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Received by the
CON Section

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Mr. Les Brown, Project Analyst
Mr. Craig Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Comments on Certificate of Need application filed by: Halifax Gastroenterology, PC and Prashanti, LLC to develop an ambulatory surgical center with two gastrointestinal procedure rooms / Halifax County / Project ID # L-8614-10

Dear Mr. Brown and Mr. Smith:

On behalf of Halifax Regional Medical Center (HRMC), thank you for the opportunity to comment on the above referenced application by Halifax Gastroenterology, P.C. and Prashanti, LLC (Halifax GI) for a Certificate of Need for a new licensed ambulatory surgical center with two gastrointestinal procedure rooms. This decision will have a major impact on the healthcare delivery system in Halifax County. Hence, I trust that you will take these comments into consideration during your review.

In the Findings of Fact for the Certificate of Need Statute (GS 131E-175), the legislature identified several guiding principles aimed at strengthening the health care delivery system in North Carolina and insuring its population of broad-based, sustainable access to services. Among those principles, numbers (3), (3a), (4) and (6) bear special consideration in this review.

- (3) That, if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.

- (3a) That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.
- (4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.
- (6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

We hope that you pay special attention to Principal (3a) which is reinforced in the Basic Principles for the 2010 State Medical Facilities Plan (SMFP), on SMFP page 3.

“The needs of rural and small communities that are distant from comprehensive urban medical facilities merit special consideration. In rural and small communities selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services.”

Halifax GI's Certificate of Need (CON) application calls attention to the insured's desire for a lower charge outpatient option, the need for another gastroenterologist in Halifax and Northampton Counties, and claims that Halifax County needs a patient-friendly GI endoscopy facility. The application fails to acknowledge that the Patient Protection and Affordable Care Act of 2010, PL 111-148, (ACA) and HRMC have already solved these issues.

First, the ACA removes all copays and deductibles for preventive colonoscopies and flexible sigmoidoscopy for Medicare recipients starting January 1, 2011. Medicare represents approximately 54 percent of Halifax GI's estimated procedures in all three Project Years. ACA legislation also prohibits commercial policies, started after March 23, 2010, from including copays and deductibles for preventive colonoscopies and flexible sigmoidoscopy. Please see Attachment C. Commercial policies started before March 23, 2010 can be "grandfathered" and exempted from the mandate. However, it is estimated that up to 69 percent of grandfathered plans will lose their status by 2013. Please see Attachment C. In North Carolina, this is already happening; North Carolina Blue Cross Blue Shield (NCBCBS) made the change in its 2011 renewals; and MedCost, a major Third Party Administrator (TPA) for independent Employment Retirement Security Act (ERISA) Plans, introduced a policy of first colonoscopy without patient cost sharing before the ACA. Finally, it is likely that Medicaid will follow Medicare policy by 2013. ACA legislation allows a one percentage point increase in federal matching payments for Medicaid preventive services for states that offer Medicaid coverage with no patient cost sharing for services recommended (rated A or B) by the U.S. Preventive Services Task Force (USPSTF). Preventive colorectal cancer screening is rated A. Please see Attachment C. Therefore, by the third project year, it is likely that most of area residents will not have a copay or deductible for preventive colorectal cancer screening procedures. As a

result, in most cases, a freestanding GI endoscopy center no longer represents lower out-of-pocket costs for patients.

Second, January 1, 2011, HRMC will start scheduling patients for Rory O'Connor, MD. Dr. O'Connor is a board-certified gastroenterologist who will join the HRMC medical staff, full-time, on or before February 22, 2011, well before Halifax GI could be certified for reimbursement. Please see Attachment H. He has already been credentialed by the HRMC medical staff and is licensed in North Carolina.

Finally, HRMC is in the planning stages of updating and refinishing its GI endoscopy suite, remodeling outpatient registration, and adding convenient outpatient parking.

Dr. O'Connor should satisfy the unmet gastroenterologist needs of Halifax and Northampton Counties. Data from the most recent estimate of physician need by specialty indicate that Halifax and Northampton Counties can reasonably support only two gastroenterologists by the third project year, 2013. See detailed methodology in Attachment D.

Approval of Halifax GI's CON will lead to unnecessary duplication of services. Material compliance with the application would require addition of a third gastroenterologist in our service area. Halifax and Northampton Counties can support only two gastroenterologists. Presence of a third gastroenterologist will strain a fragile rural health system and jeopardize Halifax and Northampton Counties resident access to quality health care services. Should an existing service fail, residents would have no service.

After Dr. Yerra opened his office-based endoscopy center, and stopped scheduling outpatients at HRMC, our GI endoscopy program went from contributing \$250,000 to operating overhead to losing approximately \$250,000 a year on direct costs. For a hospital that has a five-year average operating margin of about one percent, this is a tremendous loss. It required us to lay off a number of employees. It is also a loss HRMC will continue to shoulder. As a hospital with Joint Commission accreditation, HRMC cannot elect to drop its GI endoscopy service. HRMC must have capacity for emergency and inpatient GI endoscopy services. Without a GI endoscopy program on site, HRMC is required to provide seamless GI endoscopy care for emergency patients. Practically, this would require HRMC to transport and emergency GI endoscopy patient to another inpatient facility. This would involve transporting these patients to Nash General Hospital and back for GI endoscopy care, on our own dime. This is expensive and not ideal patient care.

Rural areas, like Halifax and Northampton Counties, cannot support the same level of health service fragmentation as an urban area. The population base is too small to sustain duplication of services like GI endoscopy. People have the impression that hospitals cannot fail. However, residents of Warren and Alexander Counties know differently; hospitals in both have closed. Small populations require economies of scale available only when services are consolidated at the hospital.

Ambulatory Surgery Centers (ASCs) are an integral part of the American healthcare delivery system. In 2008, over 40 percent of outpatient surgeries were performed in ASCs. Growth has been attributed to patient cost savings, superior patient outcomes, and high patient satisfaction. However, trends are starting to stabilize. Please see Attachment I. With the removal of copays and deductibles for preventive procedures, increased hospital spending on patient-friendly outpatient departments, and increasing programming for infection control, hospital patients can receive cost-effective, patient-friendly services similar to a freestanding facility.

HRMC is no exception to this trend. Our employee health plan offers preventive colorectal cancer screening without co-pays and deductibles and we are currently planning for GI endoscopy suite updates, remodeling of outpatient registration, and the addition of convenient outpatient parking will be next. HRMC is confident that area residents will receive the same patient-friendly services at HRMC as they would in a freestanding facility.

Because HRMC has addressed programming, facilities, payment, and gastroenterologist supply, and more capacity is not justified by need, approval of Halifax Gastroenterology, P.C. and Prashanti, LLC's CON application would cause unnecessary duplication of services.

Halifax Gastroenterology, P.C. and Prashanti, LLC's CON application also has serious technical shortcomings and is nonconforming to CON Review Criterion (1), (3), (4), (5), (6), (7), (8), (12), and (18a). The application fails to: identify the population to be served by the proposed project; demonstrate the need for the proposed project; demonstrate that the project is the least costly alternative; demonstrate financial and operational feasibility of the proposed project; demonstrate the project will not cause unnecessary duplication of services; demonstrate the availability of health manpower for the proposed project; demonstrate the availability of necessary ancillary and support services for the proposed project; demonstrate that the costs of construction are the most reasonable; and demonstrate how the proposed project will have a positive impact on cost effectiveness, quality, and access to GI endoscopy services. These issues are highlighted in more detail in Attachment A.

Given the concerns of HRMC and the number of flaws in the application, we urge you to deny Halifax GI's request.

Thank you for your time and consideration of our comments. We understand the difficulties presented in these types of reviews and appreciate your attention to details. Should you have any questions, please do not hesitate to call me at 252-535-8011.

Sincerely,



William Mahone, V
President
Halifax Regional Medical Center

Attachments:

- A- Noncompliance with CON Review Criteria and Section .3900 Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities
- B- 2008 USPSTF Colorectal Cancer Screening Guidelines
- C- Health Reform Articles: TMA Division of Medical Economic - "Preventive Health Coverage Mandates Under the Accountable Care Act"; HealthCare.gov - "Preventive Care and Services under the Affordable Care Act"; Medicare and You - "Part B Covered Services"; and HR 3590 - "Sec. 4106. Improving Access to Preventive Services for Eligible Adults in Medicaid"
- D- Physician Need Methodology
- E- Proposed Halifax GI Floor Plans
- F- CMS Memo: S&C-10-20-ASC
- G- CCME Colorectal Cancer Screening Data
- H- Documentation of New Gastroenterologist at HRMC
- I- American Hospital Association Report on ASC Utilization Trends
- J- Halifax GI Procedure to Patient Ratio Calculation
- K- AAAHC and Certification Documentation
- L- Facility and Non-Facility Medicare Reimbursement
- M- Halifax GI Revenue Calculations

Attachment A

Noncompliance with CON Review Criteria, and
Noncompliance with Criteria and Standards for GI Endoscopy Procedure Rooms in
Licensed Health Service Facilities

COMPLIANCE WITH CON REVIEW CRITERIA

This document discusses Halifax Gastroenterology, P.C. and Prashanti, LLC's (Halifax GI) Certificate of Need (CON) application within the framework of the State's CON Review Criteria and applicable Gastrointestinal Endoscopy Procedure Room Rules (10A NCAC 14C .3900). We have addressed only those Criteria for which we believe the information provided in nonconforming.

- 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, ambulatory surgery operating rooms, or home health offices that may be approved.*

The CON application proposed by Halifax GI is not consistent with all of the special rules in 10A NCAC 14C Section .3900 – Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities. It is also inconsistent with the underlying Basic Principles for the Plan. Thus, the Halifax GI application is not conforming to Criterion (1).

- 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.*

Population to be served

Halifax GI application page 47, Section III.6, projects patients to be served. However, it is impossible to verify if these data are correct for Project Year 1. Halifax GI application page 47, Section III.6, states that 2,287 patients will be served in Project Year 1. Data provided in Halifax GI application Exhibit 11 indicate that 2,391 patients will be served in Project Year 1. Furthermore, patient estimates are based on unsubstantiated assumptions. Step 4, in Halifax GI application page 36, Section III.1. (b), states that procedures are converted to patients based on a ratio of 1.15 procedures to patients. The application provides no assumption or explanation for why this is reasonable. Please see discussion in Criterion (5) below. With such inconsistent and unsubstantiated information, the application does not identify the population to be served by the proposed project.

Need

Halifax GI does not adequately demonstrate the need of the population to be served for the services proposed for the following reasons:

- Demographic data provided on Halifax GI application pages 23 and 24, Section III.1. (b) are incorrect and misleading. Halifax GI application page 24, Section III.1. (b), states that endoscopy procedures are the most critical for persons 65 and older. On the same page, the application states that the need for the proposed GI endoscopy procedure rooms is supported by the growth in size of the service area population over 65. However, these statements are inaccurate and an attempt to mislead.

The U.S. Preventive Services Task Force (USPSTF) recommends screening for colorectal cancer using high-sensitivity fecal occult blood testing, sigmoidoscopy, or colonoscopy beginning at age 50 years and continuing until age 75 years. It notes that the decision to be screened after age 75 should be made on an individual basis.¹ Furthermore, an examination of the proposed primary service area population age 50 to 74 shows an annual population growth of less than one percent over the next five years. This equates to an addition of only 854 people, or an average of 171 annual screening colonoscopy procedures (854/5=171; assumes one procedure every ten years). A population driven increase of 171 procedures in a given year does not justify more GI procedure room capacity. Please see Table 1.

Table 1. Population Trends for Persons Age 50-74

| Area | 2010 | 2011 | 2012 | 2013 | 2014 | Additional Residents | CAGR |
|----------------------------|--------|--------|--------|--------|--------|----------------------|------|
| Halifax County | 15,932 | 16,077 | 16,273 | 16,445 | 16,589 | 657 | 1.0% |
| Northampton County | 6,239 | 6,251 | 6,307 | 6,394 | 6,436 | 197 | 0.8% |
| Primary Service Area Total | 22,171 | 22,328 | 22,580 | 22,839 | 23,025 | 854 | 0.9% |

Source: *demog.state.nc.us*.

¹ http://www.cdc.gov/cancer/colorectal/basic_info/screening/guidelines.htm#1. Please see hard copy in Attachment B.

- Cancer statistics provided on Halifax GI application page 24, Section III.1. (b) are insufficient and misleading. Halifax GI application page 24, Section III.1.(b), contains a table documenting projected 2010 new colorectal cancer cases and 2010 colorectal deaths in Halifax and Northampton Counties. However, the preparer failed to show projected data for 2011, 2012, and 2013, the facility's proposed project years. Furthermore, an examination of historical data from the North Carolina Center for Health Statistics, for the proposed primary service area, shows that both new colorectal cancer cases and colorectal deaths have been decreasing. Please see Table 2 and 3. These data also reinforce the very small numbers of people involved in this service.

Table 2. New Colorectal Cancer Cases

| County | 2006 | 2007 | 2008 | 2009 | 2010 | CAGR 2006-2010 |
|---|------|------|------|------|------|-------------------|
| Halifax | 35 | 35 | 34 | 33 | 32 | -2% |
| Northampton | 15 | 15 | 15 | 14 | 14 | -2% |
| Primary Service Area Total | 50 | 50 | 49 | 47 | 46 | -2% |

Source: <http://www.schs.state.nc.us/SCHS/CCR/projections.html> -

Table 3. Colorectal Cancer Deaths

| County Cases | 2006 | 2007 | 2008 | 2009 | 2010 | Growth Rate |
|---|------|------|------|------|------|----------------|
| Halifax | 15 | 15 | 13 | 12 | 11 | -7% |
| Northampton | 5 | 5 | 6 | 5 | 5 | 0% |
| Primary Service Area Total | 20 | 20 | 19 | 17 | 16 | -5% |

Source: <http://www.schs.state.nc.us/SCHS/CCR/projections.html> -

- In a critical oversight, the preparer of Halifax GI's application failed to recognize changes already in effect as a result of the Patient Protection and Affordable Care Act of 2010, PL 111-148 (ACA). ACA mandates that preventive colonoscopies and flexible sigmoidoscopy for Medicare recipients be available independent of copayments or deductibles, starting January 1, 2011. The ACA also prohibits commercial policies, started after March 23, 2010, from applying copayments or deductibles for preventive colonoscopies and flexible sigmoidoscopy. Please see Attachment C. Although, commercial policies started before March 23, 2010 can be "grandfathered" and do not

have to participate in the mandate, analysts estimate that up to 69 percent of grandfathered plans will lose their status by 2013. Please see Attachment C. North Carolina Blue Cross Blue Shield (NCBCBS) made the change in its 2011 renewals and MedCost, a major Third Party Administrator (TPA) for independent Employment Retirement Income Security Act (ERISA) Plans, introduced a policy of first colonoscopy without patient cost sharing before ACA. NCBCBS and MedCost are two of the largest commercial insurers in Halifax County. Finally, it is likely that Medicaid will follow Medicare policy by 2013. The ACA allows a one percentage point increase in federal matching payments for preventive services in Medicaid for states that offer Medicaid coverage with no patient cost sharing for services recommended (rated A or B) by the U.S. Preventive Services Task Force (USPSTF). Please see Attachment C. By the third project year it is likely that most service area residents in need of GI endoscopy services will not have a copay or deductible at any service location. As a result, in most cases, a freestanding GI endoscopy center no longer results in lower out-of-pocket costs for patients.

- Halifax GI application page 31, Section III.1. (b) notes that all of the counties of similar size to Halifax County have one or more licensed ASCs with GI procedure rooms. This is completely false. There are a number of counties, of similar size to Halifax County, that have no ASC with GI endoscopy procedure rooms. Please see Table 4, which was drawn from the Division of Health Service Regulation (DHSR) Planning database.

Table 4. North Carolina Counties of Similar Size to Halifax County with no ASC with GI Endoscopy Procedure Rooms in 2009

| County | FY 2009 Population | Total Number of Endoscopy Procedure Rooms in licensed ASCs |
|-------------|--------------------|--|
| Beaufort | 47,393 | 0 |
| Columbus | 56,309 | 0 |
| Duplin | 53,659 | 0 |
| Edgecombe | 51,327 | 0 |
| Granville | 57,434 | 0 |
| Haywood | 58,028 | 0 |
| Hoke | 46,134 | 0 |
| Pender | 53,095 | 0 |
| Stanly | 60,079 | 0 |
| Stokes | 46,792 | 0 |
| Halifax | 55,173 | 0 |
| Northampton | 21,018 | 0 |

Source: Population data: demog.state.nc.us; Procedure rooms: DHSR Planning database

- There is no need for Halifax GI to recruit another gastroenterologist to Halifax County. On Halifax GI application page 32, Section III.1.(b), the application preparer comments that the population of Halifax County is comparatively underserved in terms of the number of gastroenterologists. This is misleading. Although Halifax County had only one gastroenterologist physically present in November 2010, another was under contract to begin practice in February 2011. Halifax Regional Medical Center (HRMC) has contracted with a second board-certified gastroenterologist. Rory O'Connor, MD is credentialed by HRMC and is scheduled to start practice at HRMC on, or before, February 22, 2011. Credentials were accepted by the HRMC medical staff prior to the date of submission of the Halifax GI application. Please see Attachment H. This information is missing from the Halifax GI application. Data from the most recent estimate of physician need by specialty indicate that Halifax and Northampton Counties can reasonably support only two gastroenterologists by Project Year 3, 2013. Please see detailed methodology in Attachment D.

