Louisiana	51.6	65.8	28.9	36.9	47.8	22.3	18.5	28.5	†	13.0	18.2	†
Maine	41.9	†	†	33.8	†	†	14.7	†	†	11.4	†	†
Maryland	40.0	47.8	28.4	33.1	35.6	22.3	15.4	22.5	7.5	11.5	13.9	5.2
Massachusetts	39.6	44.6	33.1	31.6	33.4	23.2	14.1	16.3	8.5	10.5	11.4	7.5
Michigan	40.7	55.3	36.1	32.4	40.8	25.3	15.8	23.6	11.6	11.5	17.0	9.4
Minnesota	42.1	47.9	33.6	33.4	40.0	43.5	14.3	13.2	†	10.7	13.2	12.6
Mississippi	52.9	70.4	†	37.8	48.9	†	20.2	30.5	†	13.9	18.0	†
Missouri	47.6	56.6	29.8	35.1	41.8	23.7	17.3	26.1	†	12.0	16.1	†
Montana	42.1	†	63.0	32.2	†	†	15.5	†	†	10.6	†	†
Nebraska	49.0	70.8	36.9	37.5	38.5	33.9	17.5	27.8	†	12.5	20.7	†
Nevada‡	42.3	47.1	35.2	33.5	33.3	25.5	19.9	30.4	13.6	14.9	17.0	9.1
New Hampshire	42.2	†	†	33.2	†	†	14.1	†	†	11.8	†	†
New Jersey	48.1	54.1	43.8	36.9	41.5	32.9	17.1	24.2	12.4	12.4	14.5	8.1
New Mexico	33.7	32.0	42.5	27.8	32.3	30.8	14.7	†	18.8	10.5	†	12.1
New York	44.8	50.7	43.6	34.8	36.6	29.1	15.3	18.2	13.6	11.3	13.7	8.2
North Carolina	41.7	51.6	27.8	32.0	36.3	24.2	15.3	23.2	6.4	10.6	14.8	6.0
North Dakota	51.9	†	†	36.8	†	†	16.5	†	†	11.0	†	†
Ohio	47.1	48.1	33.0	36.2	37.3	21.1	18.2	23.2	7.4	13.0	15.8	7.3
Oklahoma	46.8	54.6	37.3	35.2	40.6	33.0	20.3	28.4	14.1	13.7	15.6	6.7
Oregon	38.6	40.3	35.8	30.6	31.4	29.0	15.3	21.0	11.2	11.6	†	6.2
Pennsylvania	48.5	52.7	40.3	36.0	41.3	26.9	17.6	23.4	13.5	12.3	15.4	9.0
Rhode Island	38.5	35.7	35.3	31.4	25.2	23.0	14.9	†	†	11.5	†	†
South Carolina	42.5	54.5	29.0	32.4	37.3	30.4	16.0	24.8	†	11.1	14.9	†
South Dakota	46.4	†	†	36.2	†	†	19.5	†	†	12.5	†	†
Tennessee	45.7	56.9	21.4	35.2	41.4	17.4	17.7	28.3	†	12.5	18.0	†
Texas	44.5	56.4	46.0	32.1	40.9	28.0	17.2	26.6	17.2	11.4	16.3	8.9
Utah	32.9	58.7	38.7	25.6	†	32.2	12.7	†	12.5	9.6	†	9.1
Vermont	37.3	†	†	33.2	†	†	16.4	†	†	13.9	†	†
Virginia	39.2	49.4	25.5	31.3	38.2	24.0	15.8	24.4	9.1	10.9	15.2	6.3
Washington	39.2	42.6	36.0	32.5	33.8	26.1	14.7	17.1	9.5	10.9	13.3	6.5
West Virginia	52.0	50.1	†	41.5	43.6	†	20.4	30.6	†	15.8	15.8	†
Wisconsin	41.5	64.0	28.9	31.9	43.7	25.6	15.0	24.7	11.7	11.0	16.9	6.8
Wyoming	36.9	†	41.7	28.6	†	32.6	14.1	†	†	10.0	†	†
US	**44.0**	**53.8**	**40.8**	**33.9**	**39.9**	**28.7**	**16.3**	**23.8**	**14.1**	**11.7**	**15.6**	**8.7**

*Rates are per 100,000 and age adjusted to the 2000 US standard population. †Statistics not displayed due to fewer than 25 cases or deaths. ‡Incidence data for these states are not included in US combined incidence rates because data did not meet inclusion standards for all years during 2012-2016 according to the North American Association of Central Cancer Registries (NAACCR). §Rates are based on cases diagnosed during 2012-2014.

Sources: Incidence – NAACCR, 2019. Mortality – NCHS, 2019.

Colorectal cancer survival

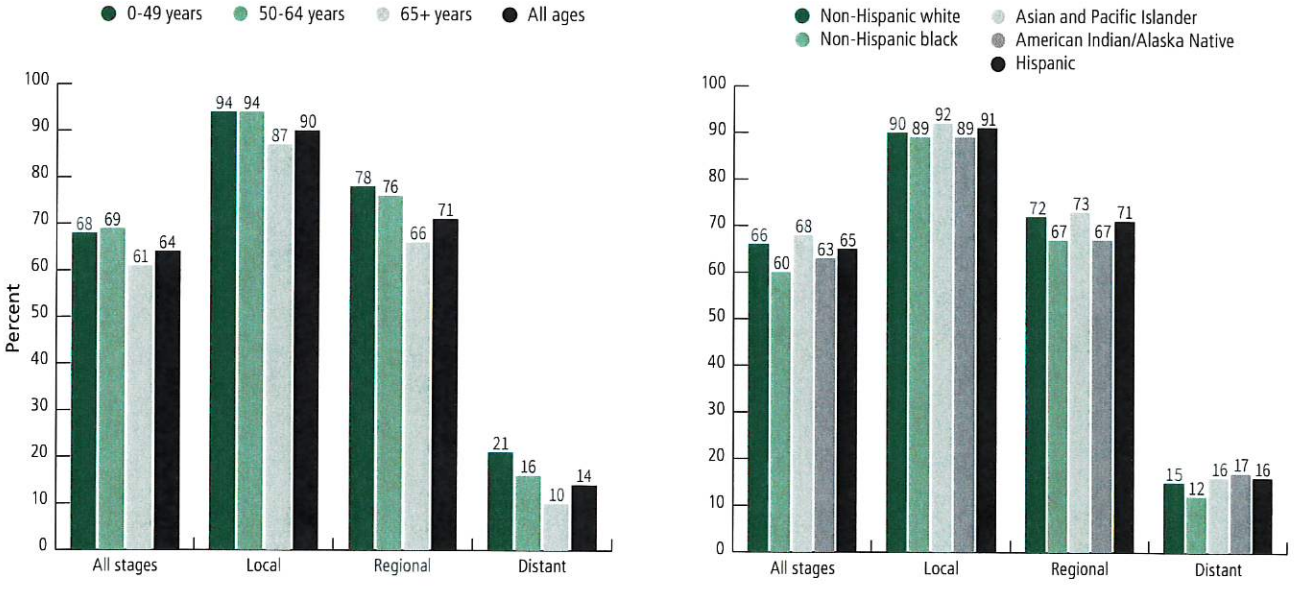
The relative survival rate for CRC is 64% at 5 years following diagnosis and 58% at 10 years.[59] The most important predictor of CRC survival is stage at diagnosis. The 5-year survival rate is 90% for the 39% of patients diagnosed with localized-stage disease, but declines to 71% and 14% for those diagnosed with regional and distant stages, respectively (Figure 10 and Figure 11). Rectal cancer is diagnosed at a localized stage slightly more often than colon cancer, 41% versus 38%, likely due to the earlier appearance of symptoms and partly explaining the higher overall 5-year relative survival (67% versus 63%). Factors associated with advanced-stage CRC diagnosis include low socioeconomic status, black race, and young age.[60, 61]

Factors associated with CRC survival in addition to stage include age at diagnosis, the presence of other illnesses, and other tumor and patient characteristics, such as race/ethnicity and socioeconomic status.[62] For reasons that are not explained by tumor differences or other known factors, women are slightly more likely than men to survive after a CRC diagnosis.[63] There is some evidence that patients with tumors located in the proximal colon have lower survival rates than those with tumors in the distal colon,[64] but this association may be confined to distant-stage diagnoses.[65]

Age

Although CRC patients younger than age 50 have higher 5-year relative survival rates than their older counterparts for every stage of diagnosis (Figure 10), overall survival among patients younger than age 50 (68%) is similar to that in ages 50-64 years (69%) because of a later stage at diagnosis. Approximately 26% of CRCs are diagnosed at a distant stage among patients younger than age 50, compared to 23% in ages 50-64 years and 19% among those ages 65 and older (Figure 11). Despite having the highest proportion of early-stage diagnoses, however, individuals ages 65 and older have the lowest overall 5-year relative survival (61%) because their stage advantage is outweighed by age-related disadvantages, such as additional health issues.

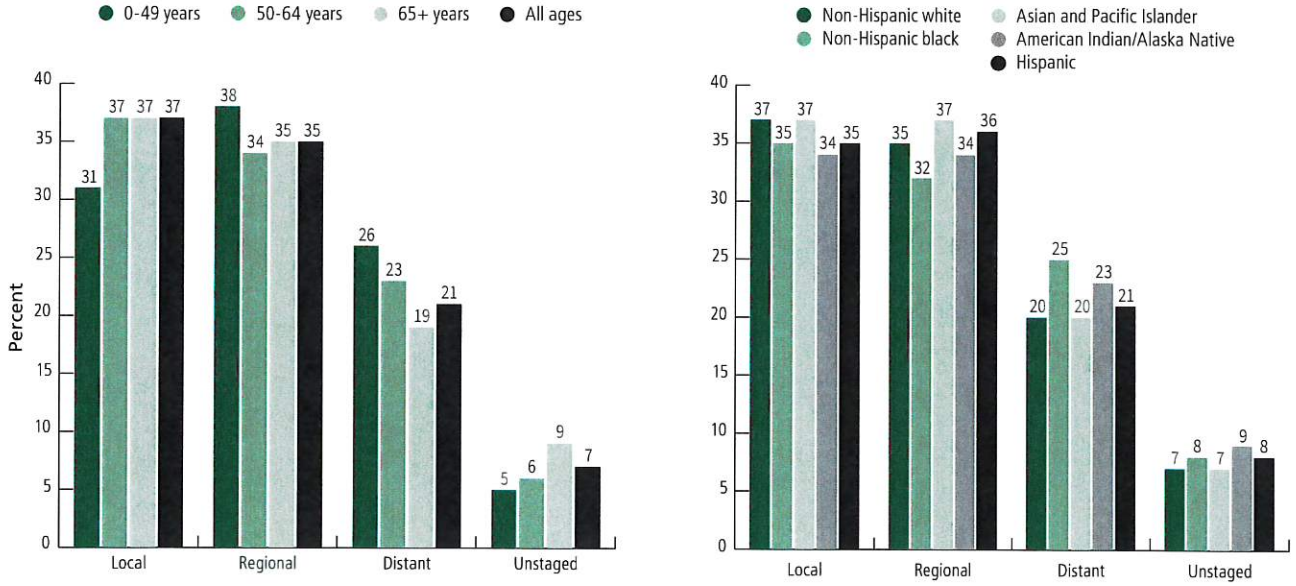
Figure 10. Colorectal Cancer Five-year Survival (%) by Age and Race/Ethnicity, 2009-2015



*Cause-specific survival rates are the probability of not dying from colorectal cancer within 5 years of diagnosis. Rates are based on cases diagnosed from 2009 to 2015, all followed through 2016. Rates for American Indians/Alaska Natives are based on small case numbers, particularly for distant-stage disease.

