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May 30, 2017

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VIA FEDERAL EXPRESS
VIA E-MAIL
Mike Constantino
Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, IL 62761

Re: Project No. 16-046 – New Lenox Endoscopy Center

Dear Mike:

This letter is in response to your request for additional information dated May 4, 2017 regarding the proposed establishment of New Lenox Endoscopy Center. The applicants for this project are New Lenox Endoscopy, LLC; SGNL, LLC; and Southwest Gastroenterology, S.C. (collectively, the "Applicants"). In addition to responding to your questions, the Applicants are modifying their application as described below, providing updated data and pertinent information and specifically responding to some of the statements made by Silver Cross Hospital in its public comment letter dated April 10, 2017. **Exhibit A** provides responses to the questions in your letter and certain statements made by Silver Cross Hospital.

1. Purpose of the Project

The physicians affiliated with this project primarily practice in the Southwest metro Chicago corridor running from Oak Lawn to Joliet. See **Exhibit B** which delineates the primary service area of the physicians who intend to refer patients to the planned endoscopy center. As described in the application, the planned location of the endoscopy center in this corridor is New Lenox which has seen significant growth both in the immediate community as well as in Mokena and Orland Park. Such growth is reflected by the significant increase in utilization of a broad scope of services at Silver Cross Hospital in New Lenox which is discussed later in this supplement.

Visualization of the GI tract with endoscopy is a critical tool for GI physicians and a material part of any gastroenterologist's practice. As the field of medicine and gastroenterology has evolved and particularly with regard to screening and early detection of pre-cancerous polyps, access to colonoscopy has become a critical part of preventative health care for patients aged 50 to 75.

According to the National Cancer Institute, more than 135,000 new cases of colorectal cancer will be diagnosed in the United States this year with over 50,000 estimated deaths attributed to colorectal cancer (or 8.4% of all cancer deaths). With improved screening and treatment of colorectal cancer (CRC), the U.S. incidence of CRC has dropped 40% since 1975. Yet CRC is still the second leading cause of cancer death in the U.S. and in Will County. It doesn't have to be. Screening saves lives. The Centers for Disease Control and Prevention (CDC) estimates that up to 13 million colonoscopies will need to be performed annually to meet the screening goal of 80% of people between the ages of 50 and 75 years of age.

According to the Will County Community Health Status Assessment Report published in August 2013, cancer is the leading cause of death in Will County, constituting 25.8% of total deaths in 2010. The Will County Report also reveals that while colorectal cancer deaths in the State of Illinois have significantly decreased overall from 2002 to 2009, the associated mortality rates for CRC in Will County have not similarly declined. The Will County Report further reveals that the Will County screening rate was still far below the 80% target for the last measured period 2007-2009 when it was 61.2%.

Access to adequate screening is essential to reducing the colorectal cancer rate in Will County. Ninety percent (90%) of colorectal cancer cases can be cured at a relatively low cost when found and treated at an early stage. Screenings should start at age 50-if not before. People who have a risk of colon cancer may need to start screenings at an earlier age.[1] Without early detection, mortality from CRC is significant and the costs for treatment are high. The U.S. spends approximately $12.2 billion on colorectal cancer treatment each year and the cost of treatment for a single advanced case of colorectal cancer can exceed $300,000. With early screening and treatment, these costs are largely avoidable. The cost of polyp removal which is completed during the colonoscopy is just a small amount more than the screening itself. Routine screening can identify colorectal cancer at the early stages when it is easiest and least expensive to treat and the possibility of cure is the greatest. Yet the screening rate for those most at risk is only 50%.

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[1] An American Cancer Society study has found that rates of CRC have risen dramatically in younger adults (younger than 55 years). The increase in incidence is seen particularly among the so-called Generation X (persons born from the early 1960s to the early 1980s) and millennials (persons born from the early 1980s to the early 2000s). Three in 10 CRC diagnoses now occur among people younger than 55 years, and rates among young and middle-aged adults have returned to what they were for people born around 1890, say the authors of the study. Source: Colorectal Cancer Incidence Patterns in the United States, 1974-2013, Siegel, Fedewa, et al, J Natl Cancer Inst (2017) 109 (8): djw322.

2. Freestanding Endoscopy Center Provides a Significantly Lower Cost Alternative to HOPD

The New Lenox Endoscopy Center proposal is consistent with emerging payor reimbursement policies and will provide government and commercial insurance programs significant cost savings. As a general matter, a hospital outpatient department is not an appropriate site for routine endoscopy and there is an increasing trend of hospitals to move uncomplicated cases to ASCs. Many Illinois hospitals, including Silver Cross Hospital, are acknowledging that routine, minor surgical procedures should be performed in a freestanding setting. This is reflected by the fact that at least eight Illinois hospitals have obtained CON permits to open surgery centers to move cases from their hospitals in the last two years. Hospitals sponsoring ASC projects recently approved by the State Board include Advocate, Rush, Lurie Children's, Palos Community Hospital, Carle Foundation Hospital, Silver Cross Hospital, Presence and Northwest Community Hospital. All of these projects cite the lower cost and more appropriate setting of the ASC for procedures that do not require an overnight stay. Consistent with this trend and the need to have care provided in the most cost effective setting, there is a payor trend of only reimbursing certain types of cases, including endoscopy, in the ASC setting. United Health Care, in fact effective 12/1/15 developed a list of surgical procedures that it will only pay for in an ASC and not in a hospital. **See Exhibit C.**

Set forth in **Exhibit D**, are the proposed charges for the New Lenox Endoscopy Center compared to those of Silver Cross Hospital from the 2015 Hospital Report Card and Consumer Guide to Health Care. We have also included a chart comparing Medicare reimbursement for endoscopy procedures to the reimbursement that Medicare pays to hospitals. Between the two sites of care, Medicare payment rates for hospital surgical services are between 141% and 492% of what CMS pays a surgery center for the same service. This comparison helps demonstrate the value provided to commercial and government payors, patients and employers by developing a freestanding endoscopy center.

3. Adequate Endoscopy Capacity Does Not Exist in the Relevant Service Area

As shown in **Exhibit B**, New Lenox Endoscopy Center's primary service area extends from Evergreen Park to the northeast to Joliet to the Southwest.

Oak Lawn Endoscopy Center. Within the primary service area, there is only one endoscopy center, Oak Lawn Endoscopy, which has been highly utilized for the past several

years. From 2012 to 2015, utilization increased 14% (or 4% annually). As reflected in the May State Board staff report, this facility is operating well over target utilization. The proposed New Lenox Endoscopy will reduce surgical volumes at Oak Lawn Endoscopy Center to allow it to operate closer to the State Board's target utilization.

Silver Cross Hospital and Silver Cross Ambulatory Surgery Center. Silver Cross Hospital's surgical program has rapidly become heavily utilized with no additional block time available.[2] Its new hospital opened five years ago in New Lenox. Due to acquiring a larger market share at its new address, it quickly outgrew its capacity for surgical services. In its ASC application, it described the fact that it operates 15 surgical operating and procedure rooms in the hospital but its surgical volumes justify 19 rooms. This information is presented on pages 20 and 21 of the State Board staff report for that project. It is building only 3[3] more rooms in its new ASC and granting block time for those rooms for those 29 physicians in ten different specialties who wrote commitment letters (none of whom are affiliated with this project). Even after moving the volume of three operating rooms, the hospital will be over target utilization for surgery cases. In fact, the Silver Cross materials do not take into account Silver Cross' three year surgical growth trend of 5% a year for the last three years. As the Silver Cross surgical department is both a high cost setting and heavily utilized, the Southwest Gastroenterology physicians need a nearby, lower cost alternative. In its application for its recently approved ambulatory surgery center, Silver Cross projects its hospital and ambulatory surgery center operating rooms will be operating at 130.6% by 2019.[4] Due to this overutilization, Silver Cross has not granted dedicated surgical block time to two Southwest Gastroenterology physicians who have requested it. While the Silver Cross Ambulatory Surgery Center will provide some capacity in the area, its surgical block time is being dedicated to the physicians who committed referral volume as set out in that CON application. Given the projected increase in endoscopy volumes and the lack of a dedicated endoscopy room, the Silver Cross Ambulatory Surgery

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[2] Surgical/procedure room cases increased at Silver Cross Hospital over five years by 36% from 14,808 cases in 2010 to 20,059 cases in 2015. Other relevant patient care increases from 2010 to 2015 were: (i) inpatient admissions from 15,346 to 20,361, (ii) emergency department visits from 57,026 to 75,515, (iii) births from 1,584 to 2,774, and (iiv) cardiac catheterization volumes from 2,056 to 3,696. Associated patient care revenues increased from $240,581,000 in 2010 to $335,000,000 in 2015.

[3] Please note that the May State Board report indicates that it is building five rooms but the CON permit letter indicates it is approved for three rooms.

[4] See page 190 of the Silver Cross Ambulatory Surgery Center CON permit application (Project 16-021).

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Center does not have sufficient capacity to meet the projected increase in endoscopy volumes. Accordingly, there is need for additional endoscopy capacity in the primary service area.

With regard to other ASTCs listed in the State Board report previously issued for this project, note the following:

Midwest Endoscopy Center. As for other endoscopy centers, Midwest Endoscopy Center is within 45 minute drive time but well outside of the relevant geographic service area as estimated based on the patient origin information provided for this project. Midwest Endoscopy Center is operating substantially over target utilization with 3,329 hour per room (2 rooms total with 6,458 hours). It does not have capacity for the volumes associated with this project. Similarly, another surgery center noted on the State Board report which is a significant distance from New Lenox is DMG Surgical Center While distant, it has a significant endoscopy program. However, the 2015 data report shows that this facility has three endoscopy procedure rooms and provided 6,982 hours of endoscopy services in those three rooms. It does not have room for these cases either.

Area ASTCs Not Offering Endoscopy. None of the following surgery centers listed on the May State Board report are approved for endoscopy services and therefore are not a permitted alternative to this project: (a) Southwest Surgery Center, (b) Ingalls Same Day Surgery, (c) Hinsdale Surgical Center, (d) Loyola Surgery Center, (e) Oak Brook Surgical Center and (f) Westmont Surgery Center (fka as Salt Creek Surgery Center). We believe it would be useful to delete them from the next State Board report since they are not permitted to provide endoscopy services based on their current license.

Preferred Surgical Center. Preferred Surgical Center opened last year and was developed with the intent of providing religiously, culturally and linguistically competent services to the 300,000 Arab-American individuals living in the Orland Park area. It is currently unclear whether Shari'a Law practices are observed at this surgery center as its operator initially represented it would. Ultimately, however, the fact is that this ASTC was developed to serve a niche population and was supported by the referral letters of other physicians not involved in this application.

Tinley Woods Surgery Center. Tinley Woods Surgery Center has a single endoscopy procedure room that is being utilized and cannot absorb the case volume of this proposal.

Other Distant Multi-Specialty ASTCs. There is no other ASTC within the relevant service area. Those that are 30 minutes or farther from New Lenox are experiencing increases in

endoscopy volumes. See for example, AmSurg Surgery Center (68% increase in cases from 2012 to 2015) and Elmhurst Outpatient ASC (36% increase during same period).

4. Safety Net Services

Medicaid. The supplemental information provided on April 4, 2017 stated the expected payor mix for the proposed endoscopy center will be approximately 8.3% Medicaid. The application for permit page 53 states that the endoscopy center projects at least 6% of its endoscopy patients will be Medicaid beneficiaries. As New Lenox Endoscopy has no history of providing Medicaid, the levels of projected Medicaid care was based on the 2016 payor mix data from the Applicant's affiliated medical practice, Southwest Gastroenterology.