Access

- The Halifax GI application does not adequately demonstrate the extent to which all residents of the area are likely to have access to the services proposed. 10A NCAC .3903 (c) states that the application must demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy rooms: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures. Halifax GI's proposal does not project esophagoscopy procedures. Therefore, the proposal is not providing access to all necessary patient types. Please see discussion in 10A NCAC .3903 (c).
- In this particular instance, access of inpatients is a critical consideration. The application does not consider the very real impact of certifying excess outpatient services on the viability of essential inpatient services. According to HRMC data, when the Halifax GI outpatient program opened, and its owner stopped doing outpatient procedures at HRMC, the number of total GI endoscopy procedures at HRMC declined from 2,352 to 692. As such, HRMC's current GI endoscopy rooms are not fully used ($692/1,500 = 0.46$). However, as a Joint Commission accredited hospital, HRMC must offer GI endoscopy services. HRMC must sustain capacity to support a full GI procedure room for inpatient and emergency patients. This requires equipment staff and space. With the service area's only gastroenterologist performing procedures primarily in his unlicensed outpatient center, HRMC's GI endoscopy program now requires an annual subsidy of approximately \$250,000. This forced the hospital to recruit another gastroenterologist and to provide salary and relocation assistance, to sustain the required program. With insufficient demand in the community to support three gastroenterologists, the service area will be at risk of the very same results feared by the North Carolina Legislature in the Findings of

Fact, G.S. 131E-175 (3) and (4) and in the 2010 State Medical Facilities Plan Access Basic Principal. At the end of the day, approval of the proposed CON could result in loss of both HRMC's gastroenterologist and the gastroenterologist proposed by Halifax GI application. This would be tragic for all.

In conclusion, the application does not adequately demonstrate the population to be served by the proposed project, does not adequately demonstrate the need that its projected population has for the services proposed and does not adequately demonstrate that all persons will have access to its proposed services. Thus, the application is nonconforming to Criterion (3).

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.*

The application is not conforming to other applicable statutory and regulatory review criteria. Therefore, Halifax GI did not demonstrate the least costly or most effective alternative has been proposed. Thus, the application is not conforming to this criterion. See discussion in Criteria (1), (3), (5), (6), (7), (8), (12), and (18a).

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.*

Operational Projections

Halifax GI application pages 36 through 45, Section III.1. (b) provides two utilization methodologies.

Both methodologies are nonconforming to this Criterion for the following reasons:

Methodology 1

- Step 1, on Halifax GI application page 36, Section III.1.(b), states that, over the next five years, a projected annual increase of 1.5 percent in Dr. Yerra's procedures, is reasonable because of an aging population, increased public awareness, decreasing number of patients referred out of the service area, and increased marketing. However, Dr. Yerra's historical utilization figures do not support such an increase. Per the information provided on Halifax GI application page 35, Section III.1.(b), in Calendar Year 2009, Dr. Yerra performed 2,062 GI endoscopy procedures at the Halifax GI Endoscopy Center and in Calendar Year 2010 Dr. Yerra is expected to

perform only 2,044 GI endoscopy procedures at the Halifax GI Endoscopy Center. This represents a decrease of 0.87 percent $((2,044/2,062-1)*100=0.87)$. Furthermore, the application contains no proof that Halifax GI's marketing budget will increase, the assumption provides no basis for assuming that patients being referred out will decrease, and the methodology does not discuss the impact of HRMC's newly recruited gastroenterologist.

- Step 3, on Halifax GI application page 36, Section III.1.(b), estimates Halifax GI's second physician's GI endoscopy procedures as a percentage of Dr. Yerra's current monthly procedure average. However, the application preparer fails to demonstrate that the percentages are reasonable. Furthermore, the application provides no documentation to show that hiring a second gastroenterologist by September 2011 is feasible. The application provides no recruitment letters, no marketing materials, no letters of intent, and no contracts with professional recruiters, and no relocation budget. As a point of reference, it took HRMC almost two years to recruit Dr. O'Connor.
- Step 4, on Halifax GI application page 36, Section III.1. (b), states that procedures are converted to patients based on a ratio of 1.15 procedures per patient. The application provides no assumption or explanation for why this is reasonable. Halifax GI application page 44 , Section III.1.(b), contains a table showing different procedure to patient ratios, but the application fails to state why 1.15 was picked or is reasonable. Halifax GI is currently providing the proposed services in an office-based center and should have utilized existing ratios for this calculation. HRMC estimates Halifax GI's ratio over the last 12 months at 1.05 $(2,089/1,989 = 1.05)$. Please see detailed discussion in Attachment J.
- Halifax GI failed to document that it will receive procedure referrals sufficient to reach its projected volumes.

Methodology 2

- Step 4, on Halifax GI application page 38, Section III.1.(b), multiplies a statewide GI endoscopy rate by the projected service area population to estimate procedures. The application states this is reasonable because the populations of Halifax and Northampton Counties are older than the state and Halifax and Northampton Counties have colon cancer rates higher than the state. This is an arbitrary assumption and not reasonable. Historically, Halifax and Northampton County colorectal cancer screening use rates have been lower than the state. Please see Attachment G. It is not reasonable to totally ignore existing county use rates when formulating baseline projections. It is possible that factors such as age and disease incidence could affect utilization in future years but it is not reasonable to totally dismiss existing local baseline data, without explanation.

- Step 7, on Halifax GI application page 39, Section III.1. (b), states that market share increases are based on the assumption that Halifax GI will recruit a second gastroenterologist. However, for this methodology as well, the application provides no documentation to show that hiring a second gastroenterologist by September 2011 is feasible. The application provides no recruitment letters, no marketing materials, no letters of intent, and no contracts with professional recruiters, and no relocation budget. Also, as stated above, it took HRMC almost two years to recruit Dr. O'Connor.
- Step 14, on Halifax GI application page 40, Section III.1. (b), estimates HRMC GI endoscopy procedure market share during the three project years. The estimates are too low. Halifax GI's consultant failed to acknowledge that HRMC has already recruited a second gastroenterologist who will begin work on or before February 22, 2010 or that the ACA changed the nature of patient incentives. Please see Attachments B and H.
- Halifax GI failed to provide documentation to support its assertion that it will receive procedure referrals sufficient to reach its projected volumes.

The final issue with Halifax GI's operational projections relates to the proposed project schedule provided in Section XII, Halifax GI application page 90. Halifax GI projects licensure and certification on the same day. This is not possible. Halifax GI is AAAHC accredited as an Office-Based Surgery Center. As such, Halifax GI is not eligible for "Deemed Status" with Medicare and will have to go through the certification process. This process can take three to six months. Please see Attachment K.

Financial Projections

Halifax GI's financial projections are unsupported and unreliable for the following reasons:

- Halifax GI's projections for utilization are unsupported and unreliable. See discussion above. Consequently, costs and revenues that are based on the utilization projections provided in the application are unreliable.
- Halifax GI's revenue projections are unreliable and unsubstantiated. The application provides no assumptions for its reimbursement rates. The ASC reimbursement methodology is very complicated.
- Based on the facility design presented in the application, it is not reasonable for the applicants to assume the proposed facility meets Medicare certification requirements. Please see discussion in Criterion (12). Without certification, Halifax GI will not receive a facility fee payment from Medicare. Halifax GI physicians can, as Dr.

Yerra does now, receive an enhanced physician payment for services. However, the enhanced physician payment does not require licensure and the amount is less than a facility fee payment for an ASC.

For Procedure Code 45378 (Halifax GI's most common), an enhanced payment is approximately \$162.97 ($\$382.00 - \$219.03 = \162.97). Please see Attachment L. The enhanced payment is \$152.03 less than Halifax GI's projected Medicare facility fee in Project Year 3 for Procedure Code 45378 ($\$315.00 - \$162.97 = \$152.03$). Attachment M applies the same methodology to all Halifax GI's projected CPT codes. Calculations show that when revenue is adjusted the project will lose approximately \$6,386 in Project Year 3.

- Halifax GI's staffing expenses are understated. The application fails to budget staff to cover Paid Time Off (PTO). Please see discussion in Criterion (7). The understated expenses will further exacerbate the losses projected above.

Availability of Funds

Halifax GI provides insufficient data to demonstrate availability of funds necessary to operate the proposed project for the following reasons:

- It is impossible to verify whether or not the applicants have sufficient funding to cover capital costs. As discussed in response to Criterion (12), Halifax GI's proposed endoscopy center waiting room is not separated from the office waiting room by a one-hour fire wall, as required by 42 CFR 416.44(b). The application provides no plan of correction or cost estimate. The application did allocate \$30,000 for additional construction or renovations but this amount must also cover any other Construction Section requirements related to infection control, life safety or engineering standards. New life safety codes have increased requirements in these areas since the facility was constructed.
- Start-up costs are underestimated. Halifax GI application page 79, Section IX.1. (a), states that there will be no start-up costs. This is unreasonable. The proposed facility will likely have staff training expenses. Halifax GI application page 67, Section VII.3. (a), states that all positions in the facility will be new.
- Halifax GI application page 79, Section IX.1. (c), states that there will be no initial operating expense. However, this assumes that licensure and certification are achievable on the same day. They are not. Medicare requires unannounced certification surveys. Generally, it takes about three to six months for certification approval once a facility is licensed. This would cause a lag in collections. Furthermore, based on the current facility design, Medicare certification is not possible for Halifax GI (Please see discussion in Criterion (12)). The resultant lag would result in a lower payment from Medicare (Please see discussion above). A cash flow lag and reduced payments would decrease receipts and could cause the applicants to need access to working capital. The application provides no documentation of access to working capital.

In conclusion, the application did not adequately demonstrate the availability of sufficient funds for capital and operating needs and the applicants' utilization and financial projections are unreliable. Thus, the application is nonconforming to Criterion (5).

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

HRMC is a licensed acute care hospital that offers outpatient and inpatient GI endoscopy services in the proposed Halifax GI service area. The application fails to adequately demonstrate that the needs of the proposed service area population require approval of the proposed Halifax GI endoscopy facility. The application also fails to prove that the service area can support the addition of a third gastroenterologist. Therefore, the Halifax GI application fails to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. As a result, the application is nonconforming with this criterion. Please see discussion in Criterion (3).

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.*

Halifax GI does not show evidence of resources, including health manpower and management personnel, for the provision of the services proposed to be provided for the following reasons:

- As stated on Halifax GI application page 39, Section III.1. (b), the success of the proposed project hinges on Halifax GI recruiting a second gastroenterologist. On this page, the application specifically states, "Projections are based on the assumption that Dr. Yerra / Halifax Gastroenterology will recruit a second board-certified gastroenterologist." Halifax GI provides no evidence in its application that recruitment of a second gastroenterologist is achievable. As stated above in Criterion (5), the application provides no recruitment letters, no marketing materials, no letters of intent, and no contracts with professional recruiters, and no relocation budget. Also, as stated above in Criterion (5), as a point of reference, it took HRMC close to two years to recruit Dr. O'Connor.
- The staffing chart in Halifax GI's application, Section VII.2, page 70, does not show adequate staffing to provide the services proposed. Halifax GI will operate 52 weeks a year, but the application does not provide staff to cover vacation coverage or sick days. If any staff member is sick or on vacation, the facility will be understaffed.

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.*

Halifax GI does not 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 for the following reasons:

- Halifax GI fails to document arrangements for radiology services. This is important because Licensure Regulation 10A NCAC 13C .0701 requires a facility to have the capacity of providing or obtaining diagnostic radiology services.
- Halifax GI fails to document arrangements for anesthetist services. This is important because Licensure Regulation 10A NCAC 13C .0401(b) requires a facility to have available an anesthetist and he or she shall be available to administer regional or general anesthesia.
- On application page 7, Section II.1, Halifax GI states that it will use contracted housekeeping services. However, Halifax GI provided no documentation that these services are available, as requested by application question II.2. (c).
- On application page 93, Form B Assumptions, Halifax GI states that Olympus will provide equipment maintenance. However, Halifax provided no documentation that these services are available, as requested by application question II.2. (c).
- Halifax GI fails to describe how linen services will be handled.

Halifax GI does not demonstrate that the proposed service will be coordinated with the existing health care system. As discussed in Criterion (5), Halifax GI failed to document a single referral from area healthcare providers. Furthermore, Halifax GI fails to provide a transfer agreement with a service area hospital. Please see discussion in 10A NCAC 14C .3904 (d) (2) and (3).

In conclusion, Halifax GI did not adequately demonstrate that it will make available or otherwise make arrangements for, the provision of the necessary ancillary and support services and does not demonstrate that the proposed services will be coordinated with the existing health care system. Thus, the application is nonconforming to Criterion (8).

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.*

The application is nonconforming to this criterion. The Halifax GI application does not demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative because the proposed facility design will not meet CMS Medicare certification standards for an ASC and the application provides no plan for conformance. Halifax GI's facility will not meet CMS Medicare certification standards because its GI endoscopy waiting room is not appropriately separated from the office waiting room.

In Halifax GI application Exhibit 4, Halifax GI provides a floor plan that clearly shows that the GI endoscopy waiting room and office space waiting room share space. Please see Attachment E. Per 42 CFR 416.2, 42 CFR 416.44 (a) (2), and 42 CFR 416.44(b), an ASC may not share space with another entity when the ASC is open, an ASC must have a separate waiting room, and a waiting room must meet the provisions applicable to Ambulatory Health Care, Chapters 20 and 21 in the National Fire Protection Association (NFPA) 101:2000 edition of the Life Safety Code (LSC). According to sections 20.3.7.1 and 21.3.7.1 of the LSC, an

"ambulatory health care facility shall be separated from other tenants and occupancies by walls having not less than a 1-hour fire resistance rating. Such walls shall extend from the floor slab below to the floor or roof slab above. Doors shall be constructed of not less than 1¾ inch thick solid-bonded wood core or the equivalent and shall be equipped with positive latches. These doors shall be self closing and shall be kept in the closed position except when in use. Any vision panels shall be of fixed fire window assemblies in accordance with 8.2.3.2.2."

This requirement applies regardless of whether or not an ASC is "temporally" distinct, i.e., it shares its space with occupancy (ies) but does not have concurrent or overlapping hours of operation. As is clearly documented in the line drawings provided in the Halifax GI application, the GI endoscopy waiting room is not separated from other tenants and occupancies by walls having not less than a 1-hour fire resistance rating. Please see Attachment E.

Although sections 20.1.2.1 and 21.1.2.1 of the LSC allow sections of an ASC to be classified as other occupancy types that are subject to lesser fire protection requirements, ASC waiting areas are not eligible for this allowance. The LSC requires that for a section of the ASC to be considered as an occupancy type other than Ambulatory Health Care it should not be intended to serve occupants for purposes of treatment or to provide customary access to patients incapable of self-preservation. Because patients occupy an ASC waiting area for the purpose of receiving treatment, and not all patients in an ASC waiting area may be capable of evacuating without assistance, CMS considers ASC waiting areas to be Ambulatory Health

Care occupancies. Therefore, the requirements of the LSC Chapters 20 or 21 apply to all new and existing ASCs waiting areas, respectively. Please see Attachment F for a memo from CMS explaining this requirement.

- 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 the service for which competition will not have a favorable impact.***

The Halifax GI application is nonconforming with Criteria (1), (3), (4), (5), (6), (7), (8), and (12). As a result, it is impossible to determine if the proposed project will have a positive impact upon the cost effectiveness, quality, and access to the services proposed. Therefore, the application is nonconforming with this criterion. Please see discussions in Criteria (1), (3), (4), (5), (6), (7), (8), and (12).

**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:

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

(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;

The application is nonconforming to this Rule. Data are inconsistent. Data provided on Halifax GI application Exhibit 10 state that 2,089 procedures were performed in the last 12 months. Data provided on Halifax GI application page 35, Section III.1. (b), state that 1,989 procedures were performed in the last 12 months.

(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;

Projections are based on flawed and undocumented assumptions. Please see discussion of Statutory Criterion (5) above.

(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;

The application is nonconforming to this Rule. The application preparer fails to answer this question. Thus, the application failed to provide 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.

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

The application is nonconforming to this Rule. The application preparer responded appropriately to this Rule. However, it is impossible to verify if Dr. Yerra served 1,989 patients in the last 12 months or if he performed 1,989 procedures. In response to this question, the application preparer references

Halifax GI application page 35, Section III.1.(b), to verify that 1,989 patients were served in the last 12 months. However, the data provided on Halifax GI application page 35, Section III.1. (b) is referenced as procedure data.