Source: SEER Program, 2019.

Figure 11. Colorectal Cancer Stage Distribution (%) by Age and Race/Ethnicity, 2012-2016



Source: NAACCR, 2019.

Race/ethnicity

Outcomes among racial/ethnic minorities are described in terms of cause-specific survival because life expectancy data for minority groups are inadequate to calculate relative survival. The highest CRC survival rates are for APIs (68%) and the lowest are for blacks (60%; Figure 10), one-quarter of whom are diagnosed with distant-stage disease (Figure 11). As described earlier, disparities in CRC outcomes are largely driven by socioeconomic inequalities that result in differences in access to early detection and receipt of timely, high-quality treatment.[61,66] Access to care is directly related to stage at diagnosis, which plays the largest role in racial/ethnic survival disparities.[67] Notably, when CRC is diagnosed at localized stage, 5-year survival is relatively similar (89%-92%) across racial/ethnic groups.

A recent nationwide study found that more than one-half of the black-white survival disparity is explained by differences in insurance status and one-quarter is due to differences in tumor characteristics (e.g., grade, location).[3] There is also compelling evidence that black patients are less likely to receive prompt follow-up after an abnormal CRC screening test[32] and appropriate surgery, adjuvant chemotherapy, and radiation treatments.[3,68-70] Although a recent study found no evidence of treatment delays in an equal-access health system,[71] equal cancer treatment does not eliminate the racial survival disparity.[72,73] Thus, equity in care across the cancer continuum, from prevention to early detection to clinical-trial participation and individualized treatment, is necessary to eliminate these disparities.[74]

Changes over time

The 5-year relative survival rate for CRC has increased moderately from 50% in the mid-1970s to 64% during 2009-2015.[24] However, recent advances in the treatment of metastatic disease, including improved surgical methods and the development of targeted therapies,[75-77] have rapidly extended survival for these patients. For example, the 2-year relative survival rate for distant-stage disease increased from 21% for patients diagnosed during the mid-1990s to 37% for those diagnosed during 2009-2015, with a larger jump for rectal cancer (22% to 41%) than for colon cancer (21% to 36%). Although progress is evident across race and age,[78] gains are most prominent among white and non-elderly patients.[79]

Colorectal Cancer Risk Factors

In the United States, more than half (55%) of all CRCs are attributable to lifestyle factors, including an unhealthy diet, insufficient physical activity, high alcohol consumption, and smoking.[80] These behaviors are traditionally associated with high-income countries, where CRC rates are highest. On a global scale, increasing CRC incidence is considered a marker of economic transition.[81] Importantly, however, numerous studies have shown that people with healthy lifestyle behaviors have a 27% to 52% lower risk of CRC compared to those without these behaviors.[82]

Nonmodifiable factors that increase risk are related to heredity and medical history, including a personal or family history of CRC or adenomas (precancerous polyps) and a personal history of long-term chronic inflammatory bowel disease. Most people at increased risk because of a medical or family history should begin CRC screening before age 45. (For more information on CRC screening guidelines, please see page 30.) The following sections present current knowledge about factors associated with CRC risk.

Heredity and family history

Up to 30% of CRC patients have a family history of the disease, making this one of the most important and actionable risk factors.[83-85] People with a first-degree relative (parent, sibling, or child) who has been diagnosed with CRC have 2 to 4 times the risk of developing the disease compared to people without this family history, with higher risk for diagnosis before age 50 and/or multiple affected relatives (Table 3).[84] However, a history of CRC among more distant relatives also increases risk,[86] as does a family history (first- or second-degree relatives) of adenomas.[87] Much of the CRC clustered in families is thought to reflect interactions between lifestyle factors and the cumulative effect of relatively common genetic variations that increase disease risk, referred to as high prevalence/low penetrance mutations.[88]

Identification of families with a history of CRC, especially high-burden families with undiagnosed genetic syndromes (i.e., low prevalence/high penetrance mutations, described below), offers substantial opportunity to lessen cancer incidence and mortality through increased surveillance with colonoscopy. However, patient family history in medical records continues to be incomplete. One study found that less than half of primary care physicians documented information about family members other than first-degree relatives, and age at cancer diagnosis was rarely collected.[89] Another study found that only 22% of CRC patient medical records had family history information sufficient to identify individuals who should be referred for genetic counseling and/or testing.[90]

Table 3. Relative Risks for Established Colorectal Cancer Risk Factors

	Relative risk*
Factors that increase risk:	
Heredity and medical history	
Family history[84]	
CRC	
1 or more first-degree relatives	2.2
1 or more first-degree relatives diagnosed before age 50	3.6
2 or more first-degree relatives	4.0
1 or more second-degree relatives	1.7
Adenoma	
1 or more first-degree relatives	2.0
Inflammatory bowel disease[115]	1.7
Type 2 diabetes[124]	
Male	1.4
Female	1.2†
Modifiable factors	
Heavy alcohol (daily average >3 drinks)[195]	1.3
Obesity (body mass index ≥30 kg/m^2)[146]	1.3
Colon, male	1.5
Colon, female	1.1
Rectum, male	1.3
Rectum, female	1.0†
Red meat (100 g/day)[166]	1.1
Processed meat (50 g/day)[166]	1.2
Smoking[190]	
Current vs. never	1.5
Former vs. never	1.2
Factors that decrease risk:	
Physical activity[138]	0.7
Dairy (400 g/day)[166]	0.9

*Relative risk compares the risk of disease among people with a particular "exposure" to the risk among people without that exposure. Relative risk for dietary factors compares the highest with the lowest consumption. If the relative risk is more than 1.0, then risk is higher among exposed than unexposed persons. Relative risks less than 1.0 indicate a protective effect.
†Relative risk was not statistically significant.

Hereditary syndromes

A recent study found that 5% of CRC patients have an inherited gene mutation (germline mutation) associated with a known high-risk hereditary condition, and an additional 5% have mutations associated with moderately increased risk.[91]

Lynch syndrome

The most common hereditary risk factor for CRC is Lynch syndrome, which accounts for about 3% of all CRCs.[91] People with Lynch syndrome are also at increased risk for many other cancers, including endometrial, ovarian, small intestine, stomach, urinary bladder, and female breast.[92] These individuals have a mutation in certain genes that hinders the cell's ability to correct errors introduced during DNA replication. These mistakes result in additional mutations that can ultimately lead to cancer,[93] the likelihood of which is dependent on which gene is affected. Among the 80% of Lynch syndrome patients with high-risk gene (*MLH1* or *MSH2*) mutations, 19% to 25% will develop CRC by age 50 and 40% will develop the disease by age 70.[94] The median age at CRC diagnosis among Lynch syndrome patients is 61 years of age,[95] and 8% of CRCs that occur in adults younger than age 50 are caused by Lynch syndrome.[96]

Although an estimated 1.2 million Americans (1 in 279) have Lynch syndrome,[97] the vast majority are undiagnosed because identification is dependent on a cancer diagnosis. However, there is increasing recognition of the need for a more proactive approach because rigorous colonoscopy surveillance leads to early-stage diagnosis and high survival in Lynch syndrome patients.[98] Numerous organizations, including the National Comprehensive Cancer Network and American Society for Clinical Oncology, recommend testing for Lynch snydrome in all patients with colorectal or endometrial cancer.[99, 100] Although implementation of universal testing has been slow in the community hospital setting,[101] most major public and private insurers cover the screening.[102]

Polyposis syndromes

Polyposis syndromes are another type of hereditary condition associated with increased CRC risk, the most common of which is familial adenomatous polyposis (FAP), which accounts for about 1% of all CRCs.[91] FAP is characterized by the development of up to thousands of colorectal polyps in the second and third decade of life. It is typically caused by a mutation in the adenomatous polyposis coli (APC) gene, which normally prevents uncontrolled cell growth and division.[103] These mutations are usually inherited, but occur spontaneously in 10% to 25% of affected people so there is not always a family history of the condition.[104] Disease severity ranges from severe (classic FAP) to mild (attenuated FAP), with the latter associated with later age at onset and fewer polyps (<100), but still high lifetime CRC risk.[105] Surgery is the standard method of cancer prevention for people with FAP once adenoma development is beyond the control of colonoscopy. MUTYH-associated polyposis (MAP) is a more recently recognized syndrome with large variability in clinical features, but in which patients typically develop a similar number of polyps as those with attenuated FAP.[103] Other colorectal polyposis syndromes include Peutz-Jeghers syndrome, juvenile polyposis syndrome, and serrated polyposis syndrome.[106]

BRCA1 and *BRCA2*

Approximately 1% of CRC patients have heritable mutations in the breast cancer susceptibility genes *BRCA1* and/or *BRCA2*,[91] which are among the most well-studied cancer predisposing genes. A gene panel study of CRC patients younger than age 50 also found a 1% prevalence.[96] In addition to breast cancer, these mutations confer increased risk for cancers of the ovary, prostate, and pancreas.[107] Although their influence on CRC risk is not well studied, a recent review reported an association limited to *BRCA1* mutation carriers, who have about a 50% increased risk of the disease compared to individuals without the mutation.[108]

Personal medical history

People with a personal history of CRC are more likely to develop a subsequent cancer in the colon or rectum, especially when the initial diagnosis was at a young age;[109] however, only 2% of patients will develop a second primary CRC.[110] A history of adenomatous polyps also increases CRC risk, especially multiple or large polyps.[111]

CRC risk is also increased among individuals with a history of other cancer types because of the carcinogenic effects of some treatments. Examples include childhood cancer survivors, especially those who received pelvic or abdominal or total-body radiotherapy, or certain drugs (e.g., cisplatin, procarbazine);[112] men treated with radiotherapy for prostate cancer;[113] and men treated with platinum-containing chemotherapy for testicular cancer.[114]

Chronic inflammatory bowel disease

Chronic inflammatory bowel disease (IBD) is a lifelong condition, usually diagnosed in early adulthood, in which the gastrointestinal tract is inflamed over a long period of time. People with IBD have almost double the risk of developing CRC compared to people in the general population.[115] The most common forms of IBD are ulcerative colitis and Crohn disease. Cancer risk increases with the extent, duration, and severity of disease,[115, 116] but has decreased over time, likely due to the increased use of medications to control inflammation and screening surveillance to detect premalignant lesions.[117] Although the efficacy of anti-inflammatory drugs for limiting IBD-related cancer occurrence remains unclear, two recent meta-analyses reported reduced CRC risk of 33% to 50% among individuals with ulcerative colitis, but no effect for those with Crohn disease.[118, 119] CRC patients with IBD are about 15 years younger than those without IBD and 70% more likely to die from their cancer after accounting for age and stage at diagnosis.[120] IBD has been diagnosed in an estimated 3.1 million Americans and is most common among non-Hispanic whites, women, and those with the least education.[121] Although surveillance data in the US are sparse, prevalence appears to have increased in recent years.[122]

Diabetes

People who have type 2 (adult onset) diabetes have a slightly increased risk of CRC that appears stronger in men than in women.[123, 124] The association between type 2 diabetes and CRC remains even after accounting for shared risk factors (physical activity, body mass index, and waist circumference).[125] Although some studies suggest that metformin, a drug commonly used to lower blood glucose levels in diabetic patients, independently reduces CRC incidence,[126-130] a randomized controlled trial found no association.[131] CRC patients with diabetes are no more likely to die from their cancer than those without diabetes, despite higher rates of cancer recurrence, as well as mortality from other causes.[132]