Reduced Global Fee Arrangement for Uninsured Patients. In addition to serving the Medicaid population, New Lenox Endoscopy Center will provide endoscopy procedures for a flat fee for self-pay patients. This program is currently in place at Oak Lawn Endoscopy and will be implemented at New Lenox Endoscopy Center. Under this program, patients without insurance may receive an upper endoscopy ("EGD") for $650, a colonoscopy for $900, an EGD and colonoscopy for $1,150, or a sigmoidoscopy for $350. This flat fee is a global fee and includes the facility, physician and anesthesiologist charges. Importantly, the flat fee is significantly less than the Silver Cross Hospital median **facility fee only charges** for these services ($5,582 for an EGD and $4,822 for a colonoscopy).

Charity Care for Free Clinic Patients. New Lenox Endoscopy Center expects to provide free endoscopies to patients referred by the Will-Grundy Medical Clinic, a not-for-profit 501(c)(3) organization that provides free medical and dental care to adults who have no health insurance or medical care entitlements and meet prescribed income guidelines. Based on this arrangement and other free services it will provide, New Lenox Endoscopy expect at least 1% of its patients will receive free services.

Finally, Silver Cross' objection to New Lenox Endoscopy's projected amounts of Medicaid and charity care is disingenuous. First, unlike Silver Cross Hospital, which receives benefits due to its tax-exempt status, New Lenox Endoscopy is a for-profit company and is required to pay income taxes. Based upon the Annual Hospital Profile, it is unclear whether Silver Cross Hospital's provision of charity care exceeds the amount of taxes it would be obligated to pay if it were a taxable entity. Additionally, it is important to note that since 2011, the last full year Silver Cross Hospital was located in Joliet, to 2015, the number of Medicaid patients served by Silver Cross Hospital decreased by 3%.

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5. Project Cost Adjustment for Leased Equipment

With this supplement, we are providing an updated project cost and sources of funds worksheet. After the recent departure of the group's administrator, the Applicants analyzed the project costs and sources of funds for the project and determined that leased equipment had been omitted from this schedule. Accordingly, the Applicants seek to modify the pending certificate of need application to revise the project costs and sources of funds. The change in project costs exceeds 10% of the original estimated project costs and constitutes a Type A modification. Therefore, we have included a check payable to the Illinois Department of Public Health in the amount of $2,000 to cover the modification fee.

If you have any questions or need additional information regarding this application for permit, please feel free to contact me.

Sincerely,

Anne M. Cooper

Attachments

EXHIBIT A

RESPONSES TO STATE BOARD MAY 5, 2017 REQUEST FOR INFO

1. Q: Page 104 of the Application for Permit states the cost to build the ASTC is $1,882,463.84. The FMV of the space as stated in the application is $1,724.622. Please provide an explanation for this difference.

   A: The fair market value of the leased space submitted in the application was incorrect. Further, in recent weeks, it was brought to our attention that the value of leased equipment was not included in the Project Costs and Sources of Funds schedule. This schedule has been modified to include updated fair market value of the leased space as well as to reflect the value of the leased endoscopy equipment. **See Attachment –A- 1**

2. Q: In supplemental information you state the fair market value of the leased space is based on the full amortization of the capitalized costs to construct the endoscopy center with a reasonable rate of return. Please provide the calculation (i.e. numbers) of how the FMV of the leased space was derived.

   A: The fair market value of the lease space is based upon the cost to build out the endoscopy center.

3. Q: Provide the projected balance sheet for New Lenox Endoscopy Center, LLC and SGNL, LLC for years 1-3.

   A: Revised pro formas for New Lenox Endoscopy Center, LLC and SGNL, LLC are attached at **Attachment –A- 2**.

4. The letter from Standard Bank and Trust Company states that the Southwest Gastroenterology S.C. maintains a balance in excess of $250,000. (Application for Permit page 103) In supplemental information that Southwest Gastroenterology S.C. provided the current assets for 2016 was -$50,307. Please provide a current bank statement and an explanation of the discrepancy between the statement in the bank letter and the financial information provided in the supplemental information.

   A: The difference between the balance reported in the October 31, 2016 Standard Bank and Trust Company letter and the December 31, 2016 balance was due to end of the year physician distributions. Typically, physician practices do not carry high cash balances and excess cash is distributed out on a periodic basis (e.g., monthly, quarterly or annually). Accordingly, the negative cash balance was a result of the end of year distributions to the Southwest Gastroenterology physicians.

   Updated bank letters from First Midwest Bank for Southwest Gastroenterology, S.C. and SGNL LLC are attached at **Attachment – A-3**. As stated in the letters, Southwest

Gastroenterology, S.C. and SGNL LLC collectively have in excess of $300.000. Please note, on February 4, 2017, Standard Bank and Trust Company merged into and currently operates as part of First Midwest Bank.

A letter from First Midwest Bank stating the available loan proceeds to fund the New Lenox Endoscopy Center project is attached at **Attachment –A- 4.**

5. Q: Principle payments and interest expense were provided for New Lenox Endoscopy Center projected financial information. In the information provided in the application for permit a mortgage or a debt instrument is not being used to finance this project. Please explain. If the principle payments and interest expense was in error please provide new projected financial statements.

   A: As noted previously, with the recent departure of the group's administrator, the Applicants reviewed the previously submitted pro forma financial statements and noted they included debt service rather than rent. As noted in the certificate of need application, New Lenox Endoscopy, LLC will lease the endoscopy center from an affiliated entity, SGNL, LLC, which will carry the debt associated with this project. Revised pro forma financial statements for New Lenox Endoscopy, LLC and SGNL, LLC are attached at **Attachment – A-2.**

6. Q: Is the depreciation expense on the projected income statement for New Lenox Endoscopy Center for the equipment or the building? The application states that SGNL, LLC is the owner of the building; therefore depreciation for the building would not be recorded on the proposed licensee's income statement.

   A: Upon further review of the pro forma financial statements, the Applicants' noted the depreciation expense included in the previously submitted pro forma financial statements included both equipment and building depreciation expenses. As shown in the revised pro forma financial statements, the New Lenox Endoscopy, LLC depreciation expense pertains to the purchased equipment. The building depreciation expense is recorded on the SGNL, LLC pro forma financial statements. **See Attachment – A-2.**

7. Q: Please clarify the expected Medicaid population that will be served by the proposed facility and the

   A: See Applicant's response in body of letter on page 3.

8. Q: The opposition letter from Silver Cross Hospital and Medical Center questions the number of outpatient GI procedures performed at Silver Cross Hospital and Medical Center by Southwest GI physicians. The application for permit states 7,359 outpatient GI procedures were performed at Silver Cross Hospital while Silver Cross Hospital states that 6,321 outpatient GI procedures were performed at the Hospital or a difference of approximately 1,038 procedures. Please explain the difference.

A: The physician referral letter in the application was based upon calendar year 2015 procedures. Silver Cross Hospital's procedure number is based on the period October 1, 2015 to September 30, 2016. In addition to different periods covered, a discrepancy could exist because the two entities pulled the data from different sources, Southwest Gastroenterology from its billing system and Silver Cross Hospital from its medical records system.

9. Q: Please provide an explanation of how many procedures will be moved from Silver Cross Hospital
to the new ASTC if approved by the State Board.

A: The Applicants propose to transfer 2,493 endoscopy procedures historically performed at Silver Cross Hospital to New Lenox Endoscopy Center. Based upon the 2015 Annual Hospital Profile, Silver Cross Hospital currently operates 11 operating rooms. Since moving to New Lenox in 2012, utilization has increased over 15% (or 5% annually). Based upon this historical growth, Silver Cross Hospital projects its 2019 surgical hours at the hospital and ASC will reach 27,426 hours. **See Attachment – A-5.** With 11 hospital operating rooms at the hospital and three operating rooms at Silver Cross Ambulatory Surgery Center, Silver Cross will operate a total of 14 operating rooms between the two facilities. Based upon its own projections, Silver Cross Hospital and Silver Cross Ambulatory Surgery Center will collectively operate at 130.6% capacity. **See Attachment – A-5.** Moving cases from Silver Cross to New Lenox Endoscopy Center will not lower the utilization of Silver Cross below the State Board utilization standard. To the contrary, it will allow the hospital and ambulatory surgery center to operate more efficiently.

Further, transferring cases from Silver Cross Hospital to New Lenox will not lower utilization of the dedicated gastroenterology procedure rooms below the State Board utilization standard. Based upon its own projections, 3,628 surgical hours are projected for the Silver Cross Ambulatory Surgery Center. The 2,493 procedures are currently performed in Silver Cross Hospitals' dedicated gastroenterology procedure rooms. Assuming 0.7 surgical hours per case, transferring the gastroenterology cases from the Silver Cross Hospital to Silver Cross Ambulatory Surgery Center, will increase the projected surgical hours for the ambulatory surgery center to 5,373 hours (119% utilization). Accordingly, there will not be sufficient capacity to accommodate the 2,493 procedures proposed to be transferred to New Lenox Endoscopy Center.

The Southwest Gastroenterology procedures were not used to justify the need for the Silver Cross Ambulatory Surgery Center which will not have a dedicated gastroenterology procedure room. There is insufficient capacity to accommodate the Southwest Gastroenterology cases. Utilizing a higher cost hospital setting for these procedures is untenable. As shown in the table attached at **Exhibit D**, the average Medicare reimbursement rate for a hospital outpatient endoscopy procedure is twice that of an ambulatory surgery center. Further, as shown in the table attached at **Exhibit D**, the median

charge of a colonoscopy at Silver Cross Hospital is over three times the median charge of a colonoscopy at the proposed New Lenox Endoscopy Center. Likewise, the median charge for an upper GI endoscopy is over four and half times higher at Silver Cross than at the proposed New Lenox Endoscopy Center. We find Silver Cross' apparent contention that these procedures should be performed in a higher cost setting to be contrary to fundamental health planning policies.

Finally, since moving to New Lenox in 2012, outpatient gastroenterology cases at Silver Cross Hospital have increased 44% (or 9.5% compounded annual growth). Based upon this historical growth rate, 10,935 outpatient gastroenterology cases are projected for 2019 (or 124% utilization of the five gastroenterology procedure rooms at Silver Cross Hospital). Moving 2,493 cases from Silver Cross Hospital to New Lenox Endoscopy will lower utilization of the Silver Cross Hospital gastroenterology procedure rooms to 101%.

Silver Cross Hospital Gastroenterology Procedure Room Utilization

	2011	2012	2013	2014	2015	Projected 2016	Projected 2017	Projected 2018	Projected 2019
Cases									
Inpatient	1,320	1,487	1,584	1,722	1,779	1,917	2,065	2,226	2,398
Outpatient	5,272	6,128	6,716	7,364	7,592	8,317	9,111	9,981	10,935
Total	**6,592**	**7,615**	**8,300**	**9,086**	**9,371**	**10,234**	**11,177**	**12,207**	**13,333**
Surgical Hours									
Inpatient	1,015	1,153	1,265	1,276	1,222	1,342	1,446	1,558	1,679
Outpatient	4,028	4,515	5,765	5,051	4,946	5,822	6,378	6,987	7,654
Total	**5,043**	**5,668**	**7,030**	**6,327**	**6,168**	**7,164**	**7,824**	**8,545**	**9,333**
Utilization	**112%**	**94%**	**156%**	**84%**	**82%**	**96%**	**104%**	**114%**	**124%**

10. Q: The application for permit stated that the average time per procedure to be fifty-two (52) minutes. The average time per procedure in the State of Illinois is 39.6 minutes or 40 minutes (2015 ASTC State Summary Profile Data). Please explain the difference.

A: The State average procedure time should not be a metric to determine the feasibility of a project. As noted in a recent article in Clinical Endoscopy, several factors affect endoscopy procedure times: (1) patient age, sex, and BMI; (2) degree of bowel preparation; (3) history

of abdominopelvic surgery; (4) type of endoscopy, i.e., diagnostic versus screening/surveillance; and (5) experience and characteristics of the gastroenterologist. **See Attachment – A-6.**

Further, a study in the New England Journal of Medicine found colonoscopy procedure times should generally take 30 minutes, approximately 8 minutes for insertion and at least 20 minutes for withdrawal. **See Attachment – A-7.** Contrary, to Silver Cross' position in its opposition letter, quicker/more efficient is not best. In fact, in the New England Journal of Medicine study found greater rates of detection of adenomas among physicians with longer mean times for withdrawal of the endoscope. **See Attachment – A-8.**

While the average case time for New Lenox Endoscopy is higher than the State average, it is important to note it is lower than the average case time of Oak lawn Endoscopy Center (59 minutes) and consistent with the average case time in HSA 9 (49 minutes).