- (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;**

The application is nonconforming to this Rule. The application preparer responded to this Rule with an appropriate format. However, it is impossible to verify if the data for Project Year 1 are correct. The data provided on Halifax GI application page 47, Section III.6, state that 2,287 patients will be served in Project Year 1. Data provided in Halifax GI application Exhibit 11 state that 2,391 patients will be served. Please see discussion of Statutory Criterion (3) above.

- (6) the type and projected average facility charge for the ten GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.**

Projections are based on flawed and undocumented assumptions. Please see discussion of Statutory Criterion (5) above.

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

The application provides no assumptions for Medicare and Medicaid reimbursement rates. Please see discussion of Statutory Criterion (5) above.

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

Halifax GI's existing facility design will not meet Medicare ASC certification requirements. Please see discussion of Statutory Criterion (12).

10A NCAC 14C .3903 PERFORMANCE STANDARDS

- (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.**

Projections are based on flawed and undocumented assumptions. Please see discussion of Statutory Criterion (5) above.

- (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.**

The application is nonconforming to this Rule. The application does not project that Halifax GI will provide esophagoscopy procedures. The CPT code for esophagoscopy procedures are 43200 through 43232. The procedure data provided on Halifax GI application page 80, Section X.1, do not show Halifax GI physicians providing any procedures with CPT codes 43200 through 43232.

- (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.**

Projections are based on flawed and undocumented assumptions. Please see discussion of Statutory Criterion (5) above.

10A NCAC 14C .3904 SUPPORT SERVICES

(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;**

The application is nonconforming to this Rule. Halifax GI application, Exhibit 21, states that a physician must maintain admitting privileges at a Medicare Certified Hospital to have privileges at the proposed GI endoscopy center. The exhibit does not state that the Medicare Certified Hospital must be in Halifax County or a contiguous 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**

The application is nonconforming to this Rule. The application contains no signed transfer agreement from any hospital.

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

The application is nonconforming to this Rule. The application contains no signed transfer agreement from any hospital.

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.

The application is nonconforming to this Rule. Halifax GI's proposed GI endoscopy facility is not physically separate from its physician office. Please see discussion of Statutory Criterion (12).

(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.

Halifax GI's existing facility design will not allow it to be certified for Medicare participation. Please see discussion of Statutory Criterion (12).

Attachment B

2008 USPSTF Colorectal Cancer Screening Guidelines



Colorectal Cancer Screening Guidelines

Regular screening, beginning at age 50, is the key to preventing colorectal cancer.¹ (#1) The U.S. Preventive Services Task Force (USPSTF) recommends screening for colorectal cancer using high-sensitivity fecal occult blood testing, sigmoidoscopy, or colonoscopy beginning at age 50 years and continuing until age 75 years.¹ (#1)

Recommended screening tests and intervals are—² (#2)

- **High-sensitivity fecal occult blood test (FOBT)**, which checks for hidden blood in three consecutive stool samples, should be administered every year.
- **Flexible sigmoidoscopy**, where physicians use a flexible, lighted tube (sigmoidoscope) to inspect visually the interior walls of the rectum and part of the colon, should be administered every five years.
- **Colonoscopy**, where physicians use a flexible, lighted tube (colonoscope) to inspect visually the interior walls of the rectum and the entire colon, should be administered every 10 years. During this procedure, samples of tissue may be collected for closer examination, or polyps may be removed. Colonoscopies can be used as screening tests or as follow-up diagnostic tools when the results of another screening test are positive.
 - Colonoscopy also is used as a diagnostic test when a person has symptoms, and it can be used as a follow-up test when the results of another colorectal cancer screening test are unclear or abnormal.

People at higher risk of developing colorectal cancer should begin screening at a younger age, and may need to be tested more frequently. The decision to be screened after age 75 should be made on an individual basis. If you are older than 75, ask your doctor if you should be screened. For more information, read the current [colorectal cancer screening guidelines](http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm) [Ⓔ](http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm) (<http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm>) from the USPSTF.

References

¹U.S. Preventive Services Task Force. *Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement*. AHRQ Publication 08-05124-EF-3, October 2008. Agency for Healthcare Research and Quality, Rockville, MD.

²U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services, 2008: Recommendations of the U.S. Preventive Services Task Force*. AHRQ Publication No. 08-05122, September 2008. Agency for Healthcare Research and Quality, Rockville, MD.

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Content source: [Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion](#)

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA
30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day -
cdcinfo@cdc.gov





Attachment C

Health Reform Articles



VISION: To improve the health of all Texans.

MISSION: TMA supports Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients.

TMA Division of Medical Economics

Preventive Health Coverage Mandates Under the Accountable Care Act.

October 19, 2010

On September 23, 2010 a number of important health insurance and consumer provisions included in the Accountable Care Act became effective. Key among them is a requirement that *new* individual and group health plans cover preventive health services, such as immunizations, cancer screenings, and well-child and well-woman services, without a coinsurance, co-pay or deductible.

Does the Preventive Health Benefit Requirement Apply to All Health Plans? When Does the Provision Take Effect?

While media coverage has led many patients to believe the new requirement applies to all health plans, the law is more complicated. The preventive health provision applies to all *new* individual and group plans written on or after Sept. 23, 2010. *For existing plans, the application of this provision will depend upon when the policy was written.* (Note: insurers may voluntarily adopt the requirement earlier than actually required by the law).

Plans in existence prior to March 23, 2010, the date the ACA took effect, are considered “grandfathered” (discussed further below) and are exempt from this particular provision (grandfathered plans are subject to certain other important consumer insurance protections in the ACA; visit the TMA health reform school for more information).

Individual or group plans written after March 23, 2010 but prior to September 23, 2010 are also subject to the provision, but not until the plan’s renewal.

What are the Plans Required to Cover?

The required preventive services include:

- All vaccinations recommended by the Center for Disease Control's Advisory Committee on Immunization Practices
- All preventive care and screening for women and children recommended in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA):
 - For children, plans must cover the services recommended by the American Academy of Pediatrics' Bright Futures guidelines, which can be found here: <http://brightfutures.aap.org/pdfs/AAP%20Bright%20Futures%20Periodicity%20Sched%20101107.pdf>
 - For women, HRSA is required to develop guidelines by August 1, 2011 to address preventive health services not otherwise encompassed by the US Preventive Health Services Task Force recommendations. Insurers are not required to include coverage from newly-published guidelines until the plan year that begins a year or more after publication.
- All services rated "A" or "B" by the USPSTF including:
 - Screening for breast cancer, cervical cancer, chlamydia, colorectal cancer, depression, gonorrhea, hypertension, lipid disorders, obesity, osteoporosis, diabetes, aortic aneurysm, more...
 - Programs to promote breastfeeding,
 - Alcohol Misuse Screening and Behavioral Counseling Interventions
 - Dietary counseling for patients with certain risks
 - Tobacco cessation counseling programs

A detailed list of the USPSTF recommendations can be found here:
<http://www.ahrq.gov/clinic/pocketgd1011/pocketgd1011.pdf>

Plans may choose to cover additional preventive health services or screenings than those developed by the USPSTF.

Also, just because the ACA does not apply to a plan does not mean the plan does not cover preventive health services. Texas mandated benefit laws still apply to regulated plans (Texas Mandated Benefits). Further, many "grandfathered" plans may have been covering some or all of these benefits prior passage of the law or may add them in the future. However, as long as a plan retains its grandfather status, then the plan may impose patient cost-sharing for preventive health services.

What Does "Grandfathered" Mean?

Individual and group plans that were in place on March 23, 2010 and are still in place now are deemed "grandfathered." Grandfathered plans are exempt from the preventive health coverage provision. However, if a currently grandfathered plan makes material changes in benefit design or patient cost-sharing at renewal, it will lose its grandfather protection. Changes that will trigger a loss of "grandfathered" status:

- Increase coinsurance percentages
- Increase deductibles or out-of-pocket maximums more than 15% plus an inflation adjustment
- Increase co-pays more than inflation plus \$5 or 15%
- Eliminate benefits for a specific condition
- Decrease the employer contribution by more than 5% below the rate on March 23.
- Impose new annual limits on benefits or reduce existing ones.

Existing grandfathered plans renew their policies at different times throughout the year, depending on whether the plan is based on a calendar year or not. The Center for Medicaid and Medicare Services estimates that 39 percent to 69 percent of plans will lose their grandfather status by 2013.

How Can I Find Out If My Patient's Plan Must Cover Preventive Care without Coinsurance, Co-pay, or Deductible?

Patients and physicians should request information directly from the plans to determine whether the preventive care coverage will be added and when that will occur.

What Happens if the Office Visit Entails Services Other than Prevention?

Published rules, though not final, have provided some guidance to determine whether coinsurance and deductibles will be due on required preventive services:

- Cost sharing is prohibited when the preventive service is the primary purpose of the visit.
- If preventive service is billed separately from an office visit, cost sharing may apply for the office visit.
- When preventive services are provided by out-of-network providers, the plan is not required to provide coverage or may apply cost-sharing.
- Deductibles or co-pays may apply for treatment of conditions found in preventive screening.

Does the Preventive Health Coverage Provision Apply to Medicare and Medicaid?

Medicare will also be adding some preventive care coverage with no coinsurance or deductibles on January 1, 2011.

The law encourages state Medicaid programs to extend preventive health services to adult enrollees by offering additional federal funding if they do. Texas implemented preventive health coverage for this population in January 2010, though the changes did not encompass all immunizations recommended by the Advisory Committee on Immunization Practices. Texas is evaluating whether to comply with the ACIP schedule.

NOTICE: This information is provided as general guidance on billing, coding and reimbursement issues. Your specific facts may affect the general information provided and may modify how to specifically bill for a service. This is not a substitute for the advice of an attorney. Although TMA has attempted to present materials that are accurate and useful, some material may be outdated and TMA shall not be liable to anyone for any inaccuracy, error or omission, regardless of cause, or for any damages resulting therefrom. Certain links and attachments are maintained by third parties. TMA has no control over this information, or the goods or services provided by such third parties. TMA shall have no liability for any use or reliance of a user on the information provided by third parties.

Preventive Care and Services

Under the Affordable Care Act, you and your family may be eligible for some important preventive services—which can help you avoid illness and improve your health—at no additional cost to you.



What This Means for You:

If your plan is subject to these new requirements, you would not have to pay a copayment, co-insurance, or any deductible to receive preventive health services, such as recommended screenings, vaccinations, and counseling.

For example, depending on your age, you may have free access to such preventive services as:

- Blood pressure, diabetes, and cholesterol tests;
- Many cancer screenings, including mammograms and colonoscopies;
- Counseling on such topics as quitting smoking, losing weight, eating healthfully, treating depression, and reducing alcohol use;
- Routine vaccinations against diseases such as measles, polio, or meningitis;
- Flu and pneumonia shots;
- Counseling, screening, and vaccines to ensure healthy pregnancies;
- Regular well-baby and well-child visits, from birth to age 21.

Some Important Details:

- This preventive services provision applies to people enrolled in job-related health plans or individual health insurance policies created after March 23, 2010. If you are in such a health plan, this provision will affect you as soon as your plan begins its first new "plan year" or "policy year" on or after September 23, 2010.
- If your plan is "grandfathered," these benefits may not be available to you.
- If your health plan uses a network of providers, be aware that health plans are only required to provide these preventive services through an in-network provider. Your health plan may allow you to receive these services from an out-of-network provider, but may charge you a fee.
- Your doctor may provide a preventive service, such as a cholesterol screening test, as part of an office visit. Be aware that your plan can require you to pay some costs of the office visit, if the preventive service is not the primary purpose of the visit, or if your doctor bills you for the preventive services separately from the office visit.
- If you have questions about whether these new provisions apply to your plan, contact your insurer or plan administrator. If you still have questions, contact your State insurance department.
- To know which covered preventive services are right for you—based on your age, gender, and health status—ask your health care provider.

[Read a list of covered services.](#)

[Learn more background on the new prevention rules.](#)

[Check out healthfinder.gov and other prevention guides.](#)

[Read the regulation \(detailed legislative information\).](#)

Posted: September 23, 2010





Part B-Covered Services



Colorectal Cancer Screenings

To help find precancerous growths or find cancer early, when treatment is most effective. One or more of the following tests may be covered. Talk to your doctor.

- **Fecal Occult Blood Test**—Once every 12 months if 50 or older. You pay nothing for the test, but you generally have to pay 20% of the Medicare-approved amount for the doctor's visit.
- **Flexible Sigmoidoscopy**—Generally, once every 48 months if 50 or older, or 120 months after a previous screening colonoscopy for those not at high risk. Starting January 1, 2011, you pay nothing for this test if the doctor accepts assignment.
- **Colonoscopy**—Generally once every 120 months (high risk every 24 months) or 48 months after a previous flexible sigmoidoscopy. No minimum age. Starting January 1, 2011, you pay nothing for this test if the doctor accepts assignment.
- **Barium Enema**—Once every 48 months if 50 or older (high risk every 24 months) when used instead of a sigmoidoscopy or colonoscopy. You pay 20% of the Medicare-approved amount for the doctor's services. In a hospital outpatient setting, you also pay the hospital a copayment.

Defibrillator (Implantable Automatic)

For some people diagnosed with heart failure. You pay the doctor 20% of the Medicare-approved amount for the doctor's services. You also pay the hospital a copayment but no more than the Part A hospital stay deductible (see page 132) if you get the device as a hospital outpatient. The Part B deductible applies.

1 **SEC. 4106. IMPROVING ACCESS TO PREVENTIVE SERVICES**
2 **FOR ELIGIBLE ADULTS IN MEDICAID.**

3 (a) *CLARIFICATION OF INCLUSION OF SERVICES.*—Sec-
4 tion 1905(a)(13) of the Social Security Act (42 U.S.C.
5 1396d(a)(13)) is amended to read as follows:

6 “(13) other diagnostic, screening, preventive, and
7 rehabilitative services, including—

8 “(A) any clinical preventive services that
9 are assigned a grade of A or B by the United
10 States Preventive Services Task Force;

11 “(B) with respect to an adult individual,
12 approved vaccines recommended by the Advisory
13 Committee on Immunization Practices (an advi-
14 sory committee established by the Secretary, act-
15 ing through the Director of the Centers for Dis-
16 ease Control and Prevention) and their adminis-
17 tration; and

18 “(C) any medical or remedial services (pro-
19 vided in a facility, a home, or other setting) rec-
20 ommended by a physician or other licensed prac-
21 titioner of the healing arts within the scope of
22 their practice under State law, for the maximum
23 reduction of physical or mental disability and
24 restoration of an individual to the best possible
25 functional level;”.

1 (b) *INCREASED FMAP.*—Section 1905(b) of the Social
2 *Security Act* (42 U.S.C. 1396d(b)), as amended by sections
3 2001(a)(3)(A) and 2004(c)(1), is amended in the first sen-
4 tence—

5 (1) by striking “, and (4)” and inserting “, (4)”;
6 and

7 (2) by inserting before the period the following:
8 “, and (5) in the case of a State that provides medical
9 assistance for services and vaccines described in sub-
10 paragraphs (A) and (B) of subsection (a)(13), and
11 prohibits cost-sharing for such services and vaccines,
12 the Federal medical assistance percentage, as deter-
13 mined under this subsection and subsection (y) (with-
14 out regard to paragraph (1)(C) of such subsection),
15 shall be increased by 1 percentage point with respect
16 to medical assistance for such services and vaccines
17 and for items and services described in subsection
18 (a)(4)(D)”.

19 (c) *EFFECTIVE DATE.*—The amendments made under
20 this section shall take effect on January 1, 2013.

21 **SEC. 4107. COVERAGE OF COMPREHENSIVE TOBACCO CES-**
22 **SATION SERVICES FOR PREGNANT WOMEN IN**
23 **MEDICAID.**

24 (a) *REQUIRING COVERAGE OF COUNSELING AND*
25 *PHARMACOTHERAPY FOR CESSATION OF TOBACCO USE BY*

1 **SEC. 4104. REMOVAL OF BARRIERS TO PREVENTIVE SERV-**
2 **ICES IN MEDICARE.**

3 (a) *DEFINITION OF PREVENTIVE SERVICES.*—Section
4 1861(ddd) of the Social Security Act (42 U.S.C.
5 1395x(ddd)) is amended—

6 (1) in the heading, by inserting “; Preventive
7 Services” after “Services”;

8 (2) in paragraph (1), by striking “not otherwise
9 described in this title” and inserting “not described
10 in subparagraph (A) or (C) of paragraph (3)”;

11 (3) by adding at the end the following new para-
12 graph:

13 “(3) The term ‘preventive services’ means the fol-
14 lowing:

15 “(A) The screening and preventive services de-
16 scribed in subsection (ww)(2) (other than the service
17 described in subparagraph (M) of such subsection).