The prevalence of Americans with a history of diabetes has more than doubled over the past two decades.[133] Although type 2 diabetes is rare among children and adolescents (ages 0-19 years), incidence rates increased by 7% per year between 2002 and 2012, from 9.0 cases per 100,000 in 2002-2003 to 12.5 in 2011-2012.[134] According to the Centers for Disease Control and Prevention, 30.3 million people (9.4% of the population) were diabetic in 2017, including 7.2 million who were undiagnosed and one-quarter of whom were 65 years of age and older.[135]

H. pylori

Results from earlier studies evaluating the link between infection with *H. pylori*, a bacteria strongly associated with excess stomach cancer risk, and CRC occurrence were inconsistent.[136] However, this may be because the association is confined to specific subtypes of the bacterium. A recent large study found that increased CRC risk is limited to individuals with a history of infection with particular *H. pylori* strains, and that this association is strongest among black Americans.[137]

Modifiable risk factors

Physical inactivity

Physical activity is strongly associated with a reduced risk of colon cancer, but not rectal cancer. Studies consistently show that the most physically active people have about a 25% lower risk of developing both proximal and distal colon tumors than the least active people.[138, 139] Being physically active from a young age may further lower risk.[140] Likewise, people who are the most sedentary (e.g., spend the most hours watching TV) have a 25% to 50% increased risk of colon cancer compared to those who are least sedentary.[141] However, sedentary people who become active later in life may reduce their risk.[142] Additionally, people who were more physically active before a CRC diagnosis are less likely to die from the disease than those who were less active.[143] Based on these findings, as well as

the numerous other health benefits of regular physical activity, the American Cancer Society and the Centers for Disease Control and Prevention recommend that adults engage in at least 150 to 300 minutes of moderate-intensity activity or 75 to 150 minutes of vigorous-intensity activity each week (or a combination of these), preferably spread throughout the week, and limit time spent sedentary in activities like watching television.

Overweight and obesity

Excess body weight increases the risk of CRC, even among those who are physically active.[144, 145] Compared to people who are normal weight, obese men have about a 50% higher risk of colon cancer and a 25% higher risk of rectal cancer, whereas obese women have about a 10% increased risk of colon cancer and no increased risk of rectal cancer.[146] Excess risk is also associated with higher abdominal fat, measured by waist circumference or waist-to-hip ratio, and fat stored within the abdominal cavity, independent of body mass index and waist circumference.[147] Thus, abdominal fat specifically may be more important than overall body weight in influencing CRC risk.[148] The timing of exposure may also be a factor, with studies suggesting a stronger influence for excess body weight during adolescence and young adulthood among women, but later in life for men.[149] Higher body weight, even within the normal range, appears to increase risk of early-onset CRC (before age 50), at least among women.[150] In addition, high body mass index measured prior to diagnosis reduces the likelihood of CRC survival.[147, 151] Excess body weight can have a negative impact on the proper functioning of many biochemical processes in the body (metabolic health), and studies indicate that poor metabolic health may be related to CRC incidence and survival independent of obesity.[152-154]

Diet

Differences in CRC incidence globally, as well as the relatively rapid changes in risk among immigrant populations in the United States, have long suggested that diet is linked to CRC occurrence.[155] Dietary patterns likely influence risk both indirectly, through excess calories and obesity, and directly through specific dietary elements. For example, diet has a large influence on the composition of the gut microbiome, which is the trillions of microorganisms, including the 1,000+ different strains of bacteria, that inhabit the large intestine. High levels of specific bacteria in the microbiome are associated with CRC risk.[156, 157] The microbiome is a very active area of research because it is thought to play a dual role in both preventing and promoting CRC and many other diseases through its influence on immune response and inflammation.[158-162] Diets with greater amounts of certain foods, such as refined carbohydrates, processed sugar, and red meat, have a higher potential to increase inflammation and are associated with increased CRC risk.[163]

However, the direct role of specific food items in cancer occurrence is extremely challenging to study for many reasons, including 1) difficulty defining and measuring intake, such as challenges in the accuracy of self-reported food questionnaires; 2) differences in the sources of dietary constituents (e.g., cereal grains, fruits, and vegetables all contribute to fiber intake); 3) the strong link between dietary patterns and other health behaviors; and 4) a constantly changing food supply. The following is a summary of current scientific evidence for dietary elements linked to CRC:

Dairy/Calcium: Most studies find that calcium consumption from dairy foods and/or supplements is associated with a decreased risk of developing adenomas and CRC,[164-166] although the mechanism remains unclear. Adequate calcium intake (approximately 700-1,000 mg/day) seems to confer protection, with limited additional benefit for higher consumption.[164] The relationship appears to require years of follow-up to observe;[167] be confined to cancers in the distal colon/rectum and particular molecular subtypes;[168, 169] and perhaps be moderated by other dietary factors.[164, 170]

Whole grains/Fiber: Although it is highly plausible that dietary fiber decreases risk of CRC for many reasons, including less exposure to carcinogens because of higher stool volume and faster transit time, study results, including those from randomized controlled trials, remain inconclusive and protective associations are weak.[164] The evidence for whole grains specifically is stronger than for overall fiber; two recent meta-analyses found that CRC risk was decreased by about 5% for every 30 grams/day of whole-grain intake.[166, 171] Importantly, the

overall health benefit of a diet high in whole grains is clear,[172] and the American Cancer Society and the World Cancer Research Fund both advocate a diet high in plant foods, including whole grains, fruits, and vegetables for the prevention of cancer and other diseases.[173, 174]

Folate: Folate intake, consumed through diet or supplements, appears to have a complex relationship with CRC risk, potentially promoting growth of preexisting tumors, while inhibiting formation of new tumors in healthy tissue.[164] There has been speculation that increased folate levels among Americans as a result of mandatory fortification of enriched flour and cereals in 1998 were responsible for the unexplained uptick in CRC incidence rates in the late 1990s (Figure 6).[175] However, this hypothesis is not supported by an analysis of data from randomized controlled trials that found no association between five years of folic acid supplementation and CRC risk.[176] Additional prospective studies conducted post-fortification found that the highest level of folate intake was associated with reduced risk of CRC.[177]

Fruits and vegetables: Results from numerous studies specifically evaluating the association between fruit and vegetable intake and CRC risk are inconsistent.[164] Two recent meta-analyses found no relationship for fruit and a possible slightly reduced risk for the highest versus lowest vegetable consumption.[166, 171] Any protective effect appears to be for moderate compared to low consumption, with high consumption providing little additional benefit.[178, 179]

Red and processed meat: Consumption of red and/or processed meat increases the risk of CRC, with a stronger association for colon cancer than rectal cancer and for processed meat than red meat.[166, 180] A recent synthesis of evidence for the World Cancer Research Fund found that the risk of CRC is increased by 18% for every 50 grams/day of processed meat (approximately 2 slices of lunchmeat) and by 12% for every 100 grams/day of red meat (marginally significant).[166] In 2015, the International Agency for Research on Cancer classified processed meat as "carcinogenic to humans" and red meat as "probably carcinogenic to humans," largely based on the evidence related to CRC risk.[181] The reasons for this association remain unclear, but may be related to the constituents of meat and/or to carcinogens (cancer-causing substances) that form during high-temperature cooking, curing, and/or smoking.[182] Although there is concern about rising consumption of processed foods overall, intake of processed meat appears to have remained stable over the past two decades.[183]

Vitamin D: Higher blood levels of vitamin D may be associated with lower risk of CRC, although research findings remain inconsistent.[164] Clinical trials have not found an association between daily supplementation with vitamin D and risk of adenomas[167] or CRC.[184] However, a recent study of pooled data from 17 cohort studies indicated that higher blood levels of vitamin D (25[OH]D up to 100 nmol/L) were associated with reduced CRC risk among women, and deficiency was associated with a 37% increased risk.[185] Forthcoming data from additional clinical trials evaluating the effect of vitamin D supplementation on cancer prevention may help clarify this association,[186, 187] although study design modifications may be necessary to reconcile the current controversy.[188]

Smoking

In November 2009, the International Agency for Research on Cancer reported that there is sufficient evidence to conclude that tobacco smoking causes CRC.[189] In the US, approximately 12% of CRCs are attributed to cigarette current or former smoking, with CRC risk in current smokers about 50% higher than that in never smokers.[80, 190] Most studies find differences in the association by anatomic and molecular subtypes of CRC.[2, 191, 192] Smoking is also associated with lower CRC-specific survival, particularly for current smokers.[193, 194]

Alcohol

An estimated 13% of CRCs in the US are attributed to alcohol consumption.[80] Although there is strong evidence that heavy consumption increases risk, the magnitude of excess risk and the association with smaller quantities is less certain. A recent meta-analysis reported that light-to-moderate alcohol consumption (up to two drinks per day) was associated with a slightly lower (8%) risk than no consumption/occasional consumption, whereas very heavy drinking (more than 3 drinks per day) was

associated with a 25% higher risk.[195] However, other studies find excess risk with just one drink per day, rising to 44% for the heaviest drinking.[166, 196] The association appears stronger in men, especially for heavy consumption, perhaps because women are less likely to drink heavily and/or because of hormone-related differences in alcohol metabolism.

Medications

Nonsteroidal anti-inflammatory drugs

There is extensive evidence that long-term regular use of aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) lowers risk of CRC.[197-199] The reduction in risk appears to be stronger among individuals younger than age 70 and without excess body weight.[200] Aspirin users who do develop CRC appear to have less aggressive tumors and better survival compared to non-aspirin users,[201, 202] although the survival benefit may be limited to certain tumor subtypes.[203, 204] The American Cancer Society has not conducted a formal evidence review, but currently does not recommend the use of NSAIDs for cancer prevention in the general population because of the potential side effects, namely serious gastrointestinal bleeding. However, the US Preventive Services Task Force currently recommends daily low-dose aspirin for the prevention of cardiovascular disease and CRC for certain individuals in their 50s who are at increased risk for cardiovascular disease; the evidence for individuals in their 60s is less convincing.[205] Decisions about aspirin use should be made after discussion with a health care provider. Visit uspreventiveservicestaskforce.org for more information about their recommendation.

Hormones

The evidence regarding the association between steroid hormones, both endogenous (naturally occurring within the body) and exogenous (e.g., hormone replacement therapy and oral contraceptives), and CRC is inconsistent.[206] Some studies have found that higher natural levels of estrogen among postmenopausal women are associated with reduced CRC risk,[207] while others have found no association.[208] Reduced risk associated with hormone replacement therapy appears to be confined to use of combined estrogen and progesterone formulations.[209, 210] Recent studies do not support an association between oral contraceptive use and CRC risk.[2, 211, 212]

Antibiotics

Emerging evidence suggests that oral antibiotic use may be associated with increased risk of CRC.[213, 214] Antibiotics might influence risk by disrupting the critical balance of the gut microbiome. For more information on the microbiome, see Diet on (page 16).

Other drugs

Oral bisphosphonates, which are used to treat and prevent osteoporosis, may reduce CRC risk.[215, 216]

Colorectal Cancer Screening

The typically slow course of growth from precancerous polyp to invasive cancer to advanced-stage disease provides a unique opportunity for the prevention and early detection of CRC.[8] Screening can prevent cancer through the detection and removal of precancerous growths and detect the disease at an early stage, when treatment is usually more successful. As a result, screening reduces CRC mortality both by decreasing incidence and increasing survival.