11. Q: 77 IAC 1110.530 (b) (1) (3) – Background of Applicant requires a listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility. The State Board Staff has become aware of additional health care facilities that members of New Lenox Endoscopy Center, LLC and SGNL, LLC have an interest. (See page 6 of the opposition letter submitted by Silver Cross Hospital and Medical Center) Please provide the name of the members of the Oak Lawn Endoscopy Center, LLC and their percentage of ownership.

    A: No Southwest Gastroenterology physician owns more than 5% direct or indirect interest in Oak Lawn Endoscopy Center. Each individual Southwest Gastroenterology physician has a 4.2% interest in Oak Lawn Endoscopy.

Project Costs and Sources of Funds

Complete the following table listing all costs (refer to Part 1120.110) associated with the project. When a project or any component of a project is to be accomplished by lease, donation, gift, or other means, the fair market or dollar value (refer to Part 1130.140) of the component must be included in the estimated project cost. If the project contains non-reviewable components that are not related to the provision of health care, complete the second column of the table below. Note, the use and sources of funds must equal.

Project Costs and Sources of Funds			
USE OF FUNDS	**CLINICAL**	**NONCLINICAL**	**TOTAL**
Preplanning Costs			
Site Survey and Soil Investigation			
Site Preparation			
Off Site Work			
New Construction Contracts			
Modernization Contracts			
Contingencies			
Architectural/Engineering Fees			
Consulting and Other Fees	$22,500	$7,500	$30,000
Movable or Other Equipment (not in construction contracts)	$174,095	$55,200	$229,295
Bond Issuance Expense (project related)			
Net Interest Expense During Construction (project related)			
Fair Market Value of Leased Space or Equipment	$2,289,377	$488,717	$2,778,094
Other Costs To Be Capitalized			
Acquisition of Building or Other Property (excluding land)			
TOTAL USES OF FUNDS	**$2,485,972**	**$551,417**	**$3,037,389**
SOURCE OF FUNDS	**CLINICAL**	**NONCLINICAL**	**TOTAL**
Cash and Securities	$196,595	$62,700	$259,295
Pledges			
Gifts and Bequests			
Bond Issues (project related)			
Mortgages			
Leases (fair market value)	$2,289,377	$488,717	$2,778,094
Governmental Appropriations			
Grants			
Other Funds and Sources			
TOTAL SOURCES OF FUNDS	**$2,485,972**	**$551,417**	**$3,037,389**
NOTE: ITEMIZATION OF EACH LINE ITEM MUST BE PROVIDED AT ATTACHMENT-7, IN NUMERIC SEQUENTIAL ORDER AFTER THE LAST PAGE OF THE APPLICATION FORM.			

2,004,622 ORIGINAL Cost

Additional Fee 2,272,08

Project Costs			
USE OF FUNDS	CLINICAL	NONCLINICAL	TOTAL
Consulting and Other Fees	22,500	7,500	30,000
Moveable or Other Equipment			
Scope Washers – Olympus	$84,295		$84,295
Shelving Units		$8,500	$8,500
Stools		$3,000	$3,000
Stretchers	$15,000		$15,000
Cardio Monitors	$13,000		$13,000
Computers/Stands/COWS		$25,000	$25,000
Olympus Software Endoscopy System	$20,000		$20,000
Anesthesia Cards	$7,500		$7,500
Speakers		$5,000	$5,000
Endoscopy Instrumentation	$8,900		$8,900
Cubicle Curtains		$3,700	$3,700
Endoscopy Suite Furniture		$10,000	$10,000
Miscellaneous Equipment	$25,400		$25,400
Total Moveable & Other Equipment	**$174,095**	**$55,200**	**$229,295**
Fair Market Value of Leased Space	$1,393,747	$488,717	$1,882,464
Fair Market Value of Leased Equipment			
Video Processor	$70,080		$70,080
Light Source	$40,320		$40,320
Remote Cable Periph Device	$57		$57
Interface Converter Device	$2064		$2064
Videoscope	$7,464		$7,464
High Definition LED CD Monitor	$21,240		$21,240
Rollstand	$3,144		$3,144
HDTV Gastroscope	$338,400		$338,400
PCF-H190DL w/ Scopeguide	$206,000		$206,000
CF-HQ190L Colonoscope	$206,000		$206,000
Freight	$861		$861
Total Fair Market Value of Leased Equipment	**$895,630**		**$895,630**
TOTAL USES OF FUNDS	**$2,485,972**	**$551,417**	**$3,037,389**

New Lenox Endoscopy Center, LLC
3 Year Pro forma
CASH BASIS

	YEAR 1	YEAR 2	YEAR 3
ASSETS			
CURRENT ASSETS			
CASH	1,000,237	1,946,814	2,926,107
TOTAL CURRENT ASSETS	**1,000,237**	**1,946,814**	**2,926,107**
PROPERTY AND EQUIPMENT			
MEDICAL EQUIPMENT	145,000	145,000	145,000
LESS: ACCUMULATED DEPRECIATION	(20,714)	(41,429)	(62,143)
NET PROPERTY & EQUIPMENT	**124,286**	**103,571**	**82,857**
OTHER ASSETS			
CONSTRUCTION DEPOSITS	-	-	-
TOTAL OTHER ASSETS	-	-	-
TOTAL ASSETS	**1,124,522**	**2,050,385**	**3,008,964**
LIABILITIES AND MEMBERS' EQUITY			
CURRENT LIABILITIES			
TOTAL CURRENT LIABILITIES	-	-	-
LONG-TERM LIABILITIES			
NOTES PAYABLE	-	-	-
TOTAL LONG-TERM LIABILITIES	-	-	-
TOTAL LIABILITIES	-	-	-
MEMBERS EQUITY			
PAID IN CAPITAL	245,000	245,000	245,000
RETAINED EARNINGS	-	879,522	1,805,385
NET INCOME OR (LOSS)	879,522	925,863	958,579
TOTAL MEMBERS' EQUITY	**1,124,522**	**2,050,385**	**3,008,964**
TOTAL LIABILITIES AND MEMBERS EQUITY	**1,124,522**	**2,050,385**	**3,008,964**

New Lenox Endoscopy, LLC
Analysis and Projection of Operations
Cash Basis

			Year 1	Year 2	Year 3
Case Volume/Year-Accrual			**3,500**	**3,640**	3,750
Case Volume/Year-Cash			**3,500**	**3,640**	3,750
Average Net Reimbursement/Case			750	750	750
REVENUE					
Net Revenue			2,625,000	2,730,000	2,812,500
Total Net Revenue			2,625,000	2,730,000	2,812,500
FIXED EXPENSES					
Salaries	140 /case		490,000	509,600	525,000
Benefits	20 /case		70,000	72,800	75,000
Rent	30 /sqft	6,344	190,320	196,030	201,910
Repairs & Maint.-Eq	4% incr		25,000	26,000	27,040
Equipment Lease			203,693	203,693	203,693
Legal & Prof. Fees	1,000 incr		32,000	33,000	34,000
Advertising	4% incr		20,000	20,800	21,632
Total Fixed Expenses			1,031,013	1,061,923	1,088,276
VARIABLE EXPENSES					
Office Expense	4% incr		85,000	88,400	91,936
Laundry	4.5 /case		15,750	16,380	16,875
Transcription	4 /case		14,000	14,560	15,000
Medical Sup. & Drugs	90 /case		315,000	327,600	337,500
Management Services	3% rev		78,750	81,900	84,375
Insurance	9 /case		31,500	32,760	33,750
Telephone	3% rev		78,750	81,900	84,375
Miscellaneous	4% incr		75,000	78,000	81,120
Total Variable Expenses			693,750	721,500	744,931
TOTAL EXPENSES			1,724,763	1,783,423	1,833,207
EBITDA			900,237	946,577	979,293
OTHER EXPENSES-CASH FLOWS					
Leashold improvements		6.50%	-	-	-
Equipment deprec			20,714	20,714	20,714
Line of Credit Payments (Principal & Int)		5.00%	-	-	-
Total Other Expenses-Cash flows			20,714	20,714	20,714
INCOME (LOSS) BEFORE TAXES			879,522	925,863	958,579

SGNL, LLC
3 Year Pro forma
CASH BASIS

	12 Months Ended December 31, 2018	12 Months Ended December 31, 2019	12 Months Ended December 31, 2020
PROFESSIONAL INCOME			
Rental Income	887,130	913,744	941,156
Total Professional Income	887,130	904,873	922,970
OPERATING EXPENSES			
Bank Charges	400	412	424
Insurance	2,500	2,575	2,652
Legal & Profesional Fees	3,000	3,090	3,183
Licenses & Permits	250	250	250
Outside Services	1,000	1,030	1,061
Total Dperating Expenses	7,150	7,357	7,570
GROSS PROFIT	879,980	897,516	915,400
OTHER INCOME (EXPENSES)			
Interest Expense	(312,729)	(300,000)	(285,000)
Depreciation	(214,881)	(214,881)	(214,881)
Prior Year Taxes	(600)	(5,277)	(5,660)
Total Other Income (Expenses)	(528,210)	(520,157)	(505,541)
NET INCOME OR (LOSS)	351,770	377,358	409,859

Variables	
Square feet	29,571
Price per Sq ft	30
Annual Rent	887,130
Loan Amount	8,380,346
Useful Life	39
Annual Depreciation	214,881

SGNL, LLC
3 Year Pro forma
CASH BASIS

	12 Months Ended December 31, 2018	12 Months Ended December 31, 2019	12 Months Ended December 31, 2020
ASSETS			
CURRENT ASSETS			
CASH	70,867	150,378	247,389
TOTAL CURRENT ASSETS	**70,867**	**150,378**	**247,389**
PROPERTY AND EQUIPMENT			
BUILDING & IMPROVEMENTS	8,471,857	8,471,857	8,471,857
LAND	1,234,346	1,234,346	1,234,346
LESS: ACCUMULATED DEPRECIATION	(214,881)	(429,762)	(644,643)
NET PROPERTY & EQUIPMENT	**9,491,322**	**9,276,441**	**9,061,560**
OTHER ASSETS			
TOTAL OTHER ASSETS	-	-	-
TOTAL ASSETS	**9,562,189**	**9,426,819**	**9,308,949**
LIABILITIES AND MEMBERS' EQUITY			
CURRENT LIABILITIES			
TOTAL CURRENT LIABILITIES	-	-	-
LONG-TERM LIABILITIES			
LOANS PAYABLE	7,880,346	7,367,617	6,839,888
TOTAL LONG-TERM LIABILITIES	**7,880,346**	**7,367,617**	**6,839,888**
TOTAL LIABILITIES	**7,880,346**	**7,367,617**	**6,839,888**
MEMBERS EQUITY			
PAID IN CAPITAL	360,000	360,000	360,000
RETAINED EARNINGS	970,073	1,321,843	1,699,202
NET INCOME OR (LOSS)	351,770	377,358	409,859
TOTAL MEMBERS' EQUITY	**1,681,843**	**2,059,202**	**2,469,061**
TOTAL LIABILITIES AND MEMBERS EQUITY	**9,562,189**	**9,426,819**	**9,308,949**
	(0)	0	-

Attachment - A-2

First Midwest Bank

May 22, 2017

Mr. Michael Constantino
Project Reviewer
Illinois Health Facilities and Services Review
Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: New Lenox Endoscopy Center, Project. No. 16-046

Dear Mr. Constantino:

Please accept this letter as verification that SGNL LLC has an account at First Midwest Bank that maintains in excess of $50,000.00 to fund the New Lenox Endoscopy Center project.