18 “(B) An initial preventive physical examination
19 (as defined in subsection (ww)).

20 “(C) Personalized prevention plan services (as
21 defined in subsection (hhh)(1)).”

22 (b) *COINSURANCE.*—

23 (1) *GENERAL APPLICATION.*—

24 (A) *IN GENERAL.*—Section 1833(a)(1) of the
25 Social Security Act (42 U.S.C. 1395l(a)(1)), as
26 amended by section 4103(c)(1), is amended—

1 (i) in subparagraph (T), by inserting
2 “(or 100 percent if such services are rec-
3 ommended with a grade of A or B by the
4 United States Preventive Services Task
5 Force for any indication or population and
6 are appropriate for the individual)” after
7 “80 percent”;

8 (ii) in subparagraph (W)—

9 (I) in clause (i), by inserting “(if
10 such subparagraph were applied, by
11 substituting ‘100 percent’ for ‘80 per-
12 cent’)” after “subparagraph (D)”; and

13 (II) in clause (ii), by striking “80
14 percent” and inserting “100 percent”;

15 (iii) by striking “and” before “(X)”;

16 and

17 (iv) by inserting before the semicolon
18 at the end the following: “, and (Y) with re-
19 spect to preventive services described in sub-
20 paragraphs (A) and (B) of section
21 1861(ddd)(3) that are appropriate for the
22 individual and, in the case of such services
23 described in subparagraph (A), are rec-
24 ommended with a grade of A or B by the
25 United States Preventive Services Task

1 *Force for any indication or population, the*
2 *amount paid shall be 100 percent of the*
3 *lesser of the actual charge for the services or*
4 *the amount determined under the fee sched-*
5 *ule that applies to such services under this*
6 *part”.*

7 (2) *ELIMINATION OF COINSURANCE IN OUT-*
8 *PATIENT HOSPITAL SETTINGS.—*

9 (A) *EXCLUSION FROM OPD FEE SCHED-*
10 *ULE.—Section 1833(t)(1)(B)(iv) of the Social*
11 *Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as*
12 *amended by section 4103(c)(3)(A), is amended—*

13 (i) *by striking “or” before “personal-*
14 *ized prevention plan services”; and*

15 (ii) *by inserting before the period the*
16 *following: “, or preventive services described*
17 *in subparagraphs (A) and (B) of section*
18 *1861(ddd)(3) that are appropriate for the*
19 *individual and, in the case of such services*
20 *described in subparagraph (A), are rec-*
21 *ommended with a grade of A or B by the*
22 *United States Preventive Services Task*
23 *Force for any indication or population”.*

24 (B) *CONFORMING AMENDMENTS.—Section*
25 *1833(a)(2) of the Social Security Act (42 U.S.C.*

1 1395l(a)(2)), as amended by section
2 4103(c)(3)(B), is amended—

3 (i) in subparagraph (G)(ii), by strik-
4 ing “and” after the semicolon at the end;

5 (ii) in subparagraph (H), by striking
6 the comma at the end and inserting “;
7 and”; and

8 (iii) by inserting after subparagraph
9 (H) the following new subparagraph:

10 “(I) with respect to preventive services de-
11 scribed in subparagraphs (A) and (B) of section
12 1861(ddd)(3) that are appropriate for the indi-
13 vidual and are furnished by an outpatient de-
14 partment of a hospital and, in the case of such
15 services described in subparagraph (A), are rec-
16 ommended with a grade of A or B by the United
17 States Preventive Services Task Force for any
18 indication or population, the amount determined
19 under paragraph (1)(W) or (1)(Y).”.

20 (c) WAIVER OF APPLICATION OF DEDUCTIBLE FOR
21 PREVENTIVE SERVICES AND COLORECTAL CANCER
22 SCREENING TESTS.—Section 1833(b) of the Social Security
23 Act (42 U.S.C. 1395l(b)), as amended by section 4103(c)(4),
24 is amended—

1 (1) *in paragraph (1), by striking “items and*
2 *services described in section 1861(s)(10)(A)” and in-*
3 *serting “preventive services described in subparagraph*
4 *(A) of section 1861(ddd)(3) that are recommended*
5 *with a grade of A or B by the United States Preven-*
6 *tive Services Task Force for any indication or popu-*
7 *lation and are appropriate for the individual.”; and*

8 (2) *by adding at the end the following new sen-*
9 *tence: “Paragraph (1) of the first sentence of this sub-*
10 *section shall apply with respect to a colorectal cancer*
11 *screening test regardless of the code that is billed for*
12 *the establishment of a diagnosis as a result of the test,*
13 *or for the removal of tissue or other matter or other*
14 *procedure that is furnished in connection with, as a*
15 *result of, and in the same clinical encounter as the*
16 *screening test.”.*

17 (d) *EFFECTIVE DATE.*—*The amendments made by this*
18 *section shall apply to items and services furnished on or*
19 *after January 1, 2011.*

20 **SEC. 4105. EVIDENCE-BASED COVERAGE OF PREVENTIVE**
21 **SERVICES IN MEDICARE.**

22 (a) *AUTHORITY TO MODIFY OR ELIMINATE COVERAGE*
23 *OF CERTAIN PREVENTIVE SERVICES.*—*Section 1834 of the*
24 *Social Security Act (42 U.S.C. 1395m) is amended by add-*
25 *ing at the end the following new subsection:*

1 “(n) *AUTHORITY TO MODIFY OR ELIMINATE COV-*
2 *ERAGE OF CERTAIN PREVENTIVE SERVICES.*—*Notwith-*
3 *standing any other provision of this title, effective begin-*
4 *ning on January 1, 2010, if the Secretary determines ap-*
5 *propriate, the Secretary may—*

6 “(1) *modify—*

7 “(A) *the coverage of any preventive service*
8 *described in subparagraph (A) of section*
9 *1861(ddd)(3) to the extent that such modification*
10 *is consistent with the recommendations of the*
11 *United States Preventive Services Task Force;*
12 *and*

13 “(B) *the services included in the initial pre-*
14 *ventive physical examination described in sub-*
15 *paragraph (B) of such section; and*

16 “(2) *provide that no payment shall be made*
17 *under this title for a preventive service described in*
18 *subparagraph (A) of such section that has not re-*
19 *ceived a grade of A, B, C, or I by such Task Force.”.*

20 (b) *CONSTRUCTION.*—*Nothing in the amendment made*
21 *by paragraph (1) shall be construed to affect the coverage*
22 *of diagnostic or treatment services under title XVIII of the*
23 *Social Security Act.*

1 **SEC. 4106. IMPROVING ACCESS TO PREVENTIVE SERVICES**
2 **FOR ELIGIBLE ADULTS IN MEDICAID.**

3 (a) *CLARIFICATION OF INCLUSION OF SERVICES.*—Sec-
4 tion 1905(a)(13) of the Social Security Act (42 U.S.C.
5 1396d(a)(13)) is amended to read as follows:

6 “(13) other diagnostic, screening, preventive, and
7 rehabilitative services, including—

8 “(A) any clinical preventive services that
9 are assigned a grade of A or B by the United
10 States Preventive Services Task Force;

11 “(B) with respect to an adult individual,
12 approved vaccines recommended by the Advisory
13 Committee on Immunization Practices (an advi-
14 sory committee established by the Secretary, act-
15 ing through the Director of the Centers for Dis-
16 ease Control and Prevention) and their adminis-
17 tration; and

18 “(C) any medical or remedial services (pro-
19 vided in a facility, a home, or other setting) rec-
20 ommended by a physician or other licensed prac-
21 titioner of the healing arts within the scope of
22 their practice under State law, for the maximum
23 reduction of physical or mental disability and
24 restoration of an individual to the best possible
25 functional level;”.

1 (b) *INCREASED FMAP.*—Section 1905(b) of the Social
2 Security Act (42 U.S.C. 1396d(b)), as amended by sections
3 2001(a)(3)(A) and 2004(c)(1), is amended in the first sen-
4 tence—

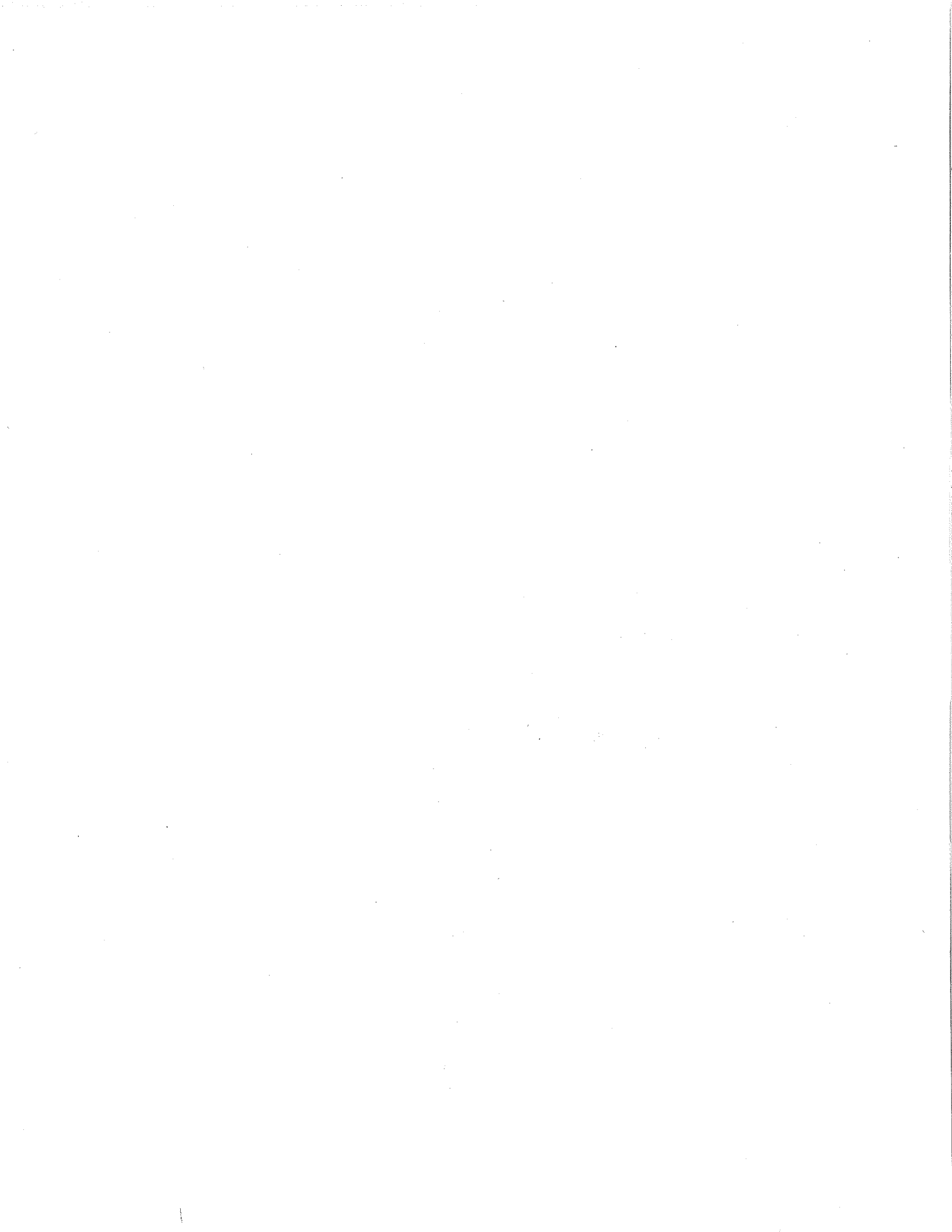
5 (1) by striking “, and (4)” and inserting “, (4)”;
6 and

7 (2) by inserting before the period the following:
8 “, and (5) in the case of a State that provides medical
9 assistance for services and vaccines described in sub-
10 paragraphs (A) and (B) of subsection (a)(13), and
11 prohibits cost-sharing for such services and vaccines,
12 the Federal medical assistance percentage, as deter-
13 mined under this subsection and subsection (y) (with-
14 out regard to paragraph (1)(C) of such subsection),
15 shall be increased by 1 percentage point with respect
16 to medical assistance for such services and vaccines
17 and for items and services described in subsection
18 (a)(4)(D)”.

19 (c) *EFFECTIVE DATE.*—The amendments made under
20 this section shall take effect on January 1, 2013.

21 **SEC. 4107. COVERAGE OF COMPREHENSIVE TOBACCO CES-**
22 **SATION SERVICES FOR PREGNANT WOMEN IN**
23 **MEDICAID.**

24 (a) *REQUIRING COVERAGE OF COUNSELING AND*
25 *PHARMACOTHERAPY FOR CESSATION OF TOBACCO USE BY*



Attachment D

Physician Need Methodology

Physician Need Methodology

2010

| | a | b | c | d | e |
|---------------|-------------------|------------------------------|-----------------------------|--|--------------------------------------|
| County | Population | GI Physicians/100,000 | GI Physicians Needed | GI Physicians in County in 2009 | Deficit/Surplus (- = surplus) |
| Halifax | 55,009 | 4.4 | 1.4 | 1 | 0.4 |
| Northampton | 20,951 | 4.4 | 0.5 | 0 | 0.5 |
| Total | 75,960 | | 2.0 | 1 | 1.0 |

2013

| | a | b | c | f | e |
|---------------|-------------------|------------------------------|-----------------------------|--|--------------------------------------|
| County | Population | GI Physicians/100,000 | GI Physicians Needed | GI Physicians in County in 2013 | Deficit/Surplus (- = surplus) |
| Halifax | 54,512 | 4.4 | 1.4 | 2 | -0.6 |
| Northampton | 20,951 | 4.4 | 0.5 | 0 | 0.5 |
| Total | 75,463 | | 1.9 | 2 | -0.1 |

Notes:

- a) www.demog.state.us.nc
- b) <http://www.nejmjobs.org/content/rpt/pdf/marapr04.pdf>. Please also see attached materials.
- c) $a/100,000 * b * .59$. Assumes HRMC's market share of Halifax County residents who received general inpatient services, 59%. Please see attached calculation. Not reasonable to assume 100% market share. A 59% market share is generous considering Halifax GI calculates the current Halifax provider GI market share of Halifax and Northampton County residents to be 49% and 61 % respectively (Halifax GI application page 33).
- d) North Carolina Medical Board
- e) c-d
- f) Total include Dr. Yerra and Dr. O'Conner. Total does not include Halifax GI's possible unnamed gastroenterologist.