The 2018 American Cancer Society CRC screening guideline recommends that adults ages 45 years and older undergo regular screening with a high-sensitivity stool-based test or visual examination (described below), depending on patient preference and test availability.[217] As part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with a timely colonoscopy because delays in follow-up of abnormal results increase the risk of advanced CRC and CRC death.[218, 219] The age to initiate CRC screening was

lowered from 50 to 45 years because incidence rates are increasing in younger populations, and modeling studies demonstrated that the balance of benefit to harm was more favorable for beginning screening at age 45 than at 50.[220, 221] Although health insurance coverage for screening those at average risk before age 50 remains variable, the American Cancer Society is working aggressively to educate insurers, lawmakers, and other stakeholders about the evidence in support of screening those ages 45-49 years and the importance of expanding coverage for this group. Screening before age 45 is recommended for those at an increased risk of CRC because of family history or certain medical conditions (see page 13), with age to initiate and rescreening intervals dependent on individual circumstances. Everyone should have a conversation with their health care provider about CRC screening that includes information about cancer family history well before age 45.[221] Visit cancer.org/cancer/colon-rectal-cancer/early-detection/acs-recommendations for more information, including specific guidelines for screening individuals at increased or high risk.

Recommended options for colorectal cancer screening

There are several recommended methods for CRC screening, including both visual examinations, which are performed at a health care facility, and high-sensitivity stool-based tests, which are collected at home (Table 4). All tests have a comparable ability to improve life expectancy when performed at the appropriate time intervals and with the recommended follow-up.[222] Patients should be given information about the benefits and limitations of each screening test, and choose one based on their health, medical history, and preferences with advice from a health care professional as needed. A growing body of evidence demonstrates that offering patients different test options substantially increases adherence to screening recommendations.[223] As a result, and because one-third of eligible adults are not up to date with CRC screening, including half of those ages 50-54 years, the American Cancer Society and the US Preventive Services Task Force guidelines do not emphasize any one test and stress that all recommended tests can help save lives.[217, 224]

Visual examinations

Visual tests allow doctors to see the lining of the colon and rectum through an endoscope or on radiological images.

Colonoscopy

Colonoscopy is the most commonly used CRC screening test in the US. This procedure, which is usually performed by a gastroenterologist (a doctor who specializes in the digestive system) or surgeon, allows for direct visual examination of the entire colon and rectum. It can be used as a singular screening test, or may be performed as a follow-up to abnormal results from stool and other visual tests to complete the screening process. Colonoscopy has the longest rescreening interval of all test options, 10 years for average-risk individuals with normal results.

Before undergoing a colonoscopy, patients are instructed to take special laxative agents to cleanse the colorectum completely so the intestinal lining can be thoroughly examined. During the exam, the colon is inflated with either air or carbon dioxide. Then a long, slender instrument called a colonoscope is inserted into the anus and moved slowly through the rectum to the cecum (beginning of the colon). The colonoscope has a light and small video camera on the end to allow for the detection and removal of most polyps with a wire loop or electric current. Sedation is usually provided during examinations in the US, although it is used less frequently in some European countries (e.g., Norway and Poland).[225]

While data are not yet available from randomized controlled trials evaluating the effectiveness of colonoscopy,[226] results from several trials of flexible sigmoidoscopy, a similar test discussed in the next section, provide indirect support for the benefits of colonoscopy. In addition, observational studies suggest that colonoscopy can help reduce CRC incidence by about 40% and mortality by about 60%.[227-229]

Like all screening tests, colonoscopy has limitations and potential harms. For example, it can lead to unnecessary procedures, such as the removal of small polyps that would not have progressed to cancer.[230] A recent study found that although >90% of polyps can be safely

Table 4. Characteristics of Recommended Colorectal Cancer Screening Tests

	Benefits	Performance & Complexity*	Limitations	Test Time Interval
Visual Examinations				
Colonoscopy	• Examines entire colon • Can biopsy and remove polyps • Can diagnose other diseases • Required for abnormal results from all other tests	**Performance:** Highest **Complexity:** Highest	• Full bowel cleansing • Can be expensive • Sedation usually needed, necessitating a chaperone to return home • Patient may miss a day of work. • Highest risk of bowel tears or infections compared with other tests	10 years†
Computed tomographic colonography (CTC)	• Examines entire colon • Fairly quick • Few complications • No sedation needed • Noninvasive	**Performance:** High (for large polyps) **Complexity:** Intermediate	• Full bowel cleansing • Cannot remove polyps or perform biopsies • Exposure to low-dose radiation • Colonoscopy necessary if positive • Not covered by all insurance plans	5 years
Flexible sigmoidoscopy	• Fairly quick • Few complications • Minimal bowel preparation • Does not require sedation or a specialist	**Performance:** High for rectum & lower one-third of the colon **Complexity:** Intermediate	• Partial bowel cleansing • Views only one-third of colon • Cannot remove large polyps • Small risk of infection or bowel tear • Slightly more effective when combined with annual fecal occult blood testing • Colonoscopy necessary if positive • Limited availability	5 years
Stool Tests (Low-sensitivity stool tests, such as single-sample FOBT done in the doctor's office or toilet bowl tests, are not recommended.)				
Fecal immunochemical test (FIT)	• No bowel cleansing or sedation • Performed at home • Low cost • Noninvasive	**Performance:** Intermediate for cancer **Complexity:** Low	• Requires multiple stool samples • Will miss most polyps • May produce false-positive test results • Slightly more effective when combined with a flexible sigmoidoscopy every five years • Colonoscopy necessary if positive	Annual
High-sensitivity guaiac-based fecal occult blood test (gFOBT)	• No bowel cleansing or sedation • Performed at home • Low cost • Noninvasive	**Performance:** Intermediate for cancer **Complexity:** Low	• Requires multiple stool samples • Will miss most polyps • May produce false-positive test results • Pre-test dietary limitations • Slightly more effective when combined with a flexible sigmoidoscopy every five years • Colonoscopy necessary if positive	Annual
Multitargeted stool DNA test (Cologuard®)	• No bowel cleansing or sedation • Performed at home • Requires only a single stool sample • Noninvasive	**Performance:** Intermediate for cancer **Complexity:** Low	• Will miss most polyps • More false-positive results than other tests • Higher cost than gFOBT and FIT • Colonoscopy necessary if positive	3 years, per manufacturer's recommendation

*Complexity involves patient preparation, inconvenience, facilities and equipment needed, and patient discomfort. †For average-risk individuals, e.g., does not apply to those who have a history of adenoma.

removed during colonoscopy, elective surgery to remove nonmalignant polyps, which has a higher risk of harms, increased by more than 50% from 2000 to 2014.[231] Other limitations of colonoscopy include a higher risk of complications compared to other screening tests, such as bowel tears and bleeding, especially when a polyp is removed or patients are older.[230,231] Although these side effects are rare, serious bleeding occurs in 1 to 2 of every 1,000 colonoscopies.[225,232,233] In addition, colonoscopy sometimes misses adenomas, especially those that are located in the proximal colon; those that occur in high-risk patients; and those that are flat (sessile adenomas), from which 20% to 30% of CRCs are thought to originate.[226,234] The quality of colonoscopy, which is variable in the US, is also associated with missed lesions, which sometimes progress to CRC before the next scheduled exam (i.e.,

interval cancer).[235,236] Low-quality colonoscopy (measured as low adenoma detection rate) is associated with a higher likelihood of interval CRC and CRC death.[236]

Flexible sigmoidoscopy

Sigmoidoscopy was a common screening test before 2000, but current availability is limited because it has mostly been replaced by colonoscopy (see page 23 for current prevalence of sigmoidoscopy and other screening tests). These tests are very similar except colonoscopy can examine the entire colon whereas sigmoidoscopy can only visualize the rectum and distal one-third of the colon, and must be repeated more often (Table 4). Simple bowel cleansing, usually with enemas, is sufficient to prepare the colon, and the procedure is often performed without sedation in a general health care practitioner's office. If there is a polyp or tumor present, the patient should be referred for a colonoscopy so that the entire colon can be examined.

Recent analysis of data from randomized controlled trials with up to 17 years of follow-up shows that sigmoidoscopy is associated with about a 20%-25% reduction in CRC incidence and a 25%-30% reduction in CRC mortality, with greater reductions in men than women.[237-239]

Computed tomographic colonography (CTC)

Also referred to as virtual colonoscopy, CTC is an imaging procedure that provides 2- or 3-dimensional views of the entire colon and rectum with the use of a special x-ray machine linked to a computer.[230] Although a full bowel cleansing is necessary for a successful examination, sedation is not required. A small, flexible tube is inserted into the rectum in order to allow carbon dioxide, or sometimes air, to inflate the colon; then the patient passes through the CT scanner, which creates multiple images of the interior of the colon. CTC is less invasive than colonoscopy or sigmoidoscopy and typically takes approximately 10 to 15 minutes to complete.[240] Patients with adenomas larger than 5 millimeters or other abnormal results are referred for colonoscopy, optimally on the same day in order to alleviate the necessity of a second bowel preparation. Studies have shown that the performance of CTC is similar to colonoscopy for the detection of invasive cancer and advanced adenomas, but has lower sensitivity for smaller adenomas.[241] Potential harms include cumulative radiation exposure from regular examinations, and unnecessary tests and/or treatment due to incidental benign findings outside the colorectum. There is less evidence on the benefits and harms of this test compared to others because it is relatively new and remains uncommon.[224] This may be because it is not covered by Medicare and commercial insurance coverage is variable; in 2019, 37 states mandated that commercial plans cover this test.[242]

Stool tests

Most cancerous tumors and some large adenomas bleed intermittently into the intestine. This blood, which may not be visible, can be detected in stool with special tests. Modeling studies suggest that annual screening with high-sensitivity stool tests and timely follow-up of abnormal results will result in a reduction in mortality similar to that achieved by colonoscopy over a lifetime of screening.[243] Except for the multitargeted stool DNA test, which is recommended every 3 years, stool tests should be repeated annually. However, adherence to yearly testing and timely follow-up with a colonoscopy after a positive test remains a challenge, especially in low-resource settings where stool tests are more common.[244-247]

Guaiac-based fecal occult blood test (gFOBT)

These tests use a chemical reaction to detect blood in the stool. Bleeding from cancers or adenomas may be sporadic or undetectable, so accurate results require annual testing of samples from 3 consecutive bowel movements. Patients are typically instructed to avoid nonsteroidal anti-inflammatory drugs and red meat for 3 days prior to the test because they can lead to a positive test result when no cancer is present (false positive); gFOBT detects blood from any source, including meat in the diet. Vitamin C and large amounts of citrus juices should also be avoided because they can lead to a negative test result when cancer is present (false negative). Only high-sensitivity gFOBT are recommended for CRC screening.