If you need any further information, please do not hesitate to contact me directly at (708)576-7091.

Sincerely,

Mohammed Abunada
Vice President
Professional Services Business Banking

Attachment - A-3

First Midwest Bank

May 22, 2017

Mr. Michael Constantino
Project Reviewer
Illinois Health Facilities and Services Review
Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: New Lenox Endoscopy Center, Project. No. 16-046

Dear Mr. Constantino:

Please accept this letter as verification that Southwest Gastroenterology, S.C. has a loan at First Midwest Bank that has an available balance of at least $798,000.00 to fund the New Lenox Endoscopy Center project.

If you need any further information, please do not hesitate to contact me directly at (708)576-7091.

Sincerely,

Mohammed Abunada
Vice President
Professional Services Business Banking

Attachment - A-3

First Midwest Bank

May 22, 2017

Mr. Michael Constantino
Project Reviewer
Illinois Health Facilities and Services Review
Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: New Lenox Endoscopy Center, Project. No. 16-046

Dear Mr. Constantino:

Please accept this letter as verification that Southwest Gastroenterology, S.C. has an account at First Midwest Bank that maintains in excess of $250,000.00 to fund the New Lenox Endoscopy Center project.

If you need any further information, please do not hesitate to contact me directly at (708)576-7091.

Sincerely.

Mohammed Abunada
Vice President
Professional Services Business Banking

Attachment - A-4

PROJECTION MODEL

SCH ENTERPRISE - TOTAL SURGERY ACTIVITY

(Inpatient and Outpatient combined – does not include any excludes GI procedure room activity)

Service Area	Historical Cases FY14 (Actual)	Historical Cases FY15 (Actual)	Historical Growth Rate	Projected Cases FY16 (Proj)	Projected Cases FY17 (Proj)	Projected Cases FY18 (Proj)	Projected Cases FY19 (Proj)	Avg Hours/Case (2015 AHQ)	Projected Surgery Hours FY16 (Proj)	Projected Surgery Hours FY17 (Proj)	Projected Surgery Hours FY18 (Proj)	Projected Surgery Hours FY19 (Proj)	CON Hours per Room	Operating Rooms Justified (rounded up) FY16 (Proj)	Operating Rooms Justified (rounded up) FY17 (Proj)	Operating Rooms Justified (rounded up) FY18 (Proj)	Operating Rooms Justified (rounded up) FY19 (Proj)
O.R.s	11	11							11	11	14	14					
Primary	6395	6622	4%	6858	7102	7355	7617	2.00	13716	14204	14710	15234					
Secondary-E	568	681	20%	817	980	1175	1409	2.00	1634	1960	2350	2818					
Secondary-N	483	491	2%	500	509	518	527	2.00	1000	1018	1036	1054					
Secondary-S	287	323	13%	364	410	462	520	2.00	728	820	924	1040					
Secondary-W	835	885	6%	938	995	1055	1119	2.00	1876	1990	2110	2238					
Immigration	1343	1523	13%	1728	1960	2223	2521	2.00	3456	3920	4446	5042					
Total	9922	10536	6.2%	11205	11956	12788	13713	2.00	22410	23912	25576	27426	1500	14.9 = 15	15.9 = 16	17.1 = 18	18.3 = 19
...ilization									135.8%	113.9%	121.8%	130.6%					

PROPOSED FREESTANDING ASTC ACTIVITY

...vice Area	Historical Cases FY14 (Actual)	Historical Cases FY15 (Actual)	Historical Growth Rate	Projected Cases FY16 (Proj)	Projected Cases FY17 (Proj)	Projected Cases FY18 (Proj)	Projected Cases FY19 (Proj)	Avg Hours/Case (2015 AHQ)	Projected Surgery Hours FY16 (Proj)	Projected Surgery Hours FY17 (Proj)	Projected Surgery Hours FY18 (Proj)	Projected Surgery Hours FY19 (Proj)	CON Hours per Room	Operating Rooms Justified (rounded up) FY16 (Proj)	Operating Rooms Justified (rounded up) FY17 (Proj)	Operating Rooms Justified (rounded up) FY18 (Proj)	Operating Rooms Justified (rounded up) FY19 (Proj)
...s											3	3					
...mary (Service Area)		1995	4.0%			2165	2252	1.6115			3489	3628	1500			2.4 = 3.0	2.4 = 3.0

SCH HOSPITAL-BASED SURGERY ACTIVITY - REMAINING

Service Area	Historical Cases FY14 (Actual)	Historical Cases FY15 (Actual)	Historical Growth Rate	Projected Cases FY16 (Proj)	Projected Cases FY17 (Proj)	Projected Cases FY18 (Proj)	Projected Cases FY19 (Proj)	Avg Hours/Case (2015 AHQ)	Projected Surgery Hours FY16 (Proj)	Projected Surgery Hours FY17 (Proj)	Projected Surgery Hours FY18 (Proj)	Projected Surgery Hours FY19 (Proj)	CON Hours per Room	Operating Rooms Justified (rounded up) FY16 (Proj)	Operating Rooms Justified (rounded up) FY17 (Proj)	Operating Rooms Justified (rounded up) FY18 (Proj)	Operating Rooms Justified (rounded up) FY19 (Proj)
).R.s	11	11							11	11	11	11					
...rimary	6395	4457		6858	7102	5190	5365		13716	14204	11221	11563					
...econdary-E	568	681		817	980	1175	1409		1634	1960	2350	2818					
...econdary-N	483	491		500	509	518	527		1000	1018	1036	1054					
...econdary-S	287	323		364	410	462	520		728	820	924	1040					
...econdary-W	835	885		938	995	1055	1119		1876	1990	2110	2238					
...migration	1343	1523		1728	1960	2223	2521		3456	3920	4446	5042					
...otal	9922	10536		11205	11956	10623	11461		22410	23912	22047	23755	1500	14.9 = 15	15.9 = 16	14.7 =15	15.8 = 16
...tilization									135.8%	144.9%	133.6%	144.0%					

0190

Attachment 27

Attachment - A-5

...-3000-4369.1

CLINICAL ENDOSCOPY
• This Article • Aims and Scope • Instructions for Authors • e-Submission

Clin Endosc. 2016 Nov; 49(6): 500–501. PMCID: PMC5152777
Published online 2016 Nov 29. doi: 10.5946/ce.2016.142

What Is the Mean Procedure Time to Optimize Colonoscopy?

Taehyun Kim and Beom Jae Lee

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Received 2016 Oct 21; Revised 2016 Nov 7; Accepted 2016 Nov 10.

See the article "Predicting Colonoscopy Time: A Quality Improvement Initiative" on page 555.

See "Predicting Colonoscopy Time: A Quality Improvement Initiative" by Deepanshu Jain, Abhinav Goyal, Stacey Zavala, on page 555-559.

Colonoscopy is the most effective and popular method for the screening, prevention, and diagnosis of colorectal cancer worldwide. However, there have been concerns on the ability of colonoscopy to detect adenoma. Colonoscopic examination is limited in this regard even if lesions are not missed because of variables such as the endoscopist's skill, experience, and the degree of bowel preparation. Thus, it is crucial to maintain and optimize the quality of colonoscopy.

Several quality indicators for colonoscopy are recommended: adenoma detection rate (ADR), the degree of bowel preparation, cecal intubation rate, and withdrawal time.

Adequate procedure time is a prerequisite for adenoma detection. In 2006, Barclay et al. reported that a minimum withdrawal time of 6 minutes enabled adequate adenoma detection during screening or diagnostic colonoscopy [1]. This has become the principal guideline of diagnostic colonoscopy and most current guidelines now recommend this minimal time of 6 minutes to avoid missing adenoma during colonoscopy.

In this issue of the journal, Jain et al. tried to define the pre-procedure factors affecting colonoscopy procedure time [2]. They retrospectively analyzed 1,239 patients undergoing screening colonoscopy using variables including age, sex, body mass index (BMI), previous abdominal surgery history, procedure timing, indication, and endoscopist experience. Total procedure time was significantly shorter in patients who underwent afternoon colonoscopy. Other factors including sex and history of surgery did not affect the procedure time. Using multiple regression analysis, the authors created a total procedure time prediction model. This model approaches the procedure time from the perspective of patient satisfaction or anxiety while awaiting colonoscopy. Jain et al. state that this prediction model might help to decrease the waiting time and improve the patient's satisfaction with the colonoscopy [2].

However, the results of this study have raised some issues for readers to consider. First, the ADR is not shown. Adequate ADR is an indicator for high quality colonoscopy. After assessing and analyzing

colonoscopy procedure time, the starting point and pre-condition status determined whether the enrolled patients underwent adequate colonoscopy. We could not evaluate the relationship between ADR and procedure time in this study. Second, it is not clear whether a prolonged or shortened procedure time is caused by delayed insertion or withdrawal time. Adequate colonoscopy procedure time is a prerequisite for optimized colonoscopy. Several factors affect colonoscopy procedure time. Patient factors include age, sex, BMI, constipation, the degree of bowel preparation status, history of abdominopelvic surgery. Additionally, the experience and characteristics of the endoscopist can affect the procedure time [3,4]. A prolonged procedure time is usually defined by the cecal intubation time and reflects a difficult examination. However, increased procedure time due to difficult insertion can lead to several negative effects on colonoscopy quality including the increased chance of missing a lesion, fatigue of the endoscopist, and prolonged waiting time. Yang et al. [5] reported that longer cecal intubation time was associated with lower ADR. They analyzed 12,679 patients who underwent screening colonoscopy. A shorter insertion time was associated with increased detection of small-sized polyps [5]. In this study, afternoon colonoscopy was the significant factor affecting total procedure time. Colonoscopies in the afternoon had a shorter procedure time. Why did afternoon colonoscopy result in a shorter procedure time? Was it related to delayed insertion or shorter withdrawal time? The reason was not clarified in this study. It is still debated whether the timing of colonoscopy affects the ADR. Teng et al. recently reported that morning colonoscopy improved ADR and increased withdrawal time [6]. Furthermore, Shinde et al. showed that there was no significant difference in ADR between morning and afternoon colonoscopy in haft –day block [7]. Previous studies have shown that endoscopists have a tendency to withdraw the scope more quickly if the colonoscopy is performed in the afternoon. One possible reason is the desire to finish the colonoscopy quickly. Pressure to finish faster [8]. Another possible reason is endoscopist fatigue causing a decline in the ADR [9]. This study showed that the time needed for diagnostic colonoscopy was significantly shorter than that of screening/surveillance colonoscopy, which is an interesting finding. Although we could not evaluate the reason for this time difference because of lack of data, the procedure time difference may be the result of quick withdrawal of the scope by the endoscopist after an expected lesion is detected. A well-designed study in the future could achieve interesting results regarding the relationship of ADR, endoscopist technique, and indications. This study evaluated a novel procedure time prediction model with the following questions: Can we use this model in the clinical fields? Is this model really valuable to the clinical practice? How is predicting colonoscopy procedure time beneficial? An adequately aliquoted number of patients could be helpful to maintain a high-quality colonoscopy with consideration to the endoscopist's physical condition. Additionally, it could shorten procedure delay and waiting time. What is the effect of procedure delay on the quality of colonoscopy? Keswani et al. [10] reported that procedure delay and increased waiting time were not associated with a lower ADR. Waiting time is getting longer [10]. In the era of conscious-sedation endoscopy, colonoscopy-associated pain and discomfort has been considerably decreased. However, from the bowel preparation to procedure, colonoscopy still causes fear, anxiety, and both physical and emotional discomfort. To make the colonoscopy comfortable for the patient, several methods have been suggested. Music [11] and clothes to decrease the patient's shame [12], and various relatively comfortable laxatives were suggested. The reason to improve the patient's satisfaction is the desire to increase follow-up study adherence by the patients. Predicting procedure time and the shortening of waiting time bench in waiting area can be the starting points for lowering patient's anxiety and increasing comfort during colonoscopy, which could increase follow-up study adherence [13]. Finally, colonoscopy should be performed within the quality indicators. Optimizing procedure time may be a starting point for improving colonoscopy quality and will be helpful to improve patient satisfaction.