2009 Halifax Cour Market Share Calculation

| Facility | Year | Service or Procedure | Patient Origin | Cases | Mkt Share |
|---|------|---------------------------------------|----------------|-------|-----------|
| Angel Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Betsy Johnson Regional Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Carolinas Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 3 | 0% |
| Craven Regional Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Duke Raleigh Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 14 | 0% |
| Duke University Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 280 | 3% |
| Durham Regional Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 22 | 0% |
| First Health Moore Regional Hospital, Pinehurst | 2009 | General Acute Care Inpatient Services | Halifax | 4 | 0% |
| First Health Richmond Memorial Hospital, Rockingham | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Forsyth Memorial Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 3 | 0% |
| Franklin Regional Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 11 | 0% |
| Granville Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 2 | 0% |
| Halifax Regional Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 5,491 | 59% |
| Heritage Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 410 | 4% |
| Iredell Memorial Hospital, Inc. | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Johnston Memorial Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 2 | 0% |
| Kindred Hospital - Greensboro | 2009 | General Acute Care Inpatient Services | Halifax | 6 | 0% |
| Lenoir Memorial Hospital, Inc. | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| Lifecare Hospitals of North Carolina | 2009 | General Acute Care Inpatient Services | Halifax | 48 | 1% |
| Maria Parham Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 4 | 0% |
| Martin General Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 9 | 0% |
| Memorial Mission | 2009 | General Acute Care Inpatient Services | Halifax | 2 | 0% |
| Moses Cone Health System | 2009 | General Acute Care Inpatient Services | Halifax | 4 | 0% |
| Nash General Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 1,273 | 14% |
| New Hanover Regional Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 2 | 0% |
| North Carolina Baptist Hospitals | 2009 | General Acute Care Inpatient Services | Halifax | 3 | 0% |
| Our Community Hospital, Inc. | 2009 | General Acute Care Inpatient Services | Halifax | 22 | 0% |
| Person Memorial Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 31 | 0% |
| Pitt County Memorial Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 825 | 9% |
| Rex Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 36 | 0% |
| Roanoke-Chowan Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 25 | 0% |
| Sampson Regional Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 7 | 0% |
| Select Specialty Hospital - Durham | 2009 | General Acute Care Inpatient Services | Halifax | 1 | 0% |
| UNC Hospitals | 2009 | General Acute Care Inpatient Services | Halifax | 331 | 4% |
| WakeMed | 2009 | General Acute Care Inpatient Services | Halifax | 466 | 5% |
| WakeMed Cary Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 3 | 0% |
| Wayne Memorial Hospital | 2009 | General Acute Care Inpatient Services | Halifax | 3 | 0% |
| Wilson Medical Center | 2009 | General Acute Care Inpatient Services | Halifax | 19 | 0% |
| Total | | | | 9,368 | |

Market Watch

2003 Full-Time Equivalent (FTE) Demand per 100,000 Population

| PHYSICIAN SPECIALTY | FTE Demand per 100,000 Population | | | | |
|------------------------------------|-----------------------------------|---------------|---------------|---------------|---------------|
| | Nation | Midwest | Northeast | South | West |
| Primary Care | | | | | |
| General & Family Practice | 22.53 | 27.85 | 18.98 | 22.48 | 20.20 |
| Internal Medicine | 19.01 | 14.22 | 21.83 | 20.05 | 19.86 |
| Pediatrics General | 13.90 | 11.91 | 17.09 | 12.70 | 15.20 |
| Medical Subspecialties | | | | | |
| Allergy/Immunology | 1.72 | 1.13 | 1.54 | 1.98 | 2.02 |
| Cardiology | 4.22 | 3.55 | 6.77 | 3.44 | 3.91 |
| Dermatology | 3.13 | 2.30 | 3.97 | 3.18 | 3.19 |
| Gastroenterology | 5.50 | 1.64 | 3.53 | 4.40 | 3.95 |
| Hematology/Oncology | 1.08 | 1.28 | 0.92 | 1.03 | 1.08 |
| Nephrology | 0.73 | 0.37 | 0.30 | 0.98 | 1.10 |
| Neurology | 1.79 | 0.92 | 1.75 | 2.10 | 2.21 |
| Physical Medicine and Rehab. | 1.44 | 1.37 | 1.95 | 1.11 | 1.64 |
| Psychiatry | 5.73 | 4.79 | 8.86 | 4.45 | 6.04 |
| Pulmonology | 1.30 | 0.94 | 1.59 | 1.82 | 0.54 |
| Rheumatology | 1.33 | 1.00 | 1.46 | 1.53 | 1.20 |
| Other Medical Subspecialties | 2.01 | 2.83 | 3.08 | 0.64 | 2.51 |
| Surgical Subspecialties | | | | | |
| General Surgery | 6.01 | 6.68 | 5.82 | 6.42 | 4.79 |
| Obstetrics and Gynecology | 10.17 | 9.10 | 10.20 | 11.81 | 8.57 |
| Ophthalmology | 4.71 | 3.98 | 5.77 | 4.52 | 4.83 |
| Orthopedic Surgery | 6.12 | 4.46 | 7.50 | 5.77 | 7.18 |
| Otolaryngology | 2.84 | 3.22 | 2.46 | 2.86 | 2.72 |
| Plastic Surgery | 2.22 | 1.72 | 3.06 | 2.28 | 1.95 |
| Urology | 2.86 | 2.52 | 3.54 | 2.95 | 2.45 |
| Other Surgical Subspecialties | 2.20 | 2.86 | 2.61 | 1.52 | 2.29 |
| Pediatric Subspecialties | | | | | |
| Pediatric Cardiology | 0.20 | 0.13 | 0.15 | 0.26 | 0.22 |
| Pediatric Neurology | 0.12 | 0.14 | 0.07 | 0.10 | 0.18 |
| Pediatric Psychiatry | 0.59 | 0.52 | 0.84 | 0.59 | 0.45 |
| Other Pediatric Subspecialties | 0.89 | 0.89 | 0.81 | 0.79 | 1.10 |
| Emergency Department* | 12.34 | 12.30 | 12.65 | 13.07 | 10.98 |
| Grand Total All Specialties | 134.69 | 124.62 | 149.10 | 134.83 | 132.36 |

* Physicians working in emergency departments can be board certified in any specialty. The most common specialties are emergency medicine, internal medicine and family medicine.

Source: *Physician Community Requirements in the 21st Century: The 2003 Physicians to Population Ratios*, a report from Solucient, LLC. For more information, go to www.solucient.com.

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Contact: Tarsis Lopez
 Solucent Public Relations
 847.440.9619
tlopez@solucent.com

Solucent Study: Physician specialty concentrations vary greatly

EVANSTON, IL – Feb. 11, 2004 – Demand for general and family medicine doctors is most concentrated in the Midwest, nephrologists in the West, and cardiologists in the Northeast, according to a new study released today by Solucent®.

In the Midwest, the demand for general and family doctors per 100,000 population is 24 percent higher than the national average, according to the study. In the Northeast, the rate for cardiologists is 60 percent higher and, in the West, the rate for nephrologists is 50 percent higher than the national average.

Among other medical subspecialties, the Northeast had the highest demand for psychiatrists per 100,000 population, or nearly 55 percent higher than the national average.

The study, *Physician Community Requirements in the 21st Century: The 2003 Physicians to Population Ratios*, examines physician demand in the United States by region and specialty. The report's physician to population ratios are based on data from public and private claims and key surveys, including the National Center for Health Statistics' National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS).

"Demand for physician services in the United States continues to grow or shift due to an aging population, relaxation of managed care restrictions, and the mounting malpractice insurance crisis," said Paul Presken, vice president, content development. "However, market changes have sometimes resulted in specific physician supply issues that could directly impact a community's access to critical procedures, preventative medicine, and the latest in medical technologies."

Among the study's other key findings:

- The South had a significantly higher demand for gastroenterologists per population than the rest of the United States
- The demand for plastic surgeons in the Northeast was nearly 38 percent higher than the rest of the United States

Methodology

The physician to population ratios in this Solucient study are based on analysis of the following:

- 2001 private and public claims to calculate national and regional population-based overall physician visit rates by age group and gender of patients. These rates do not include ambulatory surgery encounters, inpatient admissions, or ancillary services such as laboratory and diagnostic imaging.
- Data from the National Center for Health Statistics' National Ambulatory Medical Care and National Hospital Ambulatory Medical Care Surveys from 1997-2000 to determine physician specialty distribution for each patient visit.
- National average median annual ambulatory visit productivity rates reported by the Medical Group Management Association (MGMA) for 2001-2003.

Media Note: The new Solucient report, Physician Community Requirements in the 21st Century: The 2003 Physicians to Population Ratios, is available in PDF form at www.solucient.com/forms/physician_whitepaper.asp.

About Solucient

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Attachment E

Proposed Halifax GI Floor Plans

GMK Associates
 Architects/Engineers/Planners
 3000 Boulevard Court, Suite 901
 Charlotte, NC 27206
 P: 704-371-0000
 F: 704-371-4999

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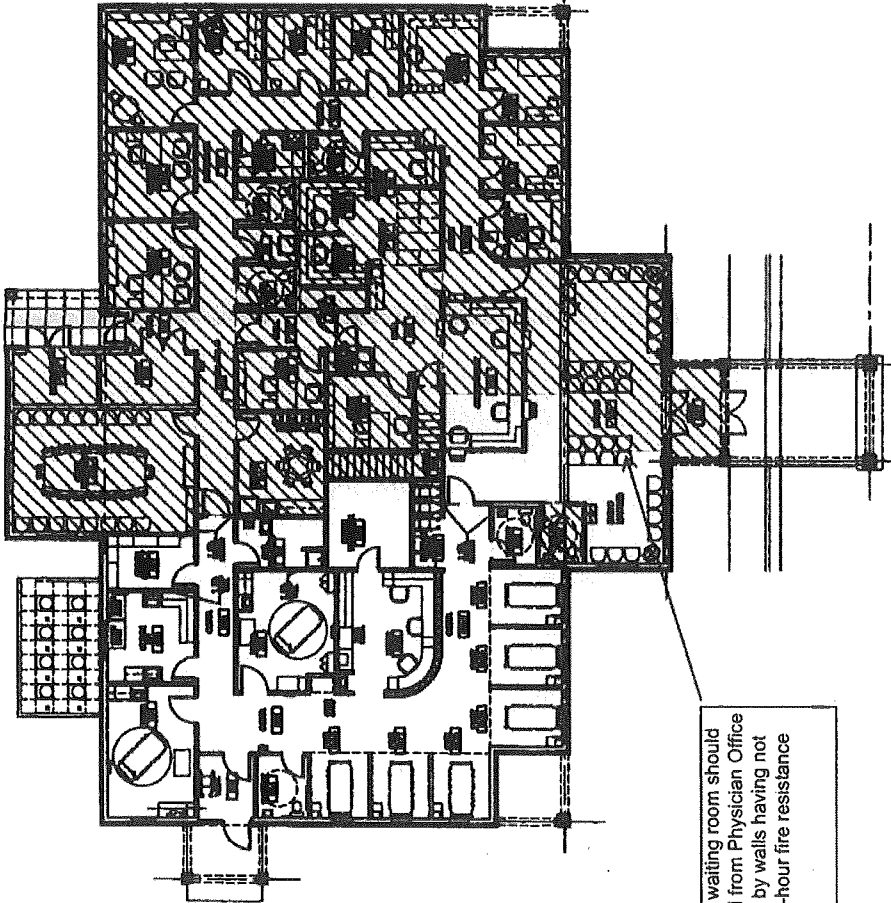
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 Medical Center/Building 2, L.C.
 Gregory Road
 Charlotte, North Carolina 27270
 PROJECT NUMBER
 GMK # 1094010R
 DATE
 11-03-10



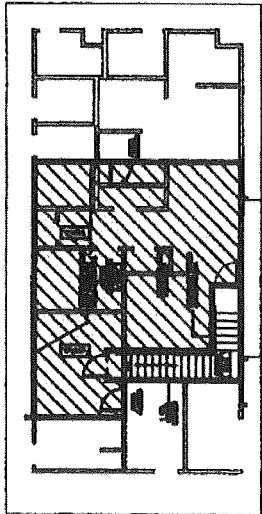
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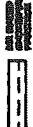


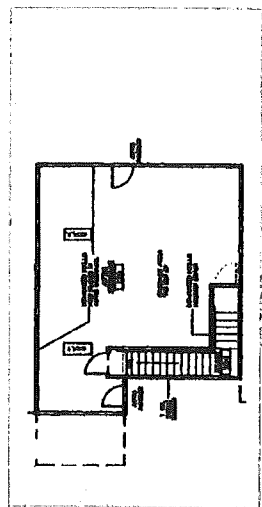
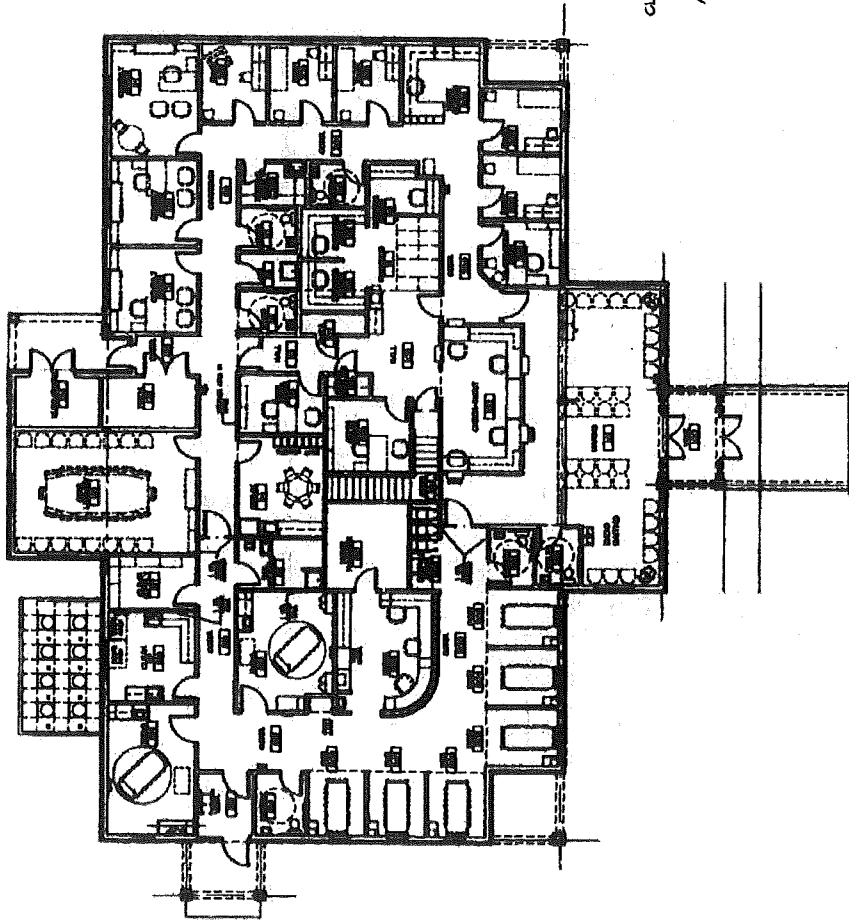
AI-01 FLOOR PLAN
 SCALE: 1/8" = 1'-0"
 ENDOSCOPY SUITE 8904 sqf
 CLINICAL/ADMIN AREA 4908 sqf
 TOTAL GROSS AREA 8,214 sqf



AI-08 ATTIC STORAGE PLAN
 SCALE: 1/8" = 1'-0"

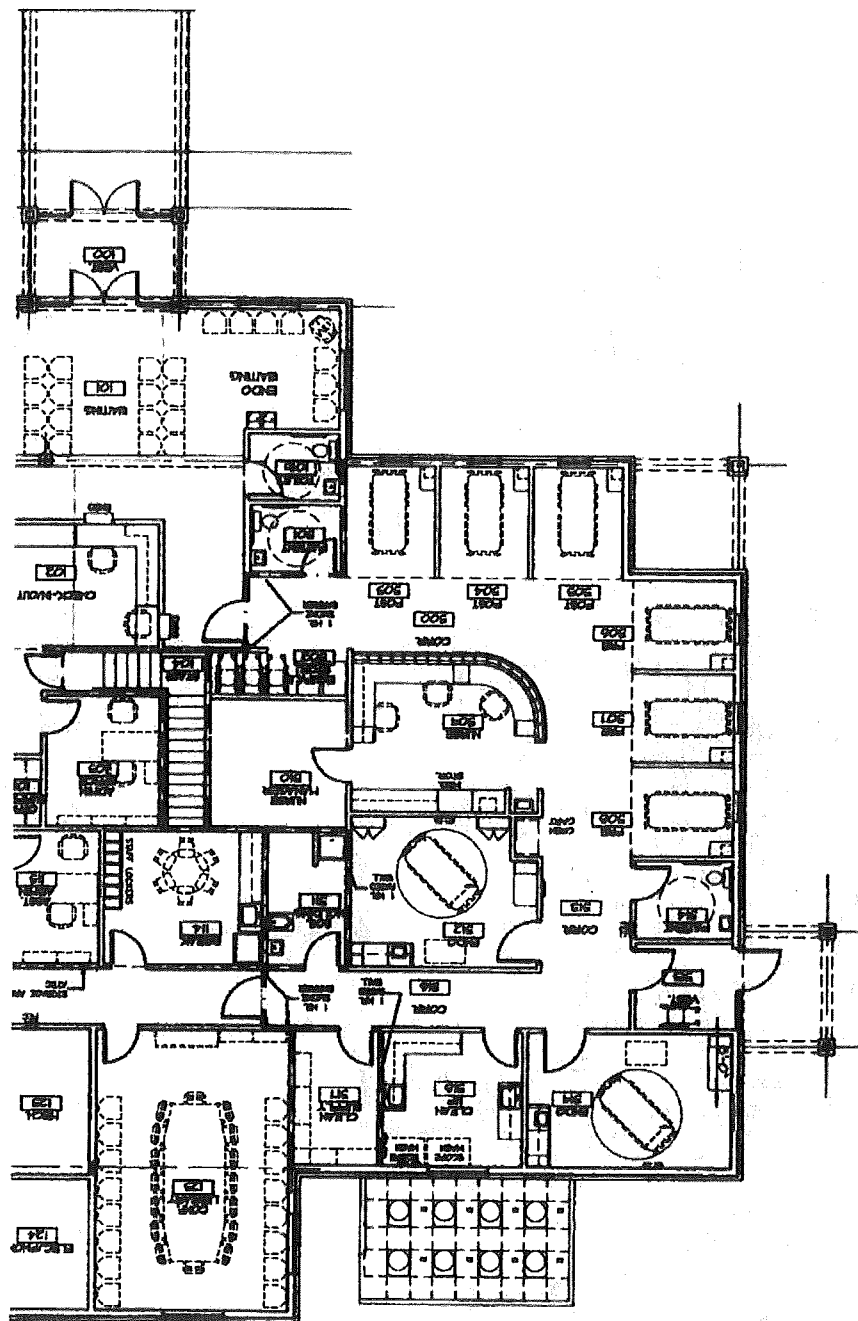
Endo Center waiting room should be separated from Physician Office waiting room by walls having not less than a 1-hour fire resistance rating.