Data from a large clinical trial indicated that the regular use of FOBT reduced the risk of CRC death by 32% after 30 years of follow-up.[248] FOBT has also been shown to decrease CRC incidence by 20% by detecting large precancerous adenomas.[249]

Fecal immunochemical test (FIT)

The FIT (also sometimes referred to as the immunochemical FOBT, or iFOBT) uses antibodies against hemoglobin to specifically detect human blood in the stool and is about twice as likely as most gFOBT products to detect both advanced adenomas and cancer.[250, 251] Many individuals prefer FIT over gFOBT because of its convenience, lack of dietary restrictions, and collection of fewer stool samples.[252]

Multitargeted stool DNA (Cologuard®)

This test is referred to as "multitargeted" because it not only detects blood in the stool, but also multiple genetic mutations in the DNA of cells that are shed into the stool by large adenomas and CRC. Cologuard® has been shown to detect cancer and precancerous lesions more often than FIT, but also results in more false-positive tests, which can lead to unnecessary colonoscopies.[253] However, because it is a relatively new test, data are still accumulating on performance characteristics in community settings. Although it is recognized as an acceptable screening option by the American Cancer Society and the US Preventive Services Task Force[224] and is covered by Medicare, some private insurance companies may not cover this test. Patient navigation services, which include phone calls and reminder letters in multiple languages to support test completion, are embedded in the cost of the test, although the services do not extend to colonoscopy follow-up of abnormal results.[254]

Non-recommended tests for colorectal cancer screening

There are several tests for CRC screening that are not recommended by the American Cancer Society or other organizations because of poorer performance. These include in-office stool tests, in which a single-stool sample is collected during a digital rectal exam and placed on an FOBT card, and "toilet bowl tests," which are over-the-counter guaiac-based tests that are often promoted as a type of FOBT. Despite recommendations against in-office FOBT, some primary care physicians continue to offer the test.[255] Toilet bowl tests have not been evaluated in the types of rigorous clinical studies done on the guaiac-based FOBT and FIT.

Double-contrast barium enema, also called barium enema with air contrast, is a test that takes an x-ray of the colon after barium sulfate is introduced. This test is no longer recommended because it has lower sensitivity for detecting CRC than other tests.

There are also emerging technologies that are not currently recommended for CRC screening because there was insufficient data on their performance compared to other recommended options at the time the guidelines were issued. These include blood-based tests that measure circulating genetic abnormalities associated with colorectal adenomas and cancer, and capsule endoscopy, in which the patient undergoes bowel cleansing and swallows a pill-sized device containing tiny encapsulated cameras that transmit images of the colon and rectum to a recording device.

Use of colorectal cancer screening

According to the National Health Interview Survey (NHIS), CRC screening in accordance with guidelines increased rapidly among adults ages 50 and older from 2000 (38%) to 2010 (59%), but more slowly in the past decade, reaching 66% in 2018 (Table 5).[44] The most recent NHIS data collected in 2018 contain a mix of respondents surveyed before and after the release of the American Cancer Society CRC screening guideline in mid-2018. Approximately 56% of those ≥45 years of age and 21% of those ages 45-49 years reported being up to date with CRC screening in 2018.

Among adults ages 50 and older in 2018:

- 61% reported having a colonoscopy in the past 10 years, and 3% and 1% reported having a sigmoidoscopy or CT colonography, respectively, in the past 5 years.
- Approximately 11% reported a recent stool test; 9% reported an FIT or FOBT in the past year and 3% reported stool DNA testing in the past 3 years.[44]

Table 5. Colorectal Cancer Screening (%), Adults 45 Years and Older, US, 2018

	Stool test*	Colonoscopy†	Up to date‡	
	≥50 years	≥50 years	≥50 years	50-75 years
Overall	11	61	66	67
Gender				
Males	12	62	67	67
Females	10	60	64	66
Age (years)				
50-64	10	56	61	62
50-54	9	42	48	–
55-64	10	63	68	–
65+	12	66	71	77
75+	10	60	63	–
Race/ethnicity				
White	10	63	68	69
Black	12	60	65	66
Hispanic	15	52	59	59
American Indian/Alaska Native	12	53	59	56
Asian	15	47	55	58
Sexual orientation				
Gay/Lesbian	18	68	76	76
Straight	11	61	66	67
Bisexual	25	49	58	§
Education				
Less than high school	11	46	52	53
High school diploma	10	57	62	63
Some college	11	62	68	68
College graduate	11	68	73	73
Immigration status				
Born in US	10	63	68	69
Born in US territory	§	76	80	84
In US fewer than 10 years	§	20	26	30
In US 10+ years	14	49	56	58
Income level				
<100% FPL	12	49	55	57
100 to <200% FPL	12	48	55	57
≥200% FPL	11	65	70	70
Insurance status				
Uninsured	5	26	30	30
Private	9	60	65	65
Medicare or Medicare & Medicaid	14	61	67	73
Private & Medicare	11	71	74	80
Medicaid or Other state plan	14	44	53	54

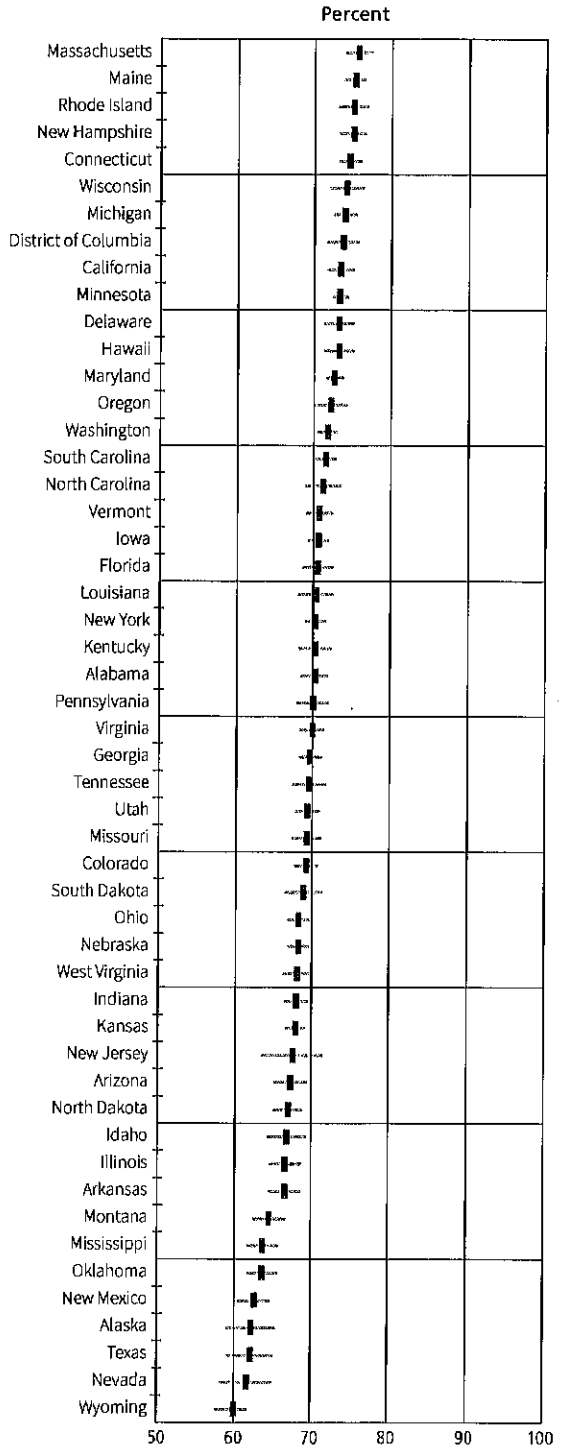
FPL: federal poverty level. *Fecal occult blood test (FOBT) OR fecal immunochemical test (FIT) in the past 1 year OR stool DNA (sDNA) test in the past 3 years. †In the past 10 years. ‡For ages ≥45 and ≥50 years: FOBT/FIT, sigmoidoscopy, colonoscopy, computed tomographic colonography (CTC), or sDNA test in the past 1, 5, 10, 5 and 3 years, respectively. For ages 50-75 years: FOBT/FIT, sigmoidoscopy, colonoscopy, CTC, or sDNA test in the past 1, 5, 10, 5 and 3 years, respectively, OR sigmoidoscopy in past 10 years with FOBT/FIT in past 1 year. §Estimate not shown due to instability. Note: Estimates do not distinguish between examinations for screening and diagnosis. All estimates except for age and insurance status are age adjusted to the 2000 US standard population.

Source: National Health Interview Survey, 2018.

- Screening was lowest among ages 50-54 years (48%); Asian Americans (55%); individuals with less than a high school education (52%); the uninsured (30%); and recent (<10 years) immigrants (26%).

The prevalence of CRC screening also varies substantially among US states and territories (see cover). According to data from the 2018 Behavioral Risk Factor Surveillance System (BRFSS):[256]

Figure 12. Colorectal Cancer Screening* (%), Adults 50 Years and Older by State, 2018



*Blood stool test, sigmoidoscopy, or colonoscopy in the past 1, 5, and 10 years, respectively. Note: Estimates are age adjusted to the 2000 US standard population and do not distinguish between examinations for screening and diagnosis.

Source: Behavioral Risk Factors Surveillance System, 2018. See Sources of Statistics (p. 32) for complete citation and more information.

- Screening utilization ranged from 58% in Puerto Rico and 60% in Wyoming to 76% in Massachusetts (Figure 12 and Table 6).
- In all states, screening prevalence is substantially lower in people ages 50-64 years than in those age 65 and older, with the largest absolute difference in Puerto Rico (22%) and Florida, Mississippi, and Oklahoma (all 19%).

Strategies to overcome screening barriers

Screening utilization for CRC remains lower than that for breast and cervical cancers despite the large body of evidence supporting its effectiveness for reducing cancer incidence and mortality.[257] Use of CRC screening is influenced by numerous individual, provider, health system, and community factors, as well as public policy. Barriers to screening include no usual source of care, inadequate insurance coverage, lack of provider recommendation, logistical factors (e.g., transportation, scheduling, and language), fear, and lack of knowledge.[258-263] These barriers are more prevalent among people with fewer financial resources, lower educational attainment, and among racial/ethnic minorities, resulting in disparities in screening prevalence and outcomes.[264]

Interventions to help overcome these barriers include increasing individual patient awareness (e.g., education and reminders), ease of access (e.g., providing transportation, reducing out-of-pocket expenses, mailed FIT kits, patient navigators), provider delivery (e.g., provider reminders, assessment, and feedback), and community demand (e.g., media campaigns).[265] Multi-component interventions are recommended because they are more effective at increasing CRC screening utilization than a single approach.[265, 266] Additionally, adherence to CRC screening guidelines increases when patients are offered a variety of tests.[222, 223, 267, 268] Importantly, however, the effectiveness of screening is compromised without timely follow-up of abnormal results. Follow-up of colonoscopy among adults with a positive stool test may be increased through the use of patient navigators and provider-level interventions, such as physician reminders and performance data, although evidence for effective strategies remains sparse.[269]

Table 6. Colorectal Cancer Screening* (%), Adults 50 Years and Older by State, 2018