Footnotes

Go to:

Conflicts of Interest: The authors have no financial conflicts of interest.

REFERENCES

Go to:

1. Barclay RL, Vicari JJ, Doughty AS, Johanson JF, Greenlaw RL. Colonoscopic withdrawal times and adenoma detection during screening colonoscopy. N Engl J Med. 2006;355:2533–2541. [PubMed]

2. Jain D, Goyal A, Zavala S. Predicting Colonoscopy Time: A Quality Improvement Initiative. Clin Endosc. 2016;49:555–559. [PMC free article] [PubMed]

3. Bernstein C, Thorn M, Monsees K, Spell R, O'Connor JB. A prospective study of factors that determine cecal intubation time at colonoscopy. Gastrointest Endosc. 2005;61:72–75. [PubMed]

4. Zuber-Jerger I, Endlicher E, Gelbmann CM. Factors affecting cecal and ileal intubation time in colonoscopy. Med Klin (Munich) 2008;103:477–481. [PubMed]

5. Yang MH, Cho J, Rampal S, et al. The association between cecal insertion time and colorectal neoplasm detection. BMC Gastroenterol. 2013;13:124. [PMC free article] [PubMed]

6. Teng TY, Khor SN, Kailasam M, Cheah WK, Lau CC. Morning colonoscopies are associated with improved adenoma detection rates. Surg Endosc. 2016;30:1796–1803. [PubMed]

7. Shinde T, Singh S, Gupta M, Aoun E, Dhawan M. Adenoma Detection Rate is Not Influenced by the Timing of Colonoscopy. Am J Gastroenterol. 2011;106:S158–S158.

8. Keswani RN, Taft TH, Coté GA, Keefer L. Increased levels of stress and burnout are related to decreased physician experience and to interventional gastroenterology career choice: findings from a US survey of endoscopists. Am J Gastroenterol. 2011;106:1734–1740. [PubMed]

9. Lee CK, Cha JM, Kim WJ. Endoscopist Fatigue May Contribute to a Decline in the Effectiveness of Screening Colonoscopy. J Clin Gastroenterol. 2015;49:e51–e56. [PubMed]

10. Keswani RN, Gawron AJ, Cooper A, Liss DT. Procedure Delays and Time of Day Are Not Associated With Reductions in Quality of Screening Colonoscopies. Clin Gastroenterol Hepatol. 2016;14:723–728. e2. [PubMed]

11. Rudin D, Kiss A, Wetz RV, Sottile VM. Music in the endoscopy suite: a meta-analysis of randomized controlled studies. Endoscopy. 2007;39:507–510. [PubMed]

12. Chung SH, Park SJ, Hong JS, et al. Comparison of double pants with single pants on satisfaction with colonoscopy. World J Gastroenterol. 2013;19:4177–4184. [PMC free article] [PubMed]

13. Pontone S, Tonda M, Brighi M, Florio M, Pironi D, Pontone P. Does anxiety or waiting time influence patients' tolerance of upper endoscopy? Saudi J Gastroenterol. 2015;21:111–115. [PMC free article] [PubMed]

Articles from Clinical Endoscopy are provided here courtesy of **Korean Society of Gastrointestinal Endoscopy**

The New York Times

HEALTH

Done Right, Colonoscopy Takes Time, Study Finds

By LINDA VILLAROSA DEC. 19, 2006

Having a colonoscopy is bad enough, but should you also have to worry that your doctor's skills are not up to snuff?

That was Shavonne Reel's fear three years ago on the way to her first colonoscopy. Before the procedure, she noticed that her gastroenterologist seemed rushed and stingy with the details of the test, which can detect abnormal growths in the colon that can lead to cancer. Afterward, though he said he found nothing to worry about, he also said he could not reach a small part of her colon.

The doctor put her on medication to ease her symptoms. This spring, when the rectal bleeding returned, Ms. Reel found another physician. During her second colonoscopy, her new doctor uncovered and removed a large growth.

"The second doctor found this huge polyp in the area the first one said he couldn't reach," said Ms. Reel, 26, an account associate at a Manhattan public relations firm. "Something this large might have turned cancerous. I definitely think the doctor missed it the first time."

Ms. Reel may be right, and her experience may be more common than was once thought. A study looking at 12 experienced gastroenterologists published last week in The New England Journal of Medicine found that the ability to detect abnormal growths in the colon could vary widely from doctor to doctor. But the central factor distinguishing the most accurate and the least was thoroughness.

Simply put, the doctors who spent more time examining the colon during the critical withdrawal phrase of the colonoscopy were better at detection than those who worked more quickly.

"Doctors who took longer found more polyps, but it's important to recognize that time is not the key," said Dr. David A. Johnson, a professor of medicine and the chief of gastroenterology at Eastern Virginia Medical School in Norfolk and president of the American College of Gastrenterology, who was not involved in the journal study. "What a longer exam really translates into is a careful, thorough, quality examination."

Colonoscopy becomes a necessary evil for most people starting at age 50. The American Cancer Society and other organizations recommend the procedure every 10 years for anyone 50 or older and advise having it more often and at younger ages for those at higher risk for colon cancer. Cancer of the colon is the second-leading cause of cancer death in the United States after lung cancer, killing 55,000 Americans each year. It usually starts with an abnormal growth, or polyp. Although the majority of polyps are harmless, over time they can become cancerous.

A colonoscopy allows a doctor to view the interior lining of the colon in search of anything out of the ordinary. During the procedure, the physician threads a thin, flexible viewing instrument through the length of the colon. As this scope is withdrawn, the physician looks for polyps and can also remove them.

The whole procedure generally takes about 30 minutes. The doctor spends about eight minutes inserting the scope and then uses the rest of the time on the critical withdrawal phase, said Dr. Robert L. Barclay, a member of the gastroenterology team that participated in the journal study. In that study, physicians who spent six minutes or more on withdrawal had the best results.

"Doing a thorough exam means looking behind folds in the lining, going back and looking at a segment again, washing away a little bit of stool residue and, of course, removing polyps," said Dr. Barclay, who practices with Rockford Gastroenterology Associates in Rockford, Ill. "All of these things take time. A physician who doesn't do any of this is able to remove the scope more quickly."

Because colonoscopy typically involves sedation, there is usually no way for a patient to tell how thorough or careful a doctor is being or how long the examination is taking. But there are ways to judge beforehand whether, in general, a doctor tends to rush procedures.

"It's fair to ask how many procedures a doctor does in a day," said Dr. Deborah A. Nagle, chief of the section of colon and rectal surgery at Beth Israel Deaconess Medical Center in Boston. "If a colonoscopy is supposed to take half an hour, you don't want someone who is doing 40 in a morning. A doctor who is doing about a dozen between 8 a.m. and noon makes sense."

Other questions can also help determine a doctor's overall skill at performing colonoscopy. The first concerns training. Gastroenterologists perform the majority of the four million colonoscopies conducted each year in this country, followed by colorectal surgeons. Both kinds of specialists must learn how to perform colonoscopies as part of their training.

"Colonoscopy is learned through repetitive practice, so it's important to make sure a doctor has been trained in a setting that allows the opportunity to do many," Dr. Nagle said. "Asking a doctor how many he has performed is a reasonable question. A couple of hundred is a sufficient number, but it's common for an experienced doctor to have done thousands."

How often a physician finds polyps — the doctor's detection rate — may also be an indication of skill and competence. A task force for the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy recommended that on average, doctors should find precancerous polyps in at least 25 percent of men and 15 percent of women 50 or older.

"Polyps are very common, but the number that is actually detected varies from doctor to doctor," Dr. Barclay said. "If a doctor tells you his detection rate is 25 percent or more, then that's a reasonable indication that he's looking carefully. If it's less than that, it raises the question of whether something is very different about that doctor's population or if he or she is not looking carefully enough."

Besides being able to find growths, doctors must also be able to remove them. Though some polyps, particularly large ones, may require a surgeon with special skills or training, in most cases the doctor performing the colonoscopy should know how to take them out.

"Doctors who are properly trained to do a colonoscopy should also be trained to do a polypectomy and do it safely and well," said Dr. David Lieberman, chief of the division of gastroenterology and professor of medicine at Oregon Health and Science University in Portland. "In this day and age, I hope we don't have people who are just looking and then sending patients to someone else to take out the polyps."

Finally, some responsibility falls on the patient. At least a day or two before a colonoscopy, patients are instructed to do a thorough "clean-out" of the colon to clear it of debris that may obscure the view. Many patients believe this "prep," which triggers loose, frequent stools, diarrhea and hunger, is the worst part of the test. But doing it correctly can make a difference.

"I've done colonoscopies for 26 years, and I've also had one, so I know that prep isn't pleasant," Dr. Johnson said. "But a good clean-out makes it easier for a doctor to see what's inside. I tell my patients that enduring the colon prep is a good investment. If they do it well, at best, we won't have to see each other for another 10 years."

The bottom line, Dr. Nagle said, is that colonoscopy is highly effective and a true preventive test in cancer treatment.

"You can avoid this cancer if you find a polyp and remove it before it becomes a cancer or find a very early cancer and remove it," she said. "Though it's important to know that there are variations in technique and ability, over all I would hate for patients to avoid colonoscopy because they fear their doctors won't take enough time and it won't be worth the effort."

A version of this article appears in print on , on Page F5 of the New York edition with the headline: Done Right, Colonoscopy Takes Time, Study Finds.

12/14/06 New Eng. J. Med. 2533
2006 WLNR 23850254

New England Journal of Medicine

December 14, 2006

Volume 355; Issue 24

Colonoscopic Withdrawal Times and Adenoma Detection during Screening Colonoscopy

Robert L. Barclay, M.D.

Joseph J. Vicari, M.D.

Andrea S. Doughty, Ph.D.

John F. Johanson, M.D.

Roger L. Greenlaw, M.D.

Background **Colonoscopy** is commonly used to screen for neoplasia. To assess the performance of screening **colonoscopy** in everyday practice, we conducted a study of the rates of detection of adenomas and the amount of time taken to withdraw the **colonoscope** among endoscopists in a large community-based practice.

Methods During a 15-month period, 12 experienced gastroenterologists performed 7882 **colonoscopies**, of which 2053 were screening examinations in subjects who had not previously undergone **colonoscopy**. We recorded the numbers, sizes, and histologic features of the neoplastic lesions detected during screening, as well as the duration of insertion and of withdrawal of the **colonoscope** during the procedure. We compared rates of detection of neoplastic lesions among gastroenterologists who had mean **colonoscopic** withdrawal times of less than 6 minutes with the rates of those who had mean withdrawal times of 6 minutes or more. According to experts, 6 minutes is the minimum length of time to allow adequate inspection during instrument withdrawal.

Results Neoplastic lesions (mostly adenomatous polyps) were detected in 23.5% of screened subjects. There were large differences among gastroenterologists in the rates of detection of adenomas (range of the mean number of lesions per subject screened, 0.10 to 1.05; range of the percentage of subjects with adenomas, 9.4 to 32.7%) and in their times of withdrawal of the colonoscope from the cecum to the anus (range, 3.1 to 16.8 minutes for procedures during which no polyps were removed). As compared with colonoscopists with mean withdrawal times of less than 6 minutes, those with mean withdrawal times of 6 minutes or more had higher rates of detection of any neoplasia (28.3% vs. 11.8%, $P<0.001$) and of advanced neoplasia (6.4% vs. 2.6%, $P=0.005$).