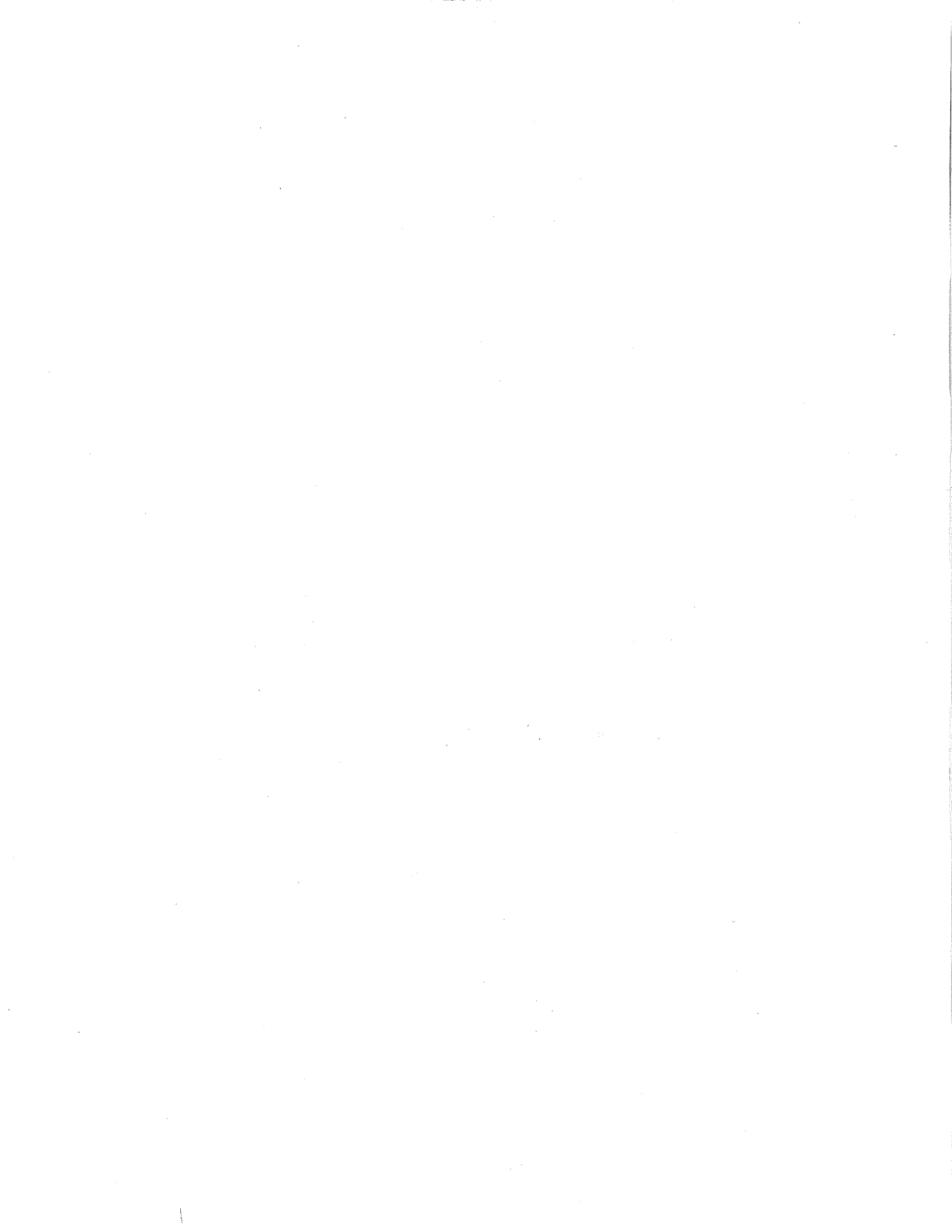




ENDOSCOPY SUITE 3,304 gsf
 CLINICAL/ADMIN AREA 4,105 gsf
 TOTAL GROSS AREA 9,214 gsf
 ATTIC STORAGE AREA 787 sqft
 TOTAL HEATED AREA 9,101 gsf

| | | | |
|---|---|--|--|
| Ramsay GMK Architects/Engineers/Planners 2200 S.W. 11th Fort Lauderdale, FL 33304 | SCHEMATIC FLOOR PLAN <small>Copy to Site</small> | DWG BY: JBR DATE: 10.24.10 CORR: 05040.DWG | SHEET NUMBER A-1 OF 8 |
| | HALIFAX GASTROENTEROLOGY P.C. <small>Halifax, North Carolina</small> | | |
| SCALE: 1/8" = 1'-0" | | | |





Attachment F

CMS Memo: S&C-10-20-ASC

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-10-20-ASC

DATE: May 21, 2010

TO: State Survey Agency Directors
State Fire Authorities

FROM: Director
Survey and Certification Group

SUBJECT: Ambulatory Surgical Center (ASC) Waiting Area Separation Requirements

Memorandum Summary

- **ASC Waiting Area Requirements:** ASC regulations require these facilities to be distinct entities, solely providing surgical services, and containing separate waiting areas which must meet Life Safety Code (LSC) requirements for Ambulatory Health Care occupancies.
- **Waivers:** Waivers will be considered for existing ASCs that share a waiting area with other building occupants when compliance with the LSC requirements is not currently feasible. Interim separation barrier and signage is required.
- **New ASCs should not be recommended by State Survey Agencies (SAs) or accreditation organizations (AOs) for waiver approval.**

This memorandum clarifies the Centers for Medicare & Medicaid Services' (CMS) requirements for ASC waiting areas, including the prohibition on the sharing of waiting areas with other entities. It also discusses opportunities for existing ASCs that have waiting areas shared with other entities to obtain waivers as part of their Plan of Correction (POC) when violations have been cited, and when it is not feasible for the ASC to correct the deficiencies.

Pertinent Regulatory Requirements

Several provisions of the Medicare ASC regulations, when taken together, require ASCs to have waiting areas separated from other entities.

- **42 CFR 416.2 – Definition of an ASC.** In part, the definition of an ASC states that it is a *distinct* entity that operates *exclusively* for the provision of surgical services. As a result, *an ASC may not share space with another entity when the ASC is open.*
- **42 CFR 416.44 (a)(2)** requires that an ASC must have a separate waiting area, i.e., a distinct area set aside for patients and families, outside of the areas used to prepare patients for their procedures, perform procedures, or recover from procedures.

- **42 CFR 416.44(b) – Environment CfC - Life Safety Code (LSC) Requirements**

As part of the ASC, a waiting area must meet the provisions applicable to Ambulatory Health Care, Chapters 20 and 21 in the National Fire Protection Association (NFPA) 101:2000 edition of the LSC. According to sections 20.3.7.1 and 21.3.7.1 of the LSC, an “ambulatory health care facility shall be separated from other tenants and occupancies by walls having not less than a 1-hour fire resistance rating. Such walls shall extend from the floor slab below to the floor or roof slab above. Doors shall be constructed of not less than 1 ¾ inch thick solid-bonded wood core or the equivalent and shall be equipped with positive latches. These doors shall be self closing and shall be kept in the closed position except when in use. Any vision panels shall be of fixed fire window assemblies in accordance with 8.2.3.2.2.” This requirement applies regardless of whether or not an ASC is “temporally” distinct, i.e., it shares its space with another occupancy(ies) but does not have concurrent or overlapping hours of operation.

Although sections 20.1.2.1 and 21.1.2.1 of the LSC allow sections of an ASC to be classified as other occupancy types that are subject to lesser fire protection requirements, ASC waiting areas are not eligible for this allowance. The LSC requires that for a section of the ASC to be considered as an occupancy type other than Ambulatory Health Care it should not be intended to serve occupants for purposes of treatment *or* to provide customary access to patients incapable of self-preservation. As patients occupy an ASC waiting area for the purpose of receiving treatment, and not all patients in an ASC waiting area may be capable of evacuating without assistance, CMS considers ASC waiting areas to be Ambulatory Health Care occupancies. Therefore, the requirements of the LSC Chapters 20 or 21 apply to all new and existing ASCs waiting areas, respectively.

Enforcement of Waiting Area Requirements

When an ASC is found to have a waiting area that is not separated appropriately from another entity, this is cited as a violation of both 42 CFR 416.2 and 42 CFR 416.44(b).

Existing ASCs

Despite these longstanding ASC regulatory requirements, some ASCs have misinterpreted the requirement for ASCs to be separated from other tenants and occupancies and may not have walls with the requisite rating of at least 1-hour fire resistance. CMS understands that the clarification provided in the updated ASC interpretive guidelines, issued via S&C-09-37 memorandum dated May 15, 2009, as well as in this memorandum may result in existing ASCs being cited for noncompliance related to non-separated waiting areas. Further, we are aware that in some cases there may be substantial hardship for the ASC to bring its waiting area into compliance with the LSC requirements.

Per 42 CFR 416.44(b)(2), CMS may waive, for periods deemed appropriate, specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship upon an ASC, but

only if the waiver will not adversely affect the health and safety of the patients. Therefore, CMS will consider issuing waivers to existing ASCs that share a waiting area with other building occupants and have been cited for a lack of adequate separation under LSC. CMS Regional Offices (RO) will require, as a condition of waiver approval, the fire protection measures identified in the following paragraph, as well as any additional measures appropriate for the individual ASC's circumstances.

While operating under an approved waiver, the ASC must assure that fire protection for the waiting area is appropriate for the occupancy to which it was designed. In addition, in order for the ASC to be a distinct entity, the ASC's patients and visitors using the waiting area must be separated from other occupants in a shared waiting area by a temporary partition, unless the ASC is "temporally" distinct from the other occupancy. The partition must not block or obstruct visibility of exits, shall be flame resistant in accordance with NFPA 701, and must be located at least 18 inches below sprinkler deflectors in accordance with NFPA 13. In addition, signage must be posted that clearly identifies the distinct separate ASC waiting area.

Existing ASCs that currently do not have a waiting area shared with other entities are not permitted to modify their current arrangement to introduce a shared waiting area, and will not be eligible for a waiver if they do so.

New ASC Agreements

ASCs applying for a new Medicare agreement (including not only new ASCs but also ASCs that have undergone a change of ownership without assumption of the previous owner's Medicare supplier agreement) should not be recommended for approval of a waiver concerning the separation of the ASC's waiting area from other occupancies.

LSC Waiver Process

The standard process for requesting LSC waivers shall be followed. In brief, this waiver process entails:

1. ASC preparation of a Plan of Correction (POC) for all identified deficiencies.
 - The POC for the lack of a proper separation of the ASC, including its waiting area, from other occupancies shall include the intent to request a waiver.
2. ASC preparation of a written request for a waiver.
 - The waiver request must specify both:
 - Unreasonable hardship (e.g., unreasonable structural change), and
 - Justification (i.e., explanation of hardship and verification that waiver will not result in adverse health and safety impact)
3. ASC submission of the POC and written request for waiver to the State Agency (SA) or Accreditation Organization (AO) that performed the survey.
4. SA or AO review of the POC and waiver request.
5. SA or AO transmittal of the POC and waiver request to the CMS RO, along with the SA's or AO's recommendation on whether the waiver should be approved or denied.

6. CMS RO review of the SA or AO recommendation along with the POC and waiver request, and determination whether or not to approve or deny the waiver.
7. CMS RO notification of both the SA or AO and the ASC of the waiver's approval or denial.

Please note that although a continuing waiver may be granted, it does not eliminate the ASC's responsibility to correct the areas of noncompliance. Once a waiver is approved for an ASC waiting area, the continuing waiver will be part of the POC and will remain in effect until such time that a renovation, alteration, or modernization will allow for the implementation of the LSC requirements. A waiver reapplication must be submitted as part of the POC for each subsequent survey until the non-conformities are corrected.

Questions concerning this memorandum should be directed to Martin Casey
Martin.Casey@cms.hhs.gov.

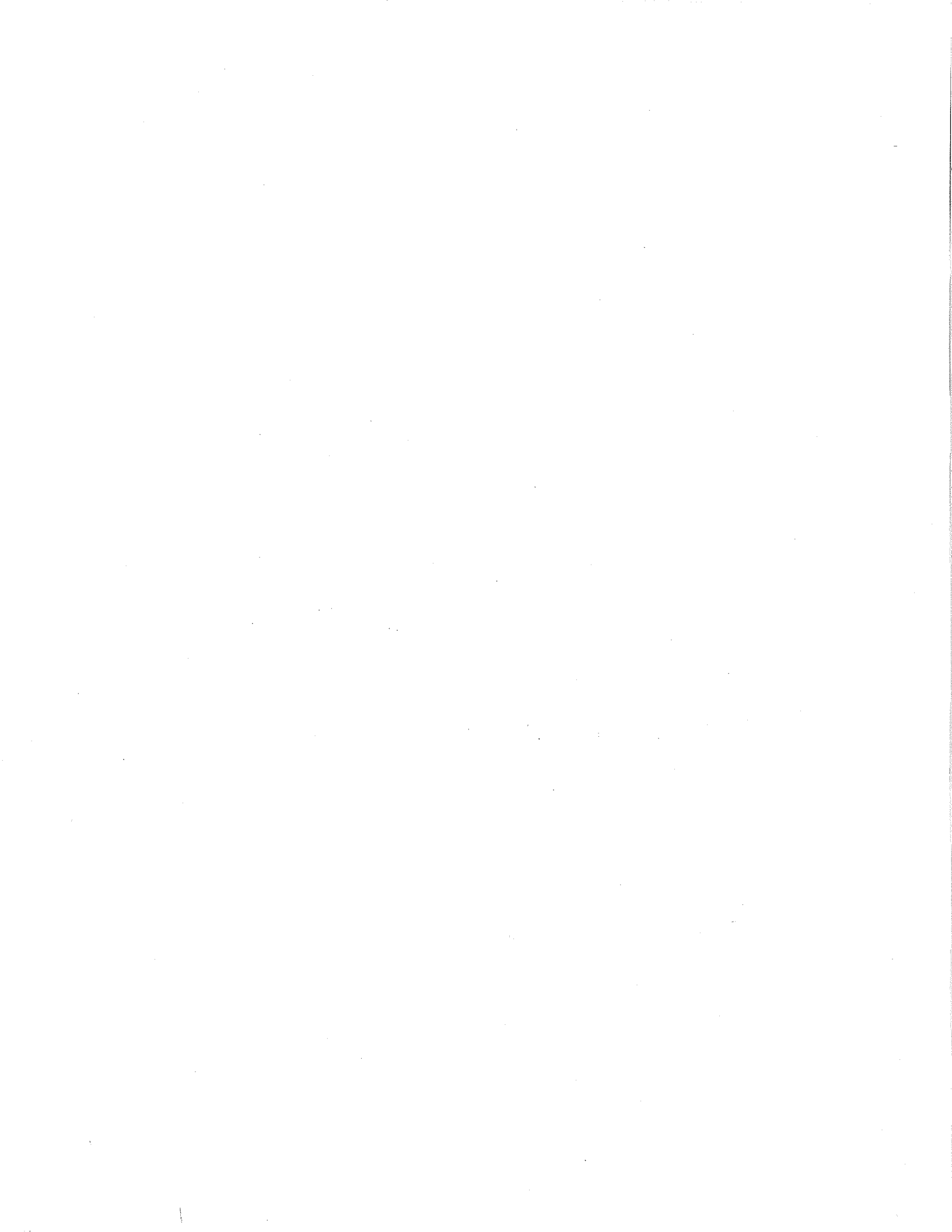
Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers and state fire authorities and their staff.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management