	All races				Non-Hispanic white	Non-Hispanic black
	≥50 years	50 to 64 years	≥65 years	50 to 75 years	≥50 years	≥50 years
United States (median)	**70**	**63**	**75**	**69**	**71**	**71**
Range	*60-76*	*50-72*	*66-82*	*58-77*	*61-80*	*63-84*
Alabama	70	63	76	70	71	67
Alaska	62	52	70	60	62	†
Arizona	67	59	76	66	69	75
Arkansas	67	58	74	66	67	69
California	73	64	82	72	80	77
Colorado	69	62	74	69	71	76
Connecticut	75	71	78	75	76	76
Delaware	73	67	78	72	75	71
District of Columbia	74	69	78	74	77	73
Florida	71	61	80	69	74	67
Georgia	70	61	78	68	71	71
Hawaii	73	69	75	75	78	†
Idaho	67	59	72	66	68	†
Illinois	67	61	70	67	67	74
Indiana	68	61	73	68	69	67
Iowa	71	66	74	71	71	84
Kansas	68	60	74	67	69	66
Kentucky	70	63	76	69	70	70
Louisiana	70	64	76	69	71	70
Maine	75	69	79	75	76	†
Maryland	73	67	78	73	73	77
Massachusetts	76	72	78	77	77	82
Michigan	74	69	77	74	75	71
Minnesota	73	68	77	73	75	66
Mississippi	64	54	73	62	64	65
Missouri	69	62	75	69	69	71
Montana	65	56	71	64	65	†
Nebraska	68	62	72	68	70	67
Nevada	62	52	69	60	67	67
New Hampshire	75	70	78	75	75	†
New Jersey	68	59	75	67	69	76
New Mexico	63	55	66	64	66	†
New York	70	65	75	70	72	70
North Carolina	71	64	77	71	73	69
North Dakota	67	61	72	67	68	†
Ohio	68	61	75	67	69	68
Oklahoma	64	54	73	62	65	68
Oregon	72	66	77	72	72	†
Pennsylvania	70	66	72	72	71	68
Rhode Island	75	70	79	76	77	75
South Carolina	72	62	80	70	72	71
South Dakota	69	63	74	69	70	†
Tennessee	70	60	77	69	71	63
Texas	62	53	71	60	68	68
Utah	69	63	73	70	72	†
Vermont	71	65	72	71	71	†
Virginia	70	63	75	70	70	72
Washington	72	65	77	72	73	71
West Virginia	68	61	74	67	69	66
Wisconsin	74	69	77	75	75	82
Wyoming	60	50	67	58	61	†
Puerto Rico	58	48	70	55	†	†

*Blood stool test, sigmoidoscopy, or colonoscopy in the past 1, 5, and 10 years, respectively. †Estimate not presented due to instability. Note: Estimates are age adjusted to the 2000 US standard population and do not distinguish between examinations for screening and diagnosis. Puerto Rico not included in ranges or medians.

Source: Behavioral Risk Factor Surveillance System, 2018.

The National Colorectal Cancer Roundtable (NCCRT), a coalition of public, private, and voluntary organizations and individuals established in 1997 by the American Cancer Society and the CDC to promote CRC screening, has produced evidence-based toolkits for policy makers, communities, health systems, and health care providers to help improve CRC screening uptake.[270, 271] Other efforts include the CDC's Colorectal Cancer Control Program (CRCCP), which uses multicomponent interventions to increase CRC screening among low-income, underinsured, or uninsured individuals and certain racial and ethnic groups, in particular. During its first year (2015-2016), CRC screening prevalence increased by 4.4% in clinics receiving CRCCP funds, resulting in an additional 24,100 people screened.[272] Integrated health systems have improved CRC screening participation and reduced CRC incidence and mortality by implementing patient reminders and mailed FIT kits.[273] Mailed outreach FIT programs may also be effective in community health center settings, which historically have low CRC screening rates and limited resources.[274]

On a broader scale, provisions of the Patient Protection and Affordable Care Act (ACA) removed some barriers to screening. For example, CRC screening increased faster in states that adopted the ACA provision to expand Medicaid eligibility compared to those that did not.[275] The ACA also reduced or eliminated out-of-pocket screening costs for those who are insured, although loopholes remain.[276] All recommended screening options, including colonoscopy, are covered without cost sharing for people with Medicare insurance and most commercial insurance plans. However, the required follow-up colonoscopy for a positive stool test is often coded as a diagnostic procedure, resulting in out-of-pocket costs for patients. In addition, Medicare still imposes cost sharing on beneficiaries who have a polyp removed during a screening colonoscopy, undermining efforts to improve CRC screening, particularly among low-income patients who are at highest risk for CRC.[277]

Visit cancer.org/colonmd for more information on programs and resources aimed at increasing CRC screening.

Colorectal Cancer Treatment

Treatment for CRC has advanced rapidly over the past several decades, particularly for advanced disease.[76, 278] However, it has also become increasingly clear that outcomes vary widely based on tumor-specific molecular features, tumor location, and patient characteristics.[279-281] Treatment decisions are made by patients with their physicians after considering the best options available for their tumor characteristics along with the risks and benefits associated with each.

Colon cancer

Most people with colon cancer will have some type of surgery to remove the tumor. Adjuvant chemotherapy (given after surgery) may also be used. Radiation is used less often to treat colon cancer.

Carcinoma in situ

Carcinoma in situ is malignant cancer that has not spread beyond the layer of cells in which it began. Surgery to remove the growth of abnormal cells may be accomplished by polyp removal through a colonoscope (polypectomy) or more invasive surgery. Resection of a segment of the colon may be necessary if the tumor is too large to be removed by local excision or if cancer cells are found after the polyp is removed.

Localized stage

Localized stage refers to invasive cancer that has penetrated into (but not completely through) the wall of the colon. Surgical resection to remove the cancer, together with a length of normal colon on either side of the tumor and nearby lymph nodes, is the standard treatment.

Regional stage

Regional stage describes cancers that have grown through the wall of the colon and/or spread to nearby lymph nodes. If the cancer has not spread to nearby lymph nodes, surgical resection to remove the tumor and nearby colon and surrounding lymph nodes may be the only treatment needed. If the cancer is likely to come back because it has spread to other tissues or has high-risk characteristics, chemotherapy may also be recommended. If the cancer has spread to nearby lymph nodes, surgical resection is usually followed by chemotherapy. Adjuvant chemotherapy based on the drug fluorouracil (5-FU) is typically used in patients with stage III or high-risk stage II disease who are in otherwise good health.[282] Oxaliplatin is often part of adjuvant chemotherapy as well.[283] However, some patients may not tolerate this regimen given its toxicity, and there is growing appreciation for the need to confine its use to patients who are most likely to benefit.[76, 284, 285] Adjuvant chemotherapy for colon cancer is as effective in patients ages 70 and older (almost half of all patients) who are otherwise as healthy as in younger patients, although certain drugs (e.g., oxaliplatin) may be avoided to limit toxicity. However, studies indicate that individuals 75 years of age and older are far less likely than younger patients to receive this treatment.[76, 286]

Distant stage

At this stage, the cancer has spread to distant organs and tissues, such as the liver, lungs, peritoneum (lining of the abdomen), or ovaries. When surgery is performed, the goal is usually to relieve or prevent blockage of the colon and to prevent other local complications. If there are only a few metastases to the liver or lungs, surgery to remove these, as well as the colon tumor, may improve survival.

Chemotherapy and targeted therapies may be given alone or in combination to relieve symptoms and prolong survival. A number of targeted therapies have been approved in recent years by the US Food and Drug Administration to treat metastatic CRC. Some of these drugs inhibit new blood vessel growth to the tumor by targeting a protein called vascular endothelial growth factor (VEGF). Others interfere with cancer cell growth by targeting the epidermal growth factor receptor (EGFR) or other proteins. Genetic testing of tumors is important because those with certain mutations (e.g., KRAS, NRAS, or BRAF) largely do not respond to these drugs.[287] Immunotherapy drugs are also now approved to treat a small portion of CRCs.

Rectal cancer

Surgery is usually the main treatment for rectal cancer, often accompanied by chemotherapy and radiation before and/or after surgery to reduce the risk of spread and recurrence. The chemotherapy drugs used in the treatment of rectal cancer are largely the same as those used for colon cancer.

Carcinoma in situ

Treatment options include polypectomy (polyp removal), local excision, or full-thickness rectal resection. This resection may be carried out through the anus. No further treatment is needed.

Localized stage

At this stage, the cancer has grown through the first layer of the rectum into deeper layers, but has not spread outside the rectal wall. Some small localized rectal cancers may be treated by removal through the anus, without an abdominal incision. For other tumors, depending on the location, surgery may involve removal of the cancer and some surrounding normal tissue through one or more small abdominal incisions. For cancers close to the anus, surgery may require removal of the anus and the sphincter muscle, so a permanent colostomy is needed (see next section for information about colostomy). In most cases, no further treatment is needed unless the tumor has high-risk features. Patients who are not candidates for surgery may be treated with radiation therapy.

Regional stage

At this stage, the cancer has grown through the wall of the rectum, and may have spread into nearby tissues and/or lymph nodes. Patients with regional-stage disease

are increasingly treated with chemotherapy and radiation (chemoradiation) before surgery. Some patients also receive chemotherapy after surgery, although the potential benefits are debated.[288-290]

Distant stage

At this stage, the cancer has spread to distant organs and tissues, such as the liver or lung. In rare cases, the cancer can be successfully treated by removing all of the tumors with surgery, along with other treatments. Otherwise, palliative treatments (surgery, chemotherapy, and/or radiation therapy) are used to relieve, delay, or prevent symptoms and prolong life. Similar to colon cancer, a number of targeted therapies have been approved to treat select metastatic rectal cancers, including VEGF and EGFR inhibitors.

Colostomy

When a section of the colon or rectum is removed during surgery, the healthy parts can usually be reconnected, allowing the patient to eliminate waste normally. When reconnection is not immediately possible, the surgeon connects the colon to an opening (stoma) that is made in the skin of the abdomen, allowing waste to leave the body. The surgical procedure to create an opening in the body for the elimination of waste is called an ostomy. When the stoma is connected to the colon it is called a colostomy; when the stoma is connected to the small intestine it is called an ileostomy. Usually a flat bag, held in place by a special adhesive, fits over the stoma to collect waste.

Most patients with CRC who require a colostomy need it only temporarily, until the colon or rectum heals from surgery. After healing takes place, usually in 6 to 8 weeks, the surgeon reconnects the ends of the colon and closes the stoma. A permanent colostomy is necessary more often for rectal than for colon cancer patients.

A person with an ostomy learns to care for it with help from doctors, nurses, and enterostomal therapists (health professionals trained to care for people with stomas). If surgery is expected to result in an ostomy, an enterostomal therapist will often visit the patient before surgery to explain what to expect and how to care for the ostomy. They also provide information about lifestyle issues, including emotional, physical, and sexual concerns, as well as resources and support groups.

Side effects of colorectal cancer treatment

Although many side effects that occur during cancer treatment are temporary, some persist after treatment has ended (long-term effects) and others do not arise until several years later (late effects). Side effects should be discussed with a clinician because treatment options are often available. For example, antiemetic drugs can prevent or lessen nausea and vomiting following chemotherapy. To manage the long-term and late effects of treatment, the American Cancer Society has established guidelines to aid primary care clinicians in delivering risk-based care to CRC survivors (see sidebar).[291] Short- and long-term effects of specific modes of CRC treatment are briefly described in the following sections. For more information on late and long-term effects of cancer and its treatment, visit cancer.org/treatment/treatments-and-side-effects.html.

Surgery

The time needed to heal after surgery is different for each person. Patients often have some pain for the first few days that can usually be controlled with medication. It can take a few days to be able to eat normally again. About 25% of patients experience a delay in bowel function (postoperative ileus) because of bowel stress caused by surgical manipulation, which may require an extended hospital stay.[292] Patients are monitored for signs of bleeding, infection, or other problems that require immediate treatment.

Other side effects from surgery for CRC may include fatigue, possibly for an extended period of time; frequent or urgent bowel movements, diarrhea, constipation, gas, and/or bloating, particularly among rectal cancer patients; a temporary or permanent colostomy; and urogenital/sexual dysfunction (e.g., erectile dysfunction in men).