Conclusions In this large community-based gastroenterology practice, we observed greater rates of detection of adenomas among endoscopists who had longer mean times for withdrawal of the **colonoscope**. The effect of variation in withdrawal times on lesion detection and the prevention of colorectal cancer in the context of widespread **colonoscopic**

screening is not known. Ours was a preliminary study, so the generalizability and implications for clinical practice need to be determined by future studies.

N Engl J Med 2006;355:2533-41.

In recent years, **colonoscopy** has become increasingly common as a screening test for colorectal neoplasia.(Ref 1,2) In part, this trend reflects a growing belief that **colonoscopy** is effective at reducing complications and death from colorectal cancer. Large prospective studies have shown substantial reductions in the expected risk of colorectal cancer during long-term follow-up after screening **colonoscopy**.(Ref 3,4,5) However, the magnitude of the estimated benefit of **colonoscopy**, in comparison with reference populations, has varied among studies. In the National Polyp Study, the estimated reduction in the incidence of colorectal cancer ranged from 76 to 90% over a prolonged period of surveillance after **colonoscopic** polypectomy.(Ref 3) Large case–control studies of screening **colonoscopy**(Ref 5) and flexible sigmoidoscopy(Ref 6) have shown a 50% reduction in the incidence of cancer within the examined segment of colorectum. Potential reasons for these differences in percentages include variations among study subjects or reference populations and variability of the screening procedure to detect lesions that are present.

Colonoscopy affords an opportunity to remove benign adenomatous polyps before they progress and become cancerous. (Ref 7) However, there are limitations in the ability of endoscopists to identify neoplasia. For example, repeated colonoscopy(Ref 8) or colonography by means of computed tomography(Ref 9) performed in close succession to colonoscopy can identify neoplastic lesions that were not detected during the initial procedure. In addition, interexaminer differences in the detection of polyps have been shown in population-based studies of screening colonoscopy(Ref 10) and screening flexible sigmoidoscopy.(Ref 11,12)

Differences among examiners in the rates of detection of adenomas may be related to the procedural technique used during withdrawal of the colonoscope,(Ref 13) which is considered the critical phase at which to assess for neoplasia. We hypothesized that the more time endoscopists devoted to examining the colorectal mucosa — that is, the longer the period of instrument withdrawal — the more neoplastic lesions they would identify. To monitor the quality of colonoscopy in our practice, we studied the rates of detection of neoplasia and the duration of colonoscopic withdrawal during screening colonoscopy by endoscopists in our practice.

Methods

We conducted this study during routine clinical examinations in a large community-based gastroenterology practice. Although the physicians in this practice have clinical appointments at the University of Illinois College of Medicine at Rockford, their day-to-day functions closely resemble those of a private, community-based gastroenterology practice. The institutional review board at the University of Illinois approved the study. Since this project examined quality control in our routine clinical practice, the review board waived the need for informed consent. However, as part of the routine consent for endoscopic procedures, we informed subjects that data might be collected to monitor the quality of our practice.

Study Population

The study population consisted of consecutive subjects who underwent screening colonoscopy in our ambulatory surgery center from January 1, 2003, to March 31, 2004. Subjects were either directly scheduled or had screening colonoscopy scheduled during a previous visit to the gastroenterology clinic for an unrelated issue. Subjects had no symptoms of colonic disorders. Subjects who had undergone colonoscopy previously, whose insurance mandated a hospital procedure, or who had a history of colorectal neoplasia were not included. These restrictions, and the large volume of diagnostic procedures we perform, limited the number of screening subjects (Figure 1(Figure 1. Enrollment of Subjects. Some subjects had more than one indication for a diagnostic examination.)).

Study Procedures

We performed colonoscopies during standard 30-minute time slots. Twelve full-time, board-certified gastroenterologists, all of whom had dedicated, hands-on colonoscopic instruction as part of their fellowship training in gastroenterology, performed the procedures. Each endoscopist had performed a minimum of 3000 colonoscopies before this study began.

Endoscopists used adult or pediatric variable-stiffness video colonoscopes (Olympus America). The standard bowel preparation was a three-dose oral regimen of aqueous sodium phosphate (Fleet Phospho-soda, C.B. Fleet), described previously,(Ref 14) or a 3.8-liter oral lavage of polyethylene glycol electrolyte solution (Nulytely, Braintree Laboratories) if there were contraindications to sodium phosphate.(Ref 14) Subjects received conscious sedation with intravenous midazolam plus fentanyl or meperidine.

Endoscopists were aware that a study examining **colonoscopic** techniques, including procedure times, was being conducted. They gave oral consent for participation in the study before its onset. The endoscopy nurse recorded times for the following procedural events: **colonoscope** insertion into the rectum, identification of the base of the cecum, and withdrawal of the **colonoscope** across the anus, with times rounded to the nearest minute. The number, locations, and method of removal of polyps were likewise recorded. We defined **colonoscopic** insertion time as the time from insertion into the rectum to identification of the base of the cecum and withdrawal time as the time from cecal identification to the time when the **colonoscope** was withdrawn across the anus. This withdrawal time included time taken for maneuvers such as polypectomy that were performed during the withdrawal phase of the examination. We estimated the sizes of lesions at the time of **colonoscopy** by in vivo comparison with two standard endoscopic instruments — an open-biopsy forceps (7 mm) or the diameter of the outer sheath of a polypectomy snare (3 mm). We confirmed the size of lesions that were 10 mm or more in diameter by means of histopathological analysis or examination of surgical specimens for intact lesions; otherwise, we used the endoscopic estimate.

Statistical Analysis

The primary outcome measure was the rate of adenoma detection of each endoscopist, calculated alternately as the total number of neoplastic lesions detected divided by the number of subjects screened and as the proportion of subjects with at least one neoplastic lesion. We also calculated the rates of detection of advanced lesions (i.e., adenomas 10 mm or more in diameter, lesions with a villous component, high-grade dysplasia, or cancer) and of hyperplastic lesions. The unit of analysis was the physician, not the subject.

Since current literature and expert opinion(Ref 15,16) suggest 6 minutes as the minimum adequate mean withdrawal time for screening colonoscopy in which no polyps are removed, we used this value to distinguish endoscopists who had a withdrawal time that was relatively fast (less than 6 minutes) or slow (6 minutes or more). We used Student's t-test to test for differences in the rates of detection of lesions between endoscopists who had a mean withdrawal time of less than 6 minutes and those who had a mean withdrawal time of 6 minutes or more. We used the chi-square test to analyze categorical data. Data are reported as means ±SD unless otherwise noted.

To control for the possible lengthening of withdrawal time due to the removal of — rather than the assessment for — polyps, we calculated withdrawal times for procedures involving the removal of polyps and for those in which no polyps were manipulated (i.e., procedures involving neither removal nor biopsy of a polyp). We used the Spearman rank-correlation coefficient to measure the relationship between the mean withdrawal times and lesion-detection rates of the endoscopists. Statistical tests were performed with the use of SPSS software, version 12.0.

Results

Study Population

Table 1(Table 1. Baseline Characteristics of the Physicians and Subjects.) shows the baseline characteristics of the physicians and the study subjects, displayed as the screening cohorts of the individual endoscopists and compared according to mean withdrawal time (for colonoscopies with no polyps removed) of less than 6 minutes or of 6 minutes or more. Of 7882 colonoscopies performed during the study period, 5349 were for diagnostic indications and 2533 were for screening. Of the screening subjects, 239 were inpatients, 125 had undergone previous colonoscopy, 90 had a history of colorectal cancer, and 26 had inflammatory bowel disease. These 480 subjects were excluded, and the remaining 2053 constituted the study population (Figure 1(Figure 1. Enrollment of Subjects. Some subjects had more than one indication for a diagnostic examination.)). The mean number of screening colonoscopies that each endoscopist performed during the study period was 171±45. There were no significant differences in the ages of the physicians or of the subjects, procedural volume, prevalence of family history of colorectal cancer, the quality of bowel preparation, or the rates of

cecal intubation between endoscopists who had a mean withdrawal time of less than 6 minutes as compared with those who had a withdrawal time of 6 minutes or more. Endoscopists whose withdrawal times were less than 6 minutes had a mean age of 54.0±5.2 years and had a mean of 20.7±6.8 years of clinical experience in gastroenterology. Endoscopists whose withdrawal times were 6 minutes or more had a mean age of 45.9±7.9 (P=0.13) and had a mean of 13.3±8.5 years of clinical experience (P=0.21).

Outcome Measures

Table 2(Table 2. Withdrawal Times and Rates of Detection of Lesions for Individual Physicians.) shows the procedure times and the lesion-detection rates for each endoscopist. The mean colonoscopic insertion time was 7.2±4.4 minutes. The overall mean withdrawal time for examinations in which no polyps were removed was 6.3±3.9 minutes (range, 3.1 to 16.8) as compared with 10.6±5.8 minutes for procedures during which polyps were removed (range, 5.6 to 19.1). We detected adenomatous polyps in 23.5% of subjects (range, 9.4 to 32.7). The mean overall rate of detection of adenomas was 0.47 lesion per subject (range, 0.10 to 1.05). The overall advanced adenoma detection rate was 0.06 lesion per subject (range, 0.01 to 0.10). We detected hyperplastic lesions in 21.4% of subjects (range, 5.5 to 55.1).

We found strong relationships between withdrawal times and lesion-detection rates, regardless of whether polyps or masses were manipulated (Table 3(Table 3. Relationships between Variables and Withdrawal Times, According to Removal or No Removal of Polyps during Colonoscopy.)). Direct correlations between withdrawal times for procedures without polyp removal and the detection of lesions were strongest for all adenomas (r_s=0.90, P<0.001), for the percentage of subjects with any adenomas (r_s=0.82, P=0.001), and for hyperplastic lesions (r_s=0.80, P=0.002). However, withdrawal times for procedures without polyp removal also correlated directly with the detection of advanced lesions (r_s=0.66, P=0.02). For procedures in which polyps were removed, there was an inverse correlation between withdrawal times and mean polyp size (r_s=−0.63, P=0.03) and a positive correlation between longer withdrawal times and the removal of polyps that were less than 5 mm in diameter (r_s=0.59, P=0.04). However, these relationships were not statistically significant for the analysis of withdrawal times during procedures in which no polyps were removed. Table 4(Table 4. Rates of Detection of Lesions According to Mean Withdrawal Time for Procedures in Which No Polyps Were Removed.) shows the rates of detection of lesions for endoscopists stratified according to whether their mean withdrawal time for procedures without polyps was less than 6 minutes or was 6 minutes or more. Rates of detection of adenomas, advanced adenomas, and hyperplastic lesions were all significantly greater among endoscopists whose mean withdrawal time was 6 minutes or more. The overall rate of detection of adenomas among endoscopists who had relatively slow mean withdrawal times was nearly four times as great as the rate among endoscopists who had relatively fast withdrawal times.

Advanced Neoplasms

A total of 113 advanced neoplasms were identified in 107 of 2053 subjects (5.2%) who were screened — 101 lesions had a diameter of 10 mm or more, 37 had villous histologic features, 3 had high-grade dysplasia, and 9 were cancers. (Some adenomas fell into more than one category; e.g., some adenomas exceeding 10 mm in diameter also had villous histologic features.) The three endoscopists whose mean withdrawal times were less than 6 minutes identified 13 advanced lesions among 540 subjects (2.6%). The remaining 100 advanced lesions were detected in 1513 subjects by the nine endoscopists whose mean withdrawal times were 6 minutes or more (6.4%). This difference was statistically significant (P=0.005) (Table 4(Table 4. Rates of Detection of Lesions According to Mean Withdrawal Time for Procedures in Which No Polyps Were Removed.)). Of the nine malignant lesions detected, only one was detected by an endoscopist with a mean withdrawal time of less than 6 minutes; the other eight were detected by endoscopists with withdrawal times of 6 minutes or more (P=0.30) (Table 4(Table 4. Rates of Detection of Lesions According to Mean Withdrawal Time for Procedures in Which No Polyps Were Removed.)). One adenomatous polyp that had high-grade dysplasia measured 5 mm in diameter; another adenomatous polyp, characterized by invasive cancer, measured 7 mm. Both these lesions were detected by endoscopists whose mean withdrawal times were 6 minutes or more.