Attachment G

CCME Colorectal Cancer Screening Data

CRC Testing Rates in the Medicare Population

Year : 2005

State : North Carolina

North Carolina:Halifax, North

County : Carolina:Northampton

| Geographic Area | | Demographics | | | | | | | | | | Eligible | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|--|--------------|------|-----|-----|-----|-----|-----|------|-------|------|----------|-----|----|-----|-----|------|-------|----|-----|-----|------|---|-----|------|-----|------|-----|-----|-----|-----|------|------|-------|------|-----|-----|---|-----|-----|------|-------|------|-----|---|-----|-----|-----|------|-------|------|-----|-----|-----|-----|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|-------|------|-----|-----|----|-----|-----|------|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|----|------|---|-----|------|----|-----|-----|-----|-----|-----|-----|------|-----|----|----|----|----|----|----|----|----|----|----|----|----|-------|------|-----|-----|-----|-----|-----|------|-------|------|-----|-----|------|-----|-----|------|-------|------|-----|-----|-----|-----|-----|------|-------|------|-----|-----|-----|---|-----|------|--------------|-------------|------------|------------|------------|------------|------------|-------------|-----|------|-----|-----|-----|-----|-----|------|-------|----|-----|------|------|-----|-----|----|-------|------|-----|----|------|-----|-----|------|-----|------|-----|-----|-----|-----|-----|------|-------|------|-----|-----|------|-----|-----|----|-------|------|-----|-----|-----|-----|-----|------|-------|----|-----|-----|-----|-----|-----|------|-----|----|----|----|----|----|----|----|----|----|----|----|----|-------|------|-----|------|------|---|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|-------|------|-----|-----|-----|-----|-----|------|-------|------|-----|------|------|-----|-----|----|-------|------|-----|-----|-----|-----|-----|------|-------|----|-----|-----|------|-----|-----|------|--------------|-------------|------------|------------|------------|------------|------------|-------------|
| | | AnyTest | | | | | BE | | | | | COLO | | | | | ENDO | | | | | FOBT | | | | | SIGM | | | | | CIM* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| North Carolina: Halifax County | | 1,934 | 14.2 | 0.6 | 8.3 | 8.8 | 5.7 | 0.7 | 32.8 | 4,066 | 18.6 | 0.4 | 9.8 | 10 | 9.8 | 0.6 | 42.5 | 2,722 | 17 | 0.2 | 8.9 | 9.1 | 9 | 0.9 | 46.1 | 832 | 10.3 | 0.2 | 5.3 | 5.6 | 5.5 | 0.7 | 39.4 | 5,602 | 17.2 | 0.4 | 8.7 | 9 | 9.2 | 0.6 | 43.8 | 3,952 | 15.7 | 0.3 | 9 | 9.4 | 7.2 | 0.9 | 37.7 | 4,378 | 15.3 | 0.3 | 7.9 | 8.2 | 7.7 | 0.6 | 38 | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 4,995 | 17.8 | 0.4 | 9.7 | 10 | 9.1 | 0.7 | 44.2 | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 80 | 15 | 0 | 10 | 11.3 | 5 | 2.5 | 37.5 | 80 | 8.8 | 1.3 | 6.3 | 6.3 | 2.5 | 1.3 | 36.3 | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 3,302 | 12.7 | 0.3 | 6.9 | 7.2 | 6.1 | 0.7 | 36.5 | 6,252 | 18.6 | 0.4 | 9.8 | 10.2 | 9.6 | 0.7 | 43.8 | 3,013 | 14.9 | 0.5 | 8.2 | 8.6 | 6.9 | 0.6 | 38.2 | 6,541 | 17.3 | 0.3 | 9.1 | 9.4 | 9 | 0.7 | 42.7 | 9,554 | 16.5 | 0.4 | 8.8 | 9.1 | 8.4 | 0.7 | 41.3 | 664 | 14.9 | 0.5 | 8.1 | 8.3 | 7.4 | 0.3 | 33.7 | 1,647 | 19 | 0.7 | 10.5 | 10.7 | 9.7 | 0.7 | 44 | 1,128 | 18.3 | 0.9 | 10 | 10.4 | 9.1 | 0.9 | 49.7 | 315 | 13.3 | 0.3 | 7.3 | 7.6 | 6.3 | 0.3 | 39.4 | 2,196 | 18.6 | 0.7 | 9.8 | 10.2 | 9.7 | 0.7 | 46 | 1,558 | 16.1 | 0.7 | 9.4 | 9.6 | 7.6 | 0.6 | 39.9 | 1,951 | 16 | 0.6 | 8.2 | 8.4 | 8.7 | 0.5 | 40.3 | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 1,792 | 19.4 | 0.8 | 11.3 | 11.6 | 9 | 0.8 | 47 | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | <10 | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 1,299 | 14.6 | 0.4 | 7.9 | 8.2 | 7.2 | 0.5 | 42.6 | 2,455 | 19.1 | 0.9 | 10.6 | 10.8 | 9.7 | 0.7 | 44 | 1,057 | 16.6 | 0.8 | 9.2 | 9.3 | 7.9 | 0.4 | 38.6 | 2,697 | 18 | 0.7 | 9.9 | 10.2 | 9.2 | 0.8 | 45.4 | 3,754 | 17.6 | 0.7 | 9.7 | 9.9 | 8.8 | 0.7 | 43.5 |

| | | | | | | | | | |
|--------------|------------------|---------|------|-----|------|------|------|-----|------|
| North Caroli | Ages 50-64 | 134,153 | 17.2 | 0.5 | 10.3 | 10.6 | 7.9 | 0.8 | 38.8 |
| | Ages 65-74 | 460,400 | 22.6 | 0.5 | 12.2 | 12.6 | 12 | 0.8 | 50.9 |
| | Ages 75-84 | 297,480 | 19.6 | 0.6 | 9.7 | 10.1 | 11 | 1 | 54.3 |
| | Ages 85+ | 91,207 | 11.3 | 0.5 | 4.4 | 4.8 | 7.1 | 0.9 | 38.3 |
| | Female | 577,778 | 20.8 | 0.6 | 10.2 | 10.5 | 12 | 0.9 | 50.2 |
| | Male | 405,462 | 18.6 | 0.4 | 10.9 | 11.3 | 8.8 | 0.9 | 47.5 |
| | African American | 167,920 | 17.1 | 0.6 | 10 | 10.4 | 8.1 | 1 | 43.3 |
| | Asian | 3,713 | 13.7 | 0.3 | 7 | 7.3 | 7.4 | 0.5 | 33.5 |
| | Caucasian | 798,604 | 20.5 | 0.5 | 10.6 | 11 | 11.3 | 0.9 | 50.5 |
| | Hispanic | 1,834 | 13.3 | 0.5 | 8.2 | 8.3 | 5.8 | 0.3 | 34.5 |
| | Native American | 4,410 | 16.9 | 1 | 9.5 | 9.8 | 8 | 0.9 | 44.5 |
| | Other | 5,957 | 19.5 | 0.7 | 10.8 | 11.1 | 10.2 | 0.7 | 42 |
| | Unknown | 802 | 11.5 | 0.2 | 5.1 | 5.5 | 6.9 | 0.5 | 40.1 |
| | State Buy-in | 190,545 | 14.5 | 0.7 | 8.3 | 8.6 | 6.9 | 1 | 40.6 |
| | Not State Buy-in | 792,695 | 21.2 | 0.5 | 11 | 11.4 | 11.6 | 0.9 | 51.1 |
| | Disabled | 206,996 | 17 | 0.6 | 10 | 10.4 | 7.9 | 1 | 43.6 |
| | Not Disabled | 776,244 | 20.6 | 0.5 | 10.6 | 10.9 | 11.4 | 0.9 | 50.6 |
| | All Eligible | 983,240 | 19.9 | 0.5 | 10.5 | 10.8 | 10.7 | 0.9 | 49.1 |

Denominator

All non-HMO Medicare enrollees, ages 50 to 114 as of January 1st, who were

Numerators

Any CRC Rate: Medicare enrollees in the denominator who have at least one

FOBT Rate: Medicare enrollees in the denominator who have at least one Medicare-paid claim for an FOBT conducted during the calendar year.

SIGM Rate: Medicare enrollees in the denominator who have at least one

COLO Rate: Medicare enrollees in the denominator who have at least one

ENDO Rate: Medicare enrollees in the denominator who have at least one

BE Rate: Medicare enrollees in the denominator who have at least one

CIM (Current Medicare): Medicare enrollees in the denominator who have at least one Medicare-paid claim for FOBT

*** The Current in Medicare rate is available for calendar years 2002 and**



Attachment H

Documentation of New Gastroenterologist at HRMC

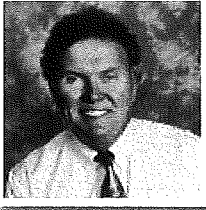
THE DIGESTIVE HEALTH CENTER

AT HALIFAX REGIONAL

[HOME](#) [WHO WE ARE](#) [DIGESTIVE DISORDERS](#) [PROCEDURES](#) [QUESTIONS](#) [PATIENT RESOURCES](#) [CONTACT US](#)



Who We Are



Rory V. O'Connor, MD is a gastroenterologist with more than 25 years of experience. He is in private practice in Roanoke Rapids at [Eastern Carolina Gastroenterology](#) and is focused on continuing his commitment to exceptional patient care and a high level of patient satisfaction.

- Board Certified in Gastroenterology and Internal Medicine
- Medical School: University of California, San Francisco
- Residency: Wadsworth VA/UCLA Medical Centers
- Fellowship in Gastroenterology: University of California, San Diego



Shantea Connell, RN, BSN
Manager of Endoscopy Services

- 10+ years' experience in Gastroenterology
- BS in Nursing: East Carolina University
- Special Certifications: N.C. Board of Nursing, Advanced Cardiac Life Support
- Joined Halifax Regional in 1990



Sylvia Dickens, RN
Staff Nurse

- 20+ years' experience in Gastroenterology
- Associate nursing degree: Halifax Community College
- Special Certifications: N.C. Board of Nursing, Advanced Cardiac Life Support
- Joined Halifax Regional 1987



Darlene Wolgemuth, RN
Staff Nurse

- 10+ years' experience in Gastroenterology
- Associate nursing degree: Halifax Community College
- Special Certifications: N.C. Board of Nursing, Advanced Cardiac Life Support
- Joined Halifax Regional in 1991

[Digestive Procedures](#)

[Frequently Asked Questions](#)

[Digestive Disorders](#)

[Who We Are](#)



[Halifax Regional Medical Center](#)



Paula Daniel, NA-GI tech.
GI Technician

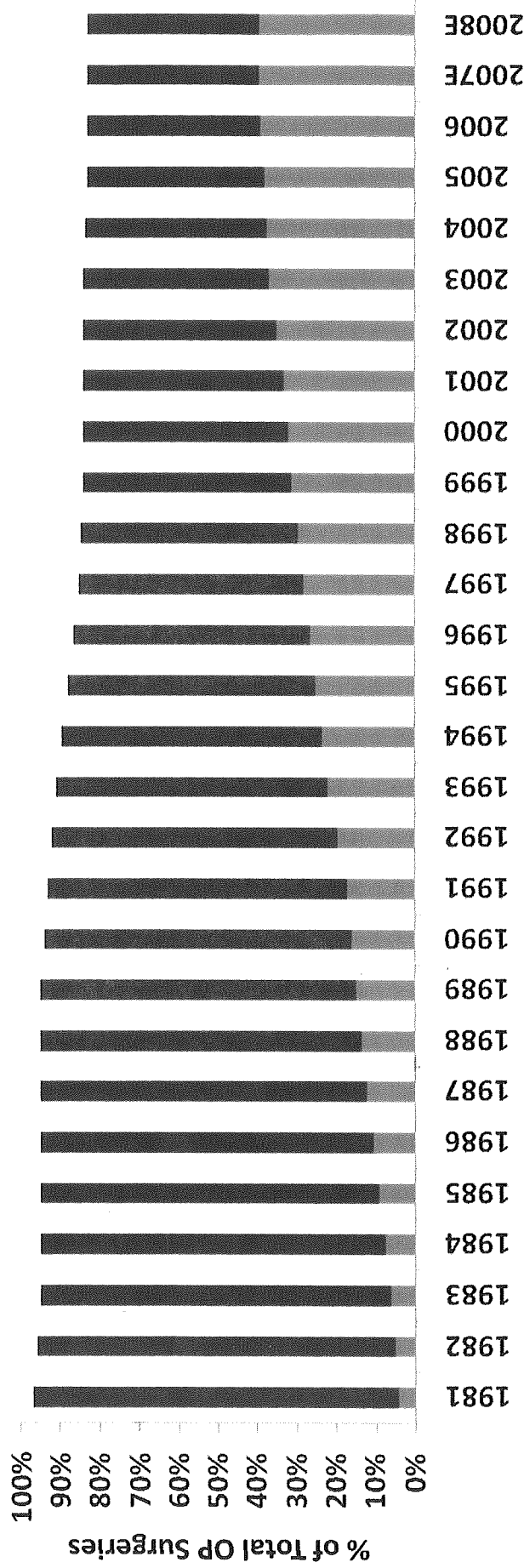
- 5+ years' experience in Gastroenterology
- Graduate, Nursing Assistance Program, Halifax Community College
- Special Certifications: N.C. Center for Aide Regulation & Education, Basic Life Support
- Joined Halifax Regional in 2005

244 Smith Church Road • Roanoke Rapids, NC 27870 • (252) 535-1800
[Home](#) [Procedures](#) [Questions](#) [Digestive Disorders](#) [Who We Are](#) [Patient Resources](#) [Contact Us](#)

Attachment I

American Hospital Association Report on ASC Utilization Trends

OP Surgeries in ASC vs. HOPD



■ ASC ■ HOPD Physician Offices

1980s 1990s 2000 - today

- Medicare approves ASCs in '82, several years after JAMA and commercial payers endorsed ASCs
- Limited to early adopters
- Increasing comfort level of physicians and anesthesiologists
- Influx of colonoscopies and cataract surgeries
- Increased use of physician offices due to payer pressures
- Trends slowing and will depend on pressure from payers to accelerate the shift from HOPD

Attachment J

Halifax GI Procedure to Patient Ratio Calculation

Halifax GI Procedures Per Patient Calculation

Background Information

| Application Page | Procedures | Patients | Time Period |
|------------------------|------------|----------|----------------|
| 12 (.3902 (a) (2) (G)) | | 1,989 | last 12 months |
| Exhibit 10 | 2,089 | | last 12 months |
| 35 (Section III.1.(b)) | 1,989 | | last 12 months |

Notes:

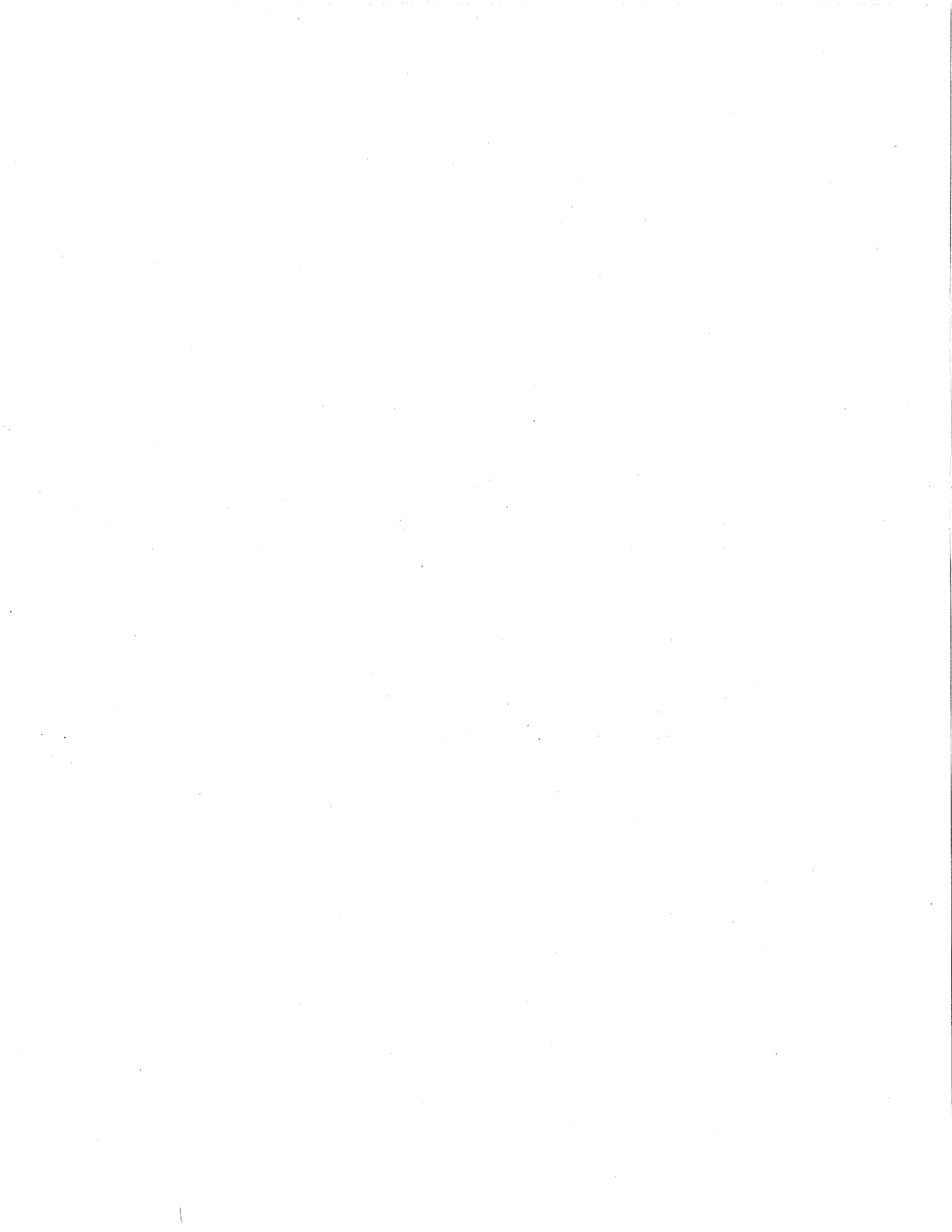
As seen above, Information provided in the document contradicts itself and makes it impossible to know if calculation is 100 percent correct. Applicants appear to have labeled patients as procedures on page 35. Logically, patients should be less than procedures.