American Cancer Society Colorectal Cancer Posttreatment Survivorship Care Guidelines

CRC patients have specific needs and concerns once treatment ends. In 2015, a multidisciplinary expert workgroup published evidence- and consensus-based posttreatment care guidelines for clinicians to aid in providing comprehensive, long-term care for colorectal cancer survivors. These guidelines include information on surveillance for cancer recurrence, screening for new cancers, management of chronic and late effects, and referrals for rehabilitation, psychosocial and palliative care, or other specialty care.

Visit cancer.org/health-care-professionals/american-cancer-society-survivorship-guidelines/colorectal-cancer-survivorship-care-guidelines.html for full text of the guidelines, as well as resources for clinicians.

Radiation therapy

Side effects of radiation therapy can include skin irritation, nausea, diarrhea, rectal irritation and/or painful inflammation, rectal bleeding, bladder dysfunction (irritation, pain, and/or frequent urination), fatigue, or sexual problems. Many of these side effects go away after treatments are completed, but some, like sexual problems and some degree of rectal and/or bladder irritation, may be permanent. Late effects include increased risk of bowel obstruction and fractures in the bone at the base of the spine (the sacrum). In addition, radiation to the pelvic area in women may damage the ovaries, causing infertility. Fertility counseling prior to treatment is recommended for women for whom this is a concern (see Sexual function and fertility, below). Radiation also increases the risk of developing second cancers in exposed areas.

Chemotherapy

The chemotherapy drugs most often used in the treatment of CRC are 5-fluorouracil (5-FU), capecitabine, oxaliplatin, and irinotecan. Side effects depend on the type and dosage of drugs, the length of treatment, and individual patient characteristics. Some side effects are temporary (e.g., hair loss), while others may persist after treatment (e.g., numbness in the hands or feet). Some patients may experience low blood cell counts because chemotherapy can harm the blood-producing cells of the bone marrow. This can increase the chance of infection (due to a shortage of white blood cells), bleeding or bruising after minor cuts or injuries (due to a shortage of blood platelets), and fatigue or shortness of breath.

Targeted therapy

Targeted therapy is a newer class of drugs resulting from an increased understanding of the molecular features of cancer development. Targeted drugs for CRC (e.g., EGFR and VEGF inhibitors) often have different but notable side effects compared to conventional chemotherapy drugs, such as dry skin or skin rash.

Sexual function and fertility

Many treatments for CRC directly or indirectly impact sexual function and fertility in both male and female patients.[293,294] This is a particularly relevant issue for the increasing number of affected young adults in their reproductive years. The American Society for Clinical Oncology clinical practice guidelines recommend that fertility preservation be discussed with all new patients at the time of diagnosis because efforts such as sperm banking, embryo/oocyte cryopreservation (the freezing of fertilized or unfertilized eggs), and ovarian transposition (a surgical repositioning of the ovaries away from the field of radiation) should be started far in advance of treatment.[295] For more information, visit cancer.org/treatment/treatments-and-side-effects/physical-side-effects/fertility-and-sexual-side-effects.html.

What Is the American Cancer Society Doing about Colorectal Cancer?

Research

Colorectal cancer is an active area of scientific research; studies span the cancer continuum from prevention and early detection to treatment and beyond. As of August 1, 2019, the American Cancer Society was funding 78 grants totaling more than $25 million in colorectal cancer research. Examples of projects in which researchers in the American Cancer Society Extramural Research program are engaged include:

- Evaluating why certain colorectal cancers evade or resist treatment
- Exploring new ways to prevent colorectal cancer by manipulating gut microbiota
- Investigating whether increased consumption of cooked dry beans, which have anti-inflammatory and anti-cancer properties, could lower the risk of colorectal cancer recurrence in survivors with obesity
- Understanding barriers to colonoscopy screening in North and South Carolina

Examples of CRC research projects conducted within the American Cancer Society Intramural Research program include:

- Monitoring disparities in CRC screening, including identifying medically underserved populations and evaluating initiatives to reduce screening disparities
- Exploring the mechanisms underlying CRC development, such as gene-environment interactions
- Analyzing disparities and emerging trends in population-based CRC incidence and mortality rates
- Investigating factors associated with survival following a CRC diagnosis
- Identifying the needs of CRC survivors as they transition from active treatment and back into the community care setting
- Developing population-based systems for monitoring cancer patient-reported quality of life and treatment-related side effects

Colorectal cancer screening guidelines

Since 1980, the American Cancer Society has issued evidence-based recommendations for CRC screening in average-risk adults that are generally updated every 5 years. These recommendations are developed by an independent Guideline Development Group of experts in cancer epidemiology, primary care, and health services research with the support of American Cancer Society staff in the Center for Cancer Screening, the Intramural Research program, and an ad hoc group of clinicians with expertise in CRC. As part of the ongoing guideline development process, American Cancer Society staff monitor the medical and scientific literature for new evidence that may support a change in the current recommendations, as well as new information about CRC screening that should be conveyed to clinicians and target populations. The most recent update of the American Cancer Society guideline for CRC screening was published in 2018.[217]

Strategies to reach the 80% in Every Community nationwide goal

In 2014, the NCCRT launched the 80% by 2018 campaign to raise CRC screening rates across the nation. Although the nation as a whole did not achieve the 80% goal, it was reached and even surpassed in some hospital and community clinic settings, as well as in some health plans. 80% in Every Community is the new NCCRT campaign to continue efforts to substantially reduce CRC as a major public health problem by increasing colorectal screening rates to 80% or higher in communities across the nation. The NCCRT, established in 1997 by the American Cancer Society and the Centers for Disease Control and

Prevention, is a coalition of more than 100 member organizations and individual experts dedicated to reducing CRC incidence and mortality in the US through coordinated leadership, strategic planning, and advocacy. Over the past five years, more than 1,750 organizations have committed to the shared goal of raising CRC screening utilization. This initiative emphasizes evidence-based screening activities that respond to individualized needs, barriers, and motivations within a community. Talking points, FAQs, press materials, downloadable graphics, and more are available at nccrt.org/80-in-every-community. The American Cancer Society is committed to the 80% in Every Community goal as one of our major initiatives and is implementing several key strategies in support of this nationwide program, including playing a major role as convener and leader of the effort.

Notably, our approximately 300-strong force of health systems staff is playing a crucial role by engaging and supporting key strategic partners – such as hospitals and health systems, community health centers, state health departments, corporate partners, payers, and state and local coalitions – to encourage and support their commitment to increasing the number of individuals who are screened for colorectal cancer. Our staff work with these partners to assist them in implementing proven strategies that are known to increase CRC screening rates, such as implementing provider and patient reminders, helping providers assess and track their screening rates, implementing quality screening navigation, and using the power of the provider recommendation. The American Cancer Society Community Health Advocates implementing Nationwide Grants for Empowerment and Equity (CHANGE) program provides one avenue for health systems staff to collaborate at the community level. CHANGE provides both financial and technical assistance to federally qualified health centers (FQHCs) and other community partners to build capacity and implement interventions to increase cancer screening rates among low income, low education, and racially diverse populations. Since 2011, the American Cancer Society has awarded 252 grants to community-based partners to implement evidence-based CRC interventions, reaching over one million men and women with cancer prevention and early detection education and outreach and providing more than 332,000 CRC screening exams. CHANGE grant-funded FQHCs have been found to increase screening rates faster than nonfunded FQHCs.

Additionally, the American Cancer Society works to unify and magnify effective communication to the public about the value of CRC screening through multiple channels. These activities include the development and implementation of targeted traditional and social media strategies to motivate unscreened consumers to get screened. Finally, we lead by example, encouraging our own staff and volunteers to be up to date with recommended cancer screening tests. Through these actions, the American Cancer Society is working to leverage the energy of multiple and diverse partners to make history and achieve this remarkable public health goal.

Advocacy

Our nonprofit, nonpartisan advocacy affiliate, the American Cancer Society Cancer Action Network℠ (ACS CAN), is involved in advocacy efforts at both the federal and state levels that increase access to quality CRC screening, treatment, and care for all adults. In partnership with the American Cancer Society, the Centers for Disease Control and Prevention (CDC), and the National Colorectal Cancer Roundtable, as well as over 1,750 other organizations, ACS CAN hopes to reach the goal of achieving 80% or higher CRC screening rates in every community. Following are some of the efforts the American Cancer Society and ACS CAN are involved in to help reach that goal:

- Implementing the provisions in the Patient Protection and Affordable Care Act, more commonly referred to as the Affordable Care Act or ACA. The reforms in the ACA, which was signed into law in March 2010, represent a profound structural change in how insurance operates and how consumers and patients use the health insurance system. ACS CAN and the American Cancer Society have a significant impact at the federal and state levels through our advocacy work, which urges policy makers to implement the law to ensure that all Americans have access to

evidence-based prevention, early detection, and treatment services critical to CRC patients. In particular, ACS CAN has advocated for expansion of Medicaid in all 50 states for those individuals up to 138% of the federal poverty level, as it was originally intended by the ACA. This would ensure that low-income, uninsured, and underinsured Americans will have access to the same CRC services as those in private and other public insurances.

- Advocating for clarification on ACA-required coverage of CRC screening modalities as recommended by the United States Preventive Services Task Force (USPSTF). This includes clarifying that there should be no cost sharing requirements for a colonoscopy that is ordered to complete the screening process following a positive CRC stool-based screening test (follow-up colonoscopy), cost sharing for short interval screening following the removal of adenomatous polyps during a screening colonoscopy, and other ambiguous coverage issues related to CRC screening.
- Supporting the work and maintaining funding for the CDC's Colorectal Cancer Control Program (CRCCP), which currently provides funding to 30 grantees across the US. The CRCCP's goal is to increase CRC screening rates in targeted populations by implementing evidence-based, system-level interventions through partnerships with health systems. The program provides grants for both population-based education and awareness campaigns and efforts to improve access to vital CRC screening tests and follow-up services for at-risk low-income, uninsured, and underinsured individuals between the ages of 50 and 75.
- Advocating for passage of the Removing Barriers to Colorectal Cancer Screening Act of 2019, which will ease the financial burden of people living on a fixed income by allowing Medicare beneficiaries to receive screenings without coinsurance, even when a polyp is removed. This legislation would help increase screening rates and reduce the incidence of CRC.
- Advocating for state legislation to ensure insurance coverage in each state aligns with the American Cancer Society's evidence-based CRC guideline, which recommends average-risk adults begin screening at age 45
- Engaging governors, mayors, and state legislators to inform them about the 80% in Every Community initiative, urging them to help make CRC screening a priority. Specifically, ACS CAN is urging state and city governments to work across all sectors to increase screening rates by eliminating cost and access barriers to screening and by investing in or creating a state CRC screening and control program.

Sources of Statistics

New cancer cases. The estimated number of CRC cases in the US in 2020 was projected using a spatiotemporal model based on incidence data from 50 states and the District of Columbia for the years 2002 to 2016 that met the North American Association of Central Cancer Registries' (NAACCR's) high-quality data standards for incidence. For more information on this method, please see Zhu et al.[296]

Incidence rates. Incidence rates are defined as the number of people newly diagnosed with cancer during a given time period per 100,000 population at risk. CRC incidence rates for the US were calculated using case data from the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute, the National Program of Cancer Registries of the Centers for Disease Control and Prevention, and NAACCR, and population data collected by the US Census Bureau. Incidence rates for Alaska Natives are based on cases reported by the Alaska Native Tumor Registry (ANTR) of the SEER Program; rates for American Indians excluding Alaska Natives are based on NAACCR Purchased/Referred Care Delivery Area (PRCDA) county regions excluding the ANTR. Incidence rates were age adjusted to the 2000 US standard population and adjusted for delays in reporting when possible. Trends exclude appendix.