Figure 2(Figure 2. Mean Rates of Detection of Adenomas According to Mean Colonoscopic Withdrawal Times for 12 Endoscopists. The values are for procedures in which no polyps were removed. The significant correlation between rates of detection of adenomas and withdrawal times was calculated with the use of the Spearman rank-correlation coefficient.) shows the mean rate of detection of adenomas by individual endoscopists, plotted against their mean

colonoscopic withdrawal times for procedures in which no polyps were removed. This graph highlights the strong correlation between withdrawal times and the rate of detection of adenomas. The Supplementary Appendix (available with the full text of this article at www.nejm.org) displays frequencies of colonoscopies as compared with colonoscopic withdrawal times for individual endoscopists A through L, according to increasing mean withdrawal time for procedures in which no polyps were removed.

Discussion

Physicians and patients have embraced colonoscopy as an effective preventive measure against colorectal cancer. For example, the American College of Gastroenterology recommends colonoscopy as the preferred screening strategy for colorectal neoplasia.(Ref 17) However, there are few reliable indicators of how well this procedure is performed in everyday practice, particularly with respect to the crucial goals of the identification and removal of neoplastic lesions. Our analysis of screening colonoscopy in a predominantly average-risk population unveiled significant variation in the rates of detection of neoplasia among experienced endoscopists. Although differences in the rates of detection did not seem to be related to baseline characteristics of the subjects, the age or experience of the physicians, or the adequacy of bowel preparation, it is possible that chance differences in risk factors for colorectal neoplasia that were not measured (e.g., a history of smoking, a history of breast cancer, and black race) contributed to differences among examiners in the detection of neoplasia.

However, our findings suggest that variation in colonoscopic withdrawal times contributes to differences in the rates of detection of neoplasia among gastroenterologists. We observed a striking, seemingly linear relationship between colonoscopic withdrawal times and rates of neoplasia detection. In addition, we found that longer withdrawal times correlated with increased rates of detection of advanced neoplasia. When categorized according to a mean withdrawal time of either less than 6 minutes or 6 minutes or more (6 minutes is a recommended estimate of the time necessary for adequate inspection in normal colons(Ref 15,16)), we observed that the rates of detection of advanced neoplasms were significantly greater for endoscopists who had longer mean procedure withdrawal times than for those who had shorter withdrawal times. The rate of detection of cancer paralleled this trend; however, we had limited power because of the small number of cancers, and this difference was not statistically significant.

The strong association between the neoplasia-detection rates of individual colonoscopists and colonoscopic withdrawal time was evident for all procedures as well as for those in which no polyps were detected. Because the additional time required to remove more polyps may have contributed to a longer withdrawal time, withdrawal times for procedures in which no polyps were detected may represent mucosal inspection times more accurately. Longer withdrawal times may reflect time spent looking for relatively small polyps. For procedures in which polyps were removed, we observed an inverse correlation between mean withdrawal time and mean polyp size, as well as a weak direct correlation between withdrawal time and the incidence of diminutive polyps. However, these relationships were not statistically significant in the analysis of withdrawal times for procedures in which no polyps were removed. This implies that part of the effect of increased detection of adenomas by endoscopists with slower withdrawal times was attributable to detection of more than just diminutive lesions.

We did not assess the specifics of mucosal inspection during colonoscopy, but it seems reasonable to suspect that endoscopists who take longer to withdraw the instrument also use techniques that improve visualization of neoplastic lesions. A study of two endoscopists with different rates of missed adenomas showed that careful methods of inspection coincided with a longer mean withdrawal time.(Ref 13) Thus, a relatively long withdrawal time may indicate careful inspection of the colorectal mucosa during screening colonoscopy. Interexaminer differences in the efficiency of endoscopic removal of polyps could indirectly affect the time available for mucosal inspection. However, further prospective study is needed to clarify the specific colonoscopic techniques for mucosal visualization and efficient polypectomy that are important for enhanced detection of neoplasia.

Few reliable benchmarks exist for the inspection component of colonoscopy. Previous authors have suggested allowing 6 to 10 minutes for adequate inspection during colonoscopic withdrawal.(Ref 15,16) Our observations support the notion

that a minimum adequate amount of time for colonoscopic withdrawal can be equated with the quality of colonoscopy. Furthermore, our results suggest that the rates of detection of neoplasia may increase further if the period of withdrawal is more than 6 to 10 minutes. Regardless, acceptance of the usefulness of a minimum colonoscopic withdrawal time — whether 6 minutes or longer — would require validation in a prospective study. Variability among observers has been reported with other screening tests for neoplasia, with superior results observed in centers that perform a relatively large number of tests with a relatively high degree of expertise.(Ref 18,19,20)

The goal of screening colonoscopy is to prevent colorectal cancer. The influence that divergent rates of adenoma detection might have on this goal is unclear. On the one hand, detection of diminutive adenomas may have little effect on the risk of colon cancer, since the majority of these lesions do not progress to cancer.(Ref 21) Also, persons found to have a single diminutive adenoma are believed to be at no greater risk for the development of colorectal cancer than are those without adenomas.(Ref 22)

On the other hand, enhanced detection of adenomas could provide long-term benefits for patients. First, support for the protective effect of colonoscopy against colorectal cancer derives from studies in which all identified adenomatous polyps, regardless of size, were removed.(Ref 3,4) Even small polyps can occasionally contain cancer,(Ref 23) a fact underlined in the present study by the discovery of a 7-mm malignant adenoma. Second, our data highlight differences among endoscopists not only in detection of neoplasia overall but also in detection of advanced neoplasia, both of which correlated with colonoscopic withdrawal times. Advanced adenomas are considered important because of their greater propensity for progression to a malignant condition.(Ref 24) Third, by definition, tubular adenomas are neoplastic lesions with the potential to progress to cancer. Patients who have adenomatous polyps that were overlooked during a screening colonoscopy may be at risk for progression to cancer, either because of a longer interval between colonic examinations than is appropriate or because of the patient's own decision to forgo colorectal cancer screening in the future. Fourth, the finding of adenomatous polyps may affect the recommendations for colorectal neoplasia screening for relatives of the index patient.(Ref 25) Therefore, although these points support the practice of carefully scrutinizing the colorectal mucosa and removing all identified adenomatous polyps during screening colonoscopy, it should be acknowledged that there is a relatively small clinical benefit of detecting and removing very small polyps.

Successful efforts to reduce the disease burden from colorectal cancer depend on implementation of effective screening practices in community settings. Our study showed wide variation in the duration of withdrawal of the colonoscope and higher rates of adenoma detection among endoscopists with longer withdrawal times. However, because of the relatively small number of endoscopists in this study, the generalizability and implications for clinical practice are uncertain and need to be determined by future studies. Furthermore, this study did not address the appropriateness or cost-effectiveness of systematically increasing colonoscopic withdrawal time. Although the findings of this preliminary observational study should be interpreted cautiously, they may inform future efforts to improve strategies for the prevention of colorectal cancer.

No potential conflict of interest relevant to this article was reported.

We thank Brenda Paulson, Evon Dowd, and Kathy Geissler for invaluable assistance with patient care, data collection, and manuscript preparation.

Bibliography:

1. Prajapati DN, Saeian K, Binion DG, et al. Volume and yield of screening colonoscopy at a tertiary medical center after change in Medicare reimbursement. Am J Gastroenterol 2003;98:194-9.

2. Harewood GC, Lieberman DA. Colonoscopy practice patterns since introduction of Medicare coverage for average-risk screening. Clin Gastroenterol Hepatol 2004; 2:72-7.

3. Winawer SJ, Zauber AG, Ho MN, et al. Prevention of colorectal cancer by colonoscopic polypectomy. N Engl J Med 1993; 329:1977-81.

4. Citarda F, Tomaselli G, Capocaccia R, et al. Efficacy in standard clinical practice of colonoscopic polypectomy in reducing colorectal cancer incidence. Gut 2001;48: 812-5.

5. Muller AD, Sonnenberg A. Prevention of colorectal cancer by flexible endoscopy and polypectomy: a case-control study of 32,702 veterans. Ann Intern Med 1995;123: 904-10.

6. Newcomb PA, Storer BE, Morimoto LM, Templeton A, Potter JD. Long-term efficacy of sigmoidoscopy in the reduction of colorectal cancer incidence. J Natl Cancer Inst 2003;95:622-5.

7. Bresalier RS. Malignant neoplasms of the large intestine. In: Feldman M, Friedman LS, Sleisenger MH, eds. Sleisenger & Fordtran's gastrointestinal and liver disease: pathophysiology, diagnosis, management. 7th ed. Philadelphia: Saunders, 2002: 2215-61.

8. Rex DK, Cutler CS, Lemmel GT, et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. Gastroenterology 1997;112:24-8.

9. Pickhardt PJ, Nugent PA, Mysliwec PA, Choi JR, Schindler WR. Location of adenomas missed by optical colonoscopy. Ann Intern Med 2004;141:352-9.

10. Sanchez W, Harewood GC, Petersen BT. Evaluation of polyp detection in relation to procedure time of screening or surveillance colonoscopy. Am J Gastroenterol 2004;99:1941-5.

11. Atkin W, Rogers P, Cardwell C, et al. Wide variation in adenoma detection rates at screening flexible sigmoidoscopy. Gastroenterology 2004;126:1247-56.

12. Pinsky PF, Schoen RE, Weissfeld JL, Kramer B, Hayes RB, Yokochi L. Variability in flexible sigmoidoscopy performance among examiners in a screening trial. Clin Gastroenterol Hepatol 2005;3:792-7.

13. Rex DK. Colonoscopic withdrawal technique is associated with adenoma miss rates. Gastrointest Endosc 2000;51:33-6.

14. Barclay RL. Safety, efficacy and patient tolerance of a three-dose regimen of orally administered aqueous sodium phosphate for colonic cleansing before colonoscopy. Gastrointest Endosc 2004;60:527-33.

15. Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol 2002;97:1296-308.

16. Lieberman D. Colonoscopy: as good as gold? Ann Intern Med 2004;141:401-3.

17. Rex DK, Johnson DA, Lieberman DA, Burt RW, Sonnenberg A. Colorectal cancer prevention 2000: screening recommendations of the American College of Gastroenterology. Am J Gastroenterol 2000;95: 868-77.

18. Beam CA, Conant EF, Sickles EA. Association of volume and volume-independent factors with accuracy in screening mammogram interpretation. J Natl Cancer Inst 2003;95:282-90.

19. Gupta DK, Komaromy-Hiller G, Raab SS, Nath ME. Interobserver and intraobserver variability in the cytologic diagnosis of normal and abnormal metaplastic squamous cells in Pap smears. Acta Cytol 2001;45:697-703.

20. Halligan S, Marshall M, Taylor S, et al. Observer variation in the detection of colorectal neoplasia on double-contrast barium enema: implications for colorectal cancer screening and training. Clin Radiol 2003;58:948-54.

21. Itzkowitz SH. Colonic polyps and polyposis syndrome. In: Feldman M, Friedman LS, Sleisenger MH, eds. Sleisenger & Fordtran's gastrointestinal and liver disease: pathophysiology, diagnosis, management. 7th ed. Philadelphia: Saunders, 2002: 2175-214.

22. Atkin WS, Morson BC, Cuzick J. Long-term risk of colorectal cancer after excision of rectosigmoid adenomas. N Engl J Med 1992;326:658-62.

23. Lee YS. Early malignant lesions of the colorectum at autopsy. Dis Colon Rectum 1988;31:291-7.

24. O'Brien MJ, Winawer SJ, Zauber AG, et al. The National Polyp Study: patient and polyp characteristics associated with high-grade dysplasia in colorectal adenomas. Gastroenterology 1990;98:371-9.