Procedures Per Patient Ratio Calculation

| | |
|----------------------|-------|
| Estimated Procedures | 2,089 |
| Estimated Patients | 1,989 |
| Estimated Ratio | 1.05 |

Notes:

Ratio is a best guess estimate based on procedure and patient data provided in the document.



Attachment K

AAAHC and Certification Documentation

PDA

C O N V E R S A T I O N L O G

DATE: 12-14-10 **TIME:** 2:15 p.m. **PDA Job #:** (58-5026-10)

CLIENT: Halifax Regional Medical Center **PROJECT:** Halifax GI Comments

INITIATED BY: Trey Adams

WITH: Brianne Kaneshiro

COMPANY: AAAHC

PHONE #: 1-847-853-6088

SUBJECT: AAAHC Accreditation Process

NOTES

- Office-based surgery centers with AAAHC Office-Based Surgery Center Accreditation are not eligible for "Deemed Status" with Medicare.
- In North Carolina, if you are an office-based surgery center that has AAAHC Office-Based Surgery Center Accreditation and are granted a CON for development of an ASC, you will be required to go through the State certification process or apply for AAAHC ASC Deemed Status Accreditation.

| Public Organization | |
|---------------------------------------|--|
| name & address information | |
| Name: | Halifax Gastroenterology, PC |
| Organization Type: | Office-Based Surgery Center |
| Specialties: | Gastroenterology |
| Address: | Halifax Gastroenterology, PC 1007 Gregory Drive Roanoke Rapids, NC 27870 |
| primary contact information | |
| Phone: | (252)535-6478 |
| Fax: | (252)535-6483 |
| Website: | |

 also known as

There are no results to display.

Close Window



Attachment L

Facility and Non-Facility Medicare Reimbursement

Physician Fee Schedule - Search Results

Thursday, December 16, 2010 3:15:43 PM

| HCPCS CODE | MODIFIER | STAT | LOCALITY | NON-FACILITY PRICE | FACILITY PRICE | NON-FACILITY LIMITING CHARGE | FACILITY LIMITING CHARGE | CONV FACT | NON-FAC PERVU | NON-FAC PERVU | FACILITY PERVU | TYPE RVU | NOT USED FOR MEDICARE | OPPS PAYMENT AMOUNT ¹ | OPPS PAYMENT AMOUNT ¹ |
|---------------|----------|------|----------|-----------------------|-------------------|------------------------------------|--------------------------------|--------------|------------------|------------------|-------------------|-------------|-----------------------------|--|--|
| 45378 | | A | 0000000 | \$382.00 | \$219.03 | \$417.34 | \$239.28 | 36.8729 | | | | | | NA | NA |

¹Section 5102(b) of the Deficit Reduction Act of 2005 requires a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services. This cap is based on the Outpatient Prospective Payment System (OPPS) payment. To implement this provision, the physician fee schedule amount is compared to the OPPS payment amount and the lower amount is used for payment.

Place of service affects your reimbursement

By Mary LeGrand, RN, MA, CCS-P, CPC

Facility, nonfacility designations make a difference

In 2008, the Office of Inspector General (OIG) for the department of Health and Human Services intends to focus on Place of Service errors for services submitted by physicians. According to the OIG work plan, *"We will review physician coding of place of service on claims for services performed in ambulatory surgical centers (ASC) and hospital outpatient departments. Federal regulations... provide for different levels of payments to physicians depending on where the services are performed. Medicare pays a physician a higher amount when a service is performed in a non-facility setting, such as a physician's office, than it does when the service is performed in a hospital outpatient department or, with certain exceptions, in an ASC. We will determine whether physicians properly coded the places of service on claims for services provided in ASCs and hospital outpatient departments."*

The practice expense RVU

The place of service can greatly affect your reimbursement, depending on the type of service provided and the location, because Medicare reimburses physicians based on Relative Value Units (RVUs). An RVU has three components: work, practice expense, and malpractice. The place of service is part of the practice expense component, and procedures that can be performed in either a facility or nonfacility setting have different practice expense RVUs, depending on the place of service.

When you provide a service in a facility such as a hospital, the total RVU is lower because you do not incur the full practice expense associated with providing that service. The most common facility locations in orthopaedics are the emergency department, an inpatient setting, an operating room, or an ASC.

When you provide services in a facility setting, you submit a CMS 1500 claim form for those services, and the hospital or ASC submits a UB-92 or CMS 1500 claim form for the "facility fee." Medicare reimburses you at the lower facility RVU rate and reimburses the facility (the hospital or ASC) for the space, staffing, and technical services it provided.

The most common nonfacility location is the physician's office when the practice is not organization-based. In the nonfacility setting, the physician practice incurs the full expense of providing the service and is therefore reimbursed at a higher total RVU. When you perform a service in a nonfacility setting (such as your office) and submit the same CMS 1500 claim form for the services provided, Medicare reimburses you based on the nonfacility RVU.

What difference does it make?

The difference in RVUs can be significant. For example, a level 3 outpatient consultation (Common Procedure Terminology [CPT] code 99243) has two different RVU values based on whether the service is performed in a facility or nonfacility location ([Table 1](#)).

Note the differences in the practice expense component for the facility and nonfacility settings and the impact on the total RVU. The practice expense component includes rent/lease of space, supplies, equipment, and clinical and administrative staff expenses. If you provide a service in a facility setting, you do not incur the full staff, equipment, space, or supply costs of providing that service; as a consequence, Medicare reduces your payment based on the location of service.

Medicare assigns the RVUs based on input from the AAOS and socioeconomic surveys on where the service is or should be performed. In some instances, both a facility and nonfacility practice expense RVU factor may be assigned,

but in other cases, such as a total knee replacement (CPT code 27447), only one practice expense RVU is applicable (Table 2). With a total knee replacement, the facility and nonfacility practice expense RVUs are exactly the same (13.59), meaning that Medicare will only reimburse this procedure in a facility setting.

Does this apply to all codes?

To find out whether a code has different facility and nonfacility practice expense RVUs, check the Medicare Fee Schedule on each carrier's Web site or Code X (Fig. 1). Although the differences between the facility and nonfacility RVUs for some procedures appear minor, when they are multiplied by the conversion factor and annualized across all orthopaedic practices, the financial risk to Medicare is large if the place of service is not reported accurately.

Does it apply to all payors?

When contracting with a private payor, you should be sure to ask whether the payor reimburses differently based on place of service (facility or nonfacility). If the payor reimburses a procedure based on a percent of Medicare, the payor probably would include a differential based on place of service. Carving this out in your contract as part of your negotiation strategy is advisable.

What is the BN adjustor?

The BN (Budget Neutrality) adjustor is part of the Tax Relief and Health Care Act of 2006 and Deficit Reduction Act. To maintain budget neutrality, Medicare implemented the BN adjustor as part of the overall Medicare payment formula. The BN adjustor reduces Medicare reimbursement for the work component of your total Medicare payment.

The BN adjustor was introduced to the Medicare fee schedule in 2007 at -0.101 and was increased to -0.119 for 2008. This represents an approximate 2 percent reduction in reimbursement for a procedure separate from any Conversion Factor reductions.

Remember, the 10.1 percent conversion factor reduction originally scheduled for 2008 was delayed by Congressional action for 6 months (until June 30), and a 0.5 percent increase was applied instead. Although this meant a temporary increase in the conversion factor, the BN adjustor was implemented as budgeted. In the example of the total knee replacement (CPT code 27747), the BN adjustor reduces the total Medicare payment by approximately \$105 from the amount payable if the BN adjustor were not in effect.

Commercial carriers do not necessarily apply a work RVU BN adjustor. Carefully review your contracts with various carriers to determine whether they are applying a work RUV BN adjustor.

The BN adjustor is specific only to Medicare and does not alter the RVUs for any procedures. It affects the payment formula only; the work, practice expense, and malpractice RVUs are all set by Medicare separately from the BN adjustor. It is inappropriate for commercial carriers to reduce RVUs, versus payment, based on the BN adjustor.

Mary LeGrand, RN, MA, CCS-P, CPC, is a consultant with KarenZupko & Associates. If you have coding questions or would like to see a coding column on a specific topic, e-mail aaoscomm@aaos.org

AAOS Now

April 2008 Issue

<http://www.aaos.org/news/aaosnow/apr08/managing1.asp>

6300 North River Road Rosemont, Illinois 60018-4262 Phone 847.823.7186 Fax 847.823.8125

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Attachment M
Halifax GI Revenue Calculations

Halifax GI Revenue Calculations

Medicare Revenue Reduction

| a | b | c | d | e | f | g | |
|----------|----------------------------|------------------------|--|---|---|-------------------------------|-----------------------------|
| CPT Code | Non-Facility Physician Fee | Facility Physician Fee | Non-Facility and Facility Physician Fee Difference | Halifax GI Projected Facility Reimbursement | Enhanced Physician Fee and Halifax GI Facility Fee Reimbursement Difference | Projected Medicare Procedures | Estimated Revenue Reduction |
| 43235 | \$286.87 | \$146.75 | \$140.12 | \$315.00 | \$174.88 | 360 | \$ 62,936.37 |
| 43239 | \$332.59 | \$173.30 | \$159.29 | \$315.00 | \$155.71 | 217 | \$ 33,820.29 |
| 45385 | \$516.22 | \$311.94 | \$204.28 | \$315.00 | \$110.72 | 196 | \$ 21,729.14 |
| 45378 | \$382.00 | \$219.03 | \$162.97 | \$315.00 | \$152.03 | 576 | \$ 87,525.21 |
| 45380 | \$456.86 | \$262.54 | \$194.32 | \$315.00 | \$120.68 | 142 | \$ 17,136.07 |
| 45384 | \$452.43 | \$273.97 | \$178.46 | \$315.00 | \$136.54 | 23 | \$ 3,141.49 |
| 45330 | \$130.16 | \$61.95 | \$68.21 | \$234.00 | \$165.79 | 21 | \$ 3,472.87 |
| 45331 | \$163.72 | \$75.22 | \$88.50 | \$234.00 | \$145.50 | 1 | \$ 99.93 |
| G0121 | \$382.00 | \$219.03 | \$162.97 | \$315.00 | \$152.03 | 130 | \$ 19,760.39 |
| G0105 | \$382.00 | \$219.03 | \$162.97 | \$234.00 | \$71.03 | 50 | \$ 3,561.19 |
| 43251 | \$0.00 | \$220.87 | \$162.97 | \$234.00 | \$234.00 | 1 | \$ 160.71 |
| 43255 | \$0.00 | \$286.87 | | \$315.00 | \$315.00 | 1 | \$ 216.34 |
| Total | | | | | | | \$ 253,559.99 |

Estimated Actual Net Revenue in Project Year 3

| | |
|--|---------------|
| Projected Project Year 3 Revenue (Form B- Halifax GI application) | \$ 247,174.00 |
| Estimated Project Year 3 Revenue Reduction (see calculation above) | \$ 253,559.99 |
| Estimated Project Year 3 Net Revenue | \$ (6,385.99) |

Notes:

- a) <http://www.cms.gov/apps/physician-fee-schedule/>. Please also see attached worksheets.
- b) <http://www.cms.gov/apps/physician-fee-schedule/>. Please also see attached worksheets.
- c) a-b
- d) Halifax Application Exhibit 12
- e) d-c
- f) Estimated by multiplying projected Medicare procedures from Halifax GI application Form E by procedure breakdown from Halifax GI Exhibit 12
- g) e*f

Physician Fee Schedule - Search Results

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| HCPCS CODE | SHORT MODIFIER | DESCRIPTION | STAT | LOCALITY | PRICE | NON-FACILITY PRICE | FACILITY LIMITING CHARGE | LIMITING CONV FACT | NA FLAG FOR | | NA FLAG FULLY | | NOT USED FOR MEDICARE | OPPS PAYMENT AMOUNT ¹ | OPPS PAYMENT AMOUNT ¹ |
|---------------|-------------------|------------------------------------|------|----------|----------|-----------------------|--------------------------------|--------------------------|------------------------|------------------------|------------------------|-------------------|-----------------------------|--|--|
| | | | | | | | | | TRANS FOR PE RVU | IMP FULLY PE RVU | TRANS FOR PE RVU | FAC IMP RVU | | | |
| 43235 | | Uppr gi endoscopy, diagnosis | A | 0000000 | \$286.87 | \$146.75 | \$313.41 | \$160.33 | 36.8729 | | | | | NA | NA |
| 43239 | | Upper GI endoscopy, biopsy | A | 0000000 | \$332.59 | \$173.30 | \$363.36 | \$189.33 | 36.8729 | | | | | NA | NA |
| 45378 | | Diagnostic colonoscopy | A | 0000000 | \$382.00 | \$219.03 | \$417.34 | \$239.28 | 36.8729 | | | | | NA | NA |
| 45380 | | Colonoscopy and biopsy | A | 0000000 | \$456.86 | \$262.54 | \$499.11 | \$286.82 | 36.8729 | | | | | NA | NA |
| 45385 | | Lesion removal colonoscopy | A | 0000000 | \$516.22 | \$311.94 | \$563.97 | \$340.80 | 36.8729 | | | | | NA | NA |

¹Section 5102(b) of the Deficit Reduction Act of 2005 requires a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services. This cap is based on the Outpatient Prospective Payment System (OPPS) payment. To implement this provision, the physician fee schedule amount is compared to the OPPS payment amount and the lower amount is used for payment.

Physician Fee Schedule - Search Results

Thursday, December 16, 2010 3:44:07 PM

| HCPCS CODE | SHORT MODIFIER | DESCRIPTION | PROCCARRIER STAT | LOCALITY | NON-FACILITY PRICE | FACILITY PRICE | LIMITING CHARGE | FACILITY LIMITING CHARGE | CONV FACT | NA FLAG | | | | NOT USED FOR MEDICARE | OPPS NON-FACILITY PAYMENT AMOUNT ¹ | OPPS FACILITY PAYMENT AMOUNT ¹ |
|---------------|-------------------|------------------------------|---------------------|----------|-----------------------|-------------------|--------------------|--------------------------------|--------------|--------------|------------|--------------|------------|-----------------------------|--|--|
| | | | | | | | | | | FOR TRANS | FOR IMP | FOR TRANS | FOR IMP | | | |
| 43251 | | Operative upper GI endoscopy | A | 0000000 | NA | \$220.87 | NA | \$241.30 | 36.8729 | NA | NA | | | | NA | NA |
| 43255 | | Operative upper GI endoscopy | A | 0000000 | NA | \$286.87 | NA | \$313.41 | 36.8729 | NA | NA | | | | NA | NA |
| 45330 | | Diagnostic sigmoidoscopy | A | 0000000 | \$130.16 | \$61.95 | \$142.20 | \$67.68 | 36.8729 | | | | | | NA | NA |
| 45331 | | Sigmoidoscopy and biopsy | A | 0000000 | \$163.72 | \$75.22 | \$178.86 | \$82.18 | 36.8729 | | | | | | NA | NA |
| 45384 | | Lesion remove colonoscopy | A | 0000000 | \$452.43 | \$273.97 | \$494.28 | \$299.31 | 36.8729 | | | | | | NA | NA |

¹Section 5102(b) of the Deficit Reduction Act of 2005 requires a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services. This cap is based on the Outpatient Prospective Payment System (OPPS) payment. To implement this provision, the physician fee schedule amount is compared to the OPPS payment amount and the lower amount is used for payment.

Physician Fee Schedule - Search Results

Thursday, December 16, 2010 3:48:17 PM

| HCPCS CODE | SHORT MODIFIER | DESCRIPTION | STAT | CARRIER LOCALITY | NON-FACILITY PRICE | FACILITY PRICE | NON-FACILITY LIMITING CHARGE | FACILITY LIMITING CHARGE | CONV FACT | NA FLAG | | NA FLAG | | NOT USED FOR MEDICARE | OPPS PAYMENT AMOUNT ¹ | OPPS PAYMENT AMOUNT ¹ |
|---------------|-------------------|-----------------------------------|------|---------------------|-----------------------|-------------------|------------------------------------|--------------------------------|--------------|--------------|---------------------|--------------|-------------------|-----------------------------|--|--|
| | | | | | | | | | | FOR TRANS | FOR FULLY IMP | FOR TRANS | FOR IMP FAC | | | |
| G0105 | | Colorectal sem; hi risk ind | A | 0000000 | \$382.00 | \$219.03 | \$417.34 | \$239.28 | 36.8729 | | | | | | NA | NA |
| G0121 | | Colon ca sem not hi rsk ind | A | 0000000 | \$382.00 | \$219.03 | \$417.34 | \$239.28 | 36.8729 | | | | | | NA | NA |

¹Section 5102(b) of the Deficit Reduction Act of 2005 requires a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services. This cap is based on the Outpatient Prospective Payment System (OPPS) payment. To implement this provision, the physician fee schedule amount is compared to the OPPS payment amount and the lower amount is used for payment.