Estimated cancer deaths. The estimated number of CRC deaths in the US in 2020 was calculated by fitting the actual number of CRC deaths from 2003 through 2017 to a statistical model that forecasts the number of deaths three years ahead. The actual number of deaths was obtained from the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention. For more information on this method, please see Chen et al.[297]

Mortality rates. Mortality rates, or death rates, are defined as the number of people who die from cancer during a given time period per 100,000 population. Mortality rates are based on counts of cancer deaths compiled by NCHS and population data from the US Census Bureau. Death rates for Alaska Natives are based on deaths occurring in the Alaska Community Health Service Delivery Area region. Due to data limitations, there may be a small degree of cross-contamination between rates for American Indians and Alaska Natives where they are presented separately. Death rates are age adjusted to the 2000 US standard population.

Survival. Relative and cause-specific (herein referred to as cancer-specific) survival rates were calculated using data from the SEER registries. Relative survival rates account for normal life expectancy by comparing overall survival among a group of cancer patients to that of people not diagnosed with cancer who are of the same age, race, and sex. Cancer-specific survival is the probability of not dying from a specific cancer (e.g., colorectal) within a specified time period following a diagnosis. Cancer-specific survival was used for rates by race and ethnicity because reliable estimates of normal life expectancy historically have not been available by Hispanic ethnicity or for Asians/Pacific Islanders and American Indians/Alaska Natives.

Screening. The national prevalence of CRC screening was estimated from the National Health Interview Survey (NHIS) 2018 data file, obtained from NCHS, released in 2019 (cdc.gov/nchs/nhis.htm). The NHIS is conducted by the US Census Bureau and is designed to provide national prevalence estimates on health characteristics such as cancer screening behaviors. Data are collected through in-person interviews.

CRC screening prevalence by state was estimated from the 2018 Behavioral Risk Factor Surveillance System (BRFSS) public use data files, obtained from the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention. The BRFSS is a telephone survey designed to provide state prevalence estimates of health behaviors and was conducted by state health departments.

Important note about estimated cases and deaths. The projected number of new cancer cases and deaths for the current year are model based. For this reason, we discourage the use of our estimates to track cancer trends. Age-standardized incidence and mortality rates are used to track cancer incidence and mortality trends.

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Attachment 4

Table 1: Summary of Selected Preventive Services for Adults Covered by Non-Grandfathered Private Plans without Cost Sharing

Cancer

- Breast cancer
  - Mammography (women 40+*)
  - Genetic (BRCA) screening and counseling (women at high risk)
  - Preventive medication (women at high risk)
- Cervical cancer
  - Pap testing (women 21+ with cervix)
  - HPV DNA testing♀ (women 30–65 with normal pap results)
- Colorectal cancer
  - Fecal occult blood testing, sigmoidoscopy, and/or colonoscopy. (adults 50–75)
- Lung cancer screening
  - Annual tomography (adults 55–80 with history)
- Skin cancer
  - Counseling (adults 18–24)

Chronic Conditions

- Abdominal aortic aneurysm screening (men 65–75 who have ever smoked)
- Cardiovascular health
  - Hypertension screening
  - Blood pressure
  - Lipid disorders screenings (high risk women 20+; at risk men 20–35; all men 35+)
  - Aspirin (men 45–79; women 55–79)
  - Behavioral Counseling (overweight or obese adults with CVD risk factors)
- Diabetes (Type 2) screening (adults with elevated blood pressure
- Depression screening (adults when follow up supports available)
- Hepatitis B screening (adults at high risk for infection)
- Hepatitis C screening (high risk adults; one time screening for adults born between 1945 and 1965)
- Obesity Screening and Management (all adults via body mass index (BMI))
  - Referral for intervention for adults ≥ BMI of 30 kg/m^2
- Osteoporosis screening (all women 65+; high risk women <60)

Immunizations

- Haemophilus influenzae type b (adults 18+ with risk factors)
- Hepatitis A (adults with risk factors)
- Hepatitis B (adults with risk factors)
- HPV (women 18–26 and men 18–21 not previously vaccinated; at risk men 22–26)
- Influenza (yearly)
- Meningococcal (adults 18+ with risk factors)
- Measles, Mumps and Rubella (adults 18–49; 50+ with risk factors)
- Pneumococcal (adults 19–64 with risk factors; adults 65+)
- Td booster, Tdap
- Varicella
- Zoster (adults 60+)

Health Promotion

- Alcohol misuse screening and counseling (risk assessment all adults)
- Fall Prevention Counseling and Preventive Medication (community-dwelling adults 65+)
- Intimate partner violence screening, counseling♀ (women)
- Tobacco counseling and cessation interventions
- Well-woman visits♀ (women 18–64; visits for recommended preventive services, preconception care, and/or prenatal care)

Pregnancy-Related**

- Alcohol misuse screening and counseling
- Breastfeeding supports
  - Counseling
  - Consultations with trained provider♀
  - Equipment rental♀
- Folic acid supplements (women with reproductive capacity)
- Gestational diabetes screenings♀ (after 24 weeks gestation)
- Iron deficiency anemia screening
- Preeclampsia preventive medicine (pregnant women at high risk)
- Low-dose aspirin (at risk women after 12 weeks of gestation)
- Screenings for pregnant women
  - Hepatitis B
  - Chlamydia (women ≤24 years; older women at risk)
  - Gonorrhea
  - Syphilis
  - Bacteriurea
- Tobacco counseling and cessation interventions

Reproductive Health

- Contraception (all women with reproductive capacity)♀ *
  - All FDA-approved contraceptive methods as prescribed
  - Sterilization procedures
  - Patient education and counseling
  - Services related to follow-up, management of side effects, and device removal
- Screenings
  - Chlamydia (sexually active women ≤24 years old, older women at risk)
  - Gonorrhea ((sexually active women ≤24 years old, older women at risk)
  - Syphilis (adults at high risk)
  - HIV (adults 15–65; at-risk younger adolescents and older adults)
- STI and HIV counseling (adults at high risk; all sexually-active women♀)

Notes: Unless noted, applicable age for the recommendations is age 18+. Pregnancy-related applies to pregnant women. Age ranges are meant to encompass the broadest range possible. Each service may only be covered for certain age groups or based on risk factors. *The ACA defines the recommendations of the USPSTF regarding breast cancer services to "the most current other than those issued in or around November 2009." Thus, coverage for mammography is guided by the 2002 USPSTF guideline. **Services in this column apply to all pregnant or lactating women, unless otherwise specified. ***Certain religious employers exempt from this requirement. ♀Recommendation from HRSA Women's Preventive Services; coverage for these services without cost sharing in "non-grandfathered" plans began August 1, 2012. Coverage without cost sharing for all other services went into effect Sep. 23, 2010.

Sources: CMS, Affordable Care Act Implementation FAQ's Set 18. CMS, Preventive Health Services for Adults. More information about each of the items in this table, including details on periodicity, age, risk factors, and specific tests and procedures are available at the following websites: USPSTF; ACIP; HRSA Women's Preventive Services.

Table 2: Summary of Selected Preventive Services for Children Covered by Non-Grandfathered Private Plans without Cost Sharing

Chronic Conditions

- Cardiovascular health
  - Blood pressure (screening for at risk newborn children – 3 years; children 3 years+)
  - Lipid disorders screenings (children 2 years+ risk assessment/ screening)
- Depression screening (adolescents 11 years+)
- Hepatitis B screening (adolescents at high risk for infection)
- Skin cancer counseling (children 10 years+)
- Obesity
  - Screening (children 2 years+ via body mass index (BMI)
  - Counseling and behavioral interventions (obese children 6 years+)

Immunizations

- DTaP (children 2 months– 6 years)
- Haemophilus influenzae type b (children 2 months – 4 years)
- Hepatitis A (children 1 year+; 2 years+ with risk factors)
- Hepatitis B (at birth; then newborn+)
- HPV (children 11 years+)
- Inactivated Poliovirus (children 2 months+)
- Influenza (yearly) (children 6+ months+)
- Meningococcal (children 11 years+; 2 months+ with risk factors)
- Measles, Mumps and Rubella (children 1 year+)
- Pneumococcal
  - Pneumococcal conjugate (children 2 months – 4 years; 5 years+ with risk factors)
  - Pneumococcal polysaccharide (children 2 years+ with risk factors)
- Td booster, Tdap (children 7 years+)
- Varicella (children 1 year+)
- Rotavirus (children 2– 6 months)

Health Promotion

- Anemia screening, supplements (children 6 months+ iron supplements for high risk 6 – 12 months)
- Dental caries prevention
  - Fluoride varnish (infants and children at age of primary teeth eruption)
  - Fluoride supplements(children 6+ months without fluoride in water source)
- Gonorrhea prophylaxis treatment (newborn)
- History and physical exams (prenatal+)
- Measurements:
  - Length/height and weight (children newborn–adolescence)
  - Head circumference, weight for length (newborn – 2 years)
  - Body mass index (BMI) (children 2 years+)
  - Blood pressure (risk assessment at birth; children 3 years+)
- Oral health: risk assessment, referral to dental home (children 6 months – 6 years)
- Screenings
  - Blood screening(newborn– 2 months)
  - Critical congenital health defect (newborn)
  - Lead screening(children risk assessment and/or test 6 months – 6 years)
  - Metabolic/hemoglobin, phenylketonuria, sickle cell, congenital hypothyroidism screenings (newborn+)
  - Tuberculin (children risk assessment 1 month+)
- Tobacco counseling and cessation interventions (children 5 years– adolescence)
- Vision and hearing screenings/assessment (children newborn+)

Reproductive Health

- Contraception (all women with reproductive capacity)♀*
  - All FDA-approved contraceptive methods as prescribed
  - Sterilization procedures
  - Patient education and counseling
  - Services related to follow-up, management of side effects, and device removal
- STI and HIV counseling (sexually-active adolescents)
- Screenings
  - Chlamydia (sexually active females)
  - Gonorrhea (sexually active females)
  - HIV (adolescents and at risk children; screening ages 16–18)
  - STIs (risk assessment for adolescents; screening ages 16– 18)

Development and Behavioral Health

- Alcohol misuse screening and counseling (risk assessment adolescents 11 years+)
- Autism screening: (infants 18– 24 months)
- Developmental screenings and surveillance (newborn+)
- Psychosocial/ behavioral assessment (newborn+)

Notes: Age ranges are meant to encompass the broadest range possible, up to age 21. Each service may only be covered for certain age groups or based on risk factors. For specific details on recommendations, please consult the websites listed below. *Certain religious employers exempt from this requirement. ♀Recommendation from HRSA Women's Preventive Services; coverage for these services without cost sharing in "non-grandfathered" plans began August 1, 2012. Coverage without cost sharing for all other services went into effect Sep. 23, 2010.
Sources: CMS, Affordable Care Act Implementation FAQ's Set 18. CMS, Preventive health services for children. More information about each of the items in this table, including details on periodicity, age, risk factors, and specific tests and procedures are available at the following websites: USPSTF; Bright Futures and American Academy of Pediatrics; ACIP; HRSA Women's Preventive Services.