25. Winawer S, Fletcher R, Rex D, et al. Colorectal cancer screening and surveillance: clinical guidelines and rationale — update based on new evidence. Gastroenterology 2003;124:544-60.

---- Index References ----

Company: ZAUBER; OLYMPUS AMERICA INC; SPSS INC; BRAINTREE LABORATORIES INC

News Subject: (Health & Family (1HE30))

Industry: (Healthcare (1HE06); Internal Medicine (1IN54); Gastroenterology (1GA59); Oncology & Hematology (1ON95); Clinical Laboratory (1CL83); Clinical Diagnostics (1DI45); Healthcare Services (1HE13); Pharmaceuticals & Biotechnology (1PH13); Healthcare Practice Specialties (1HE49))

Region: (North America (1NO39); U.S. Midwest Region (1MI19); U.S. Mid-Atlantic Region (1MI18); USA (1US73); Illinois (1IL01); Americas (1AM92); Pennsylvania (1PE71))

Language: EN

Other Indexing: (Ann Intern Med; Kathy Geissler; Evon Dowd; Brenda Paulson)

Word Count: 3899

End of Document

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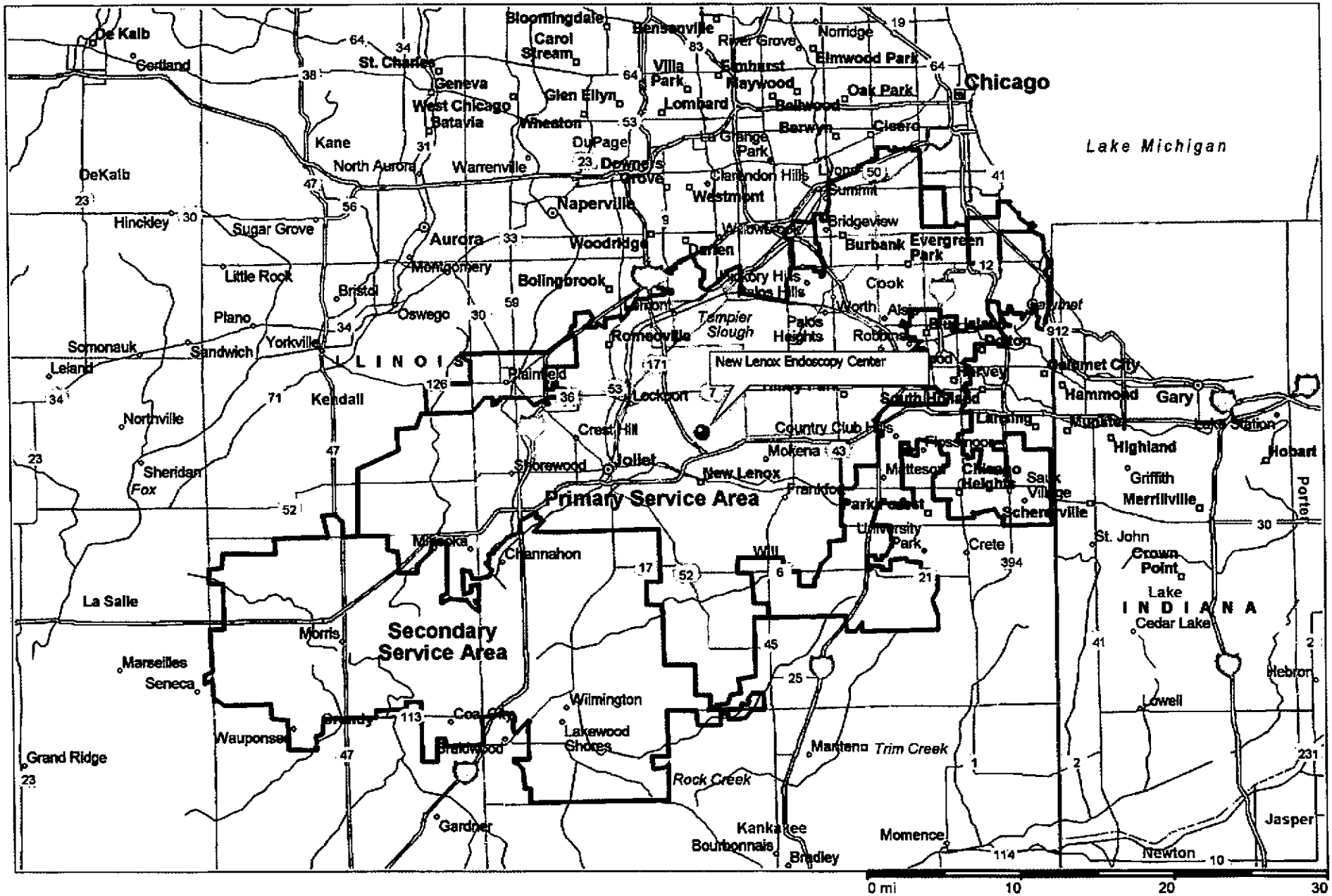

EXHIBIT - B

UnitedHealthcare®

Front & Center

Reminder: Updated Site of Service Guidelines for Certain Outpatient Surgical Procedures

In an effort to minimize out-of-pocket costs for UnitedHealthcare members and to improve cost efficiencies for the overall health care system, we are implementing prior authorization guidelines that aim to encourage more cost-effective sites of service for certain outpatient surgical procedures, when medically appropriate. These guidelines were previously communicated in the July Network Bulletin.

These procedures will require prior authorization if performed in an outpatient hospital setting. No prior authorization will be required if they are performed at a participating network ambulatory surgery center. Coverage determinations will consider availability of a participating network facility, specialty requirements, physician privileges and whether a patient has an individual need for access to more intensive services. To help ease this transition, we encourage you to familiarize yourself with ambulatory surgery centers in your area and obtain privileges to perform procedures in those settings, if you do not already have them.

These guidelines are effective for dates of service on or after Oct. 1, 2015, in most states, except for Colorado, where the effective date is Nov. 1, 2015, and for Illinois and Iowa, where the effective date is Dec. 1, 2015.

The prior authorization requirement applies to the UnitedHealthcare Commercial and Exchange membership, including the following plans:

- Golden Rule Insurance Company (group 902667)
- Mid-AtlanticMD Healthplan
- Individual Practice Association, Inc. ("M.D. IPA") or Optimum Choice Inc. ("Optimum Choice") products
- Neighborhood Health Partnership
- UnitedHealthcare of the River Valley Health Plan
- Health Exchanges
- UnitedHealthcare Oxford Health Plans*
- UnitedHealthcare
- UnitedHealthcare Life Insurance Company (group 755870)

It was previously communicated that UnitedHealthcare West would be included in scope for these new guidelines. However, those plans will not be included.

The guidelines apply to the following codes and procedures:

Procedures & Services	Codes for UnitedHealthcare Commercial Plans
Abdominal Paracentesis	49083
Carpal Tunnel Surgery	64721
Cataract Surgery	66821 66982 66984
Hernia Repair	49585 49587 49650 49651 49652 49653 49654 49655
Liver Biopsy	47000
Tonsillectomy & Adenectomy	42821 42826
Upper & Lower Gastrointestinal Endoscopy	43235 43239 43249 45378 45380 45384 45385
Urologic Procedures	50590 52000 52005 52204 52224 52234 52235 52260 52281 52310 52332 52351 52352 52353 52356 57288

Continued >

Front & Center

Reminder: Updated Site of Service Guidelines for Certain Outpatient Surgical Procedures

< Continued

Prior authorization requests can be filed in multiple ways, including online or by phone

- Go to **UnitedHealthcareOnline.com > Notifications/Prior Authorizations > Notification/Prior Authorizations Submission.** Using UnitedHealthcareOnline.com is an easy way to initiate prior authorization and is the preferred option.
- Call the Provider Services number on the back of your patient's member health care ID card.

If you do not obtain prior authorization before performing these procedures in an outpatient hospital, claims may be denied. Providers cannot bill members for services that are denied due to lack of prior authorization.

For more information on this requirement, please see the frequently asked questions and answers at UnitedHealthcareOnline.com > Tools & Resources > Policies, Protocols and Guides > Protocols > Site of Service for Outpatient Surgical Procedures FAQ.

If you have questions, please contact your local Network Management representative or call the Provider Services number on the back of the member's ID card. Thank you.

EXHIBIT D

New Lenox Endoscopy v Silver Cross Hospital Charges				
Description	**New Lenox Endoscopy**	**Silver Cross Hospital[1]**	**Difference**	**%**
EGD				
Diagnostic EGD	$1,100			
EGD with Biopsy	$1,150			
EGD with Dilation	$1,175			
EGD with Polypectomy	$1,175			
EGD with Lesion Removal	$1,175			
EGD Snare Biopsy	$1,210			
EGD with Control of Bleeding	$1,375			
EGD w/Varices Banding	$1,440			
EGD with Removal of FB	$1,500			
EGD W/Submucosal Injection	$1,712			
Median EGD Charge	**$1,210**	**$5,582.10**	**$4,372.10**	**461%**
Colonoscopy				
Colon Endoscopy	$1,450			
Diagnostic Colonoscopy	$1,450			
Colorectal Cancer Screening, No High Risk	$1,450			
Colonoscopy with Biopsy	$1,480			
Colonoscopy and Biopsy	$1,480			
Colorectal Cancer Screening; Colonoscopy High Risk	$1,480			
Colonoscopy W/FB Removal	$1,510			
Colonoscope, Submucous Inj.	$1,525			
Lesion Removal Colonoscopy	$1,745			
Colonoscopy/Control Bleeding	$1,880			
Colonoscopy W/Dilation	$1,900			
Median Colonoscopy Charge	**$1,480**	**$4,821.55**	**$3,341.55**	**326%**
Litigation of Hemorhoid(s)	$980	$6,908[2]	$5,928	705%

[1] Illinois Department of Public Health, Illinois Hospital Report Card and Consumer Guide to Healthcare

[2] Silver Cross Ambulatory Surgery Center, Certificate of Need Application 261. Proposed charge at Silver Cross Ambulatory Surgery Center is $1,260 (29% higher than New Lenox Endoscopy proposed charge ($980))

HOSPITAL AND ENDOSCOPY CENTER MEDICARE REIMBURSEMENT RATES

	Description	Charge	National Medicare OPPS Fee Schedule	Local OPPS Reimb	National Medicare ASC Fee Schedule	Local ASC Fee Schedule	Hospital - ASC Medicare Reimb. Difference ($)	Hospital - ASC Medicare Reimb. Difference (%)
43235	Diagnostic EGD	$1,100	$699.79	$715.29	$378.37	$386.75	$328.54	185%
43236	EGD W/Submucosal Injection	$1,712	$699.79	$715.29	$378.37	$386.75	$328.54	185%
43239	EGD with Biopsy	$1,150	$699.79	$715.29	$378.37	$386.75	$328.54	185%
43244	EGD wNarices Banding	$1,440	$1,334.83	$1,364.40	$608.53	$622.01	$742.39	219%
43247	EGD with Removal of FB	$1,500	$699.79	$715.29	$378.37	$386.75	$328.54	185%
43249	EGD with Dilation	$1,175	$1,334.83	$1,364.40	$608.53	$622.01	$742.39	219%
43251	EGD Snare Biopsy	$1,210	$1,334.83	$1,364.40	$608.53	$622.01	$742.39	219%
43250	EGD with Polypectomy	$1,175	$1,334.83	$1,364.40	$608.53	$622.01	$742.39	219%
43252	EGD with Lesion Removal	$1,175	$2,510.70	$2,566.31	$1,135.68	$1,160.84	$1,405.48	221%
43255	EGD with Control of Bleeding	$1,375	$1,334.83	$1,364.40	$608.53	$622.01	$742.39	219%
44388	Colon Endoscopy	$1,450	$667.67	$682.46	$361.01	$369.01	$313.45	185%
44389	Colonoscopy with Biopsy	$1,480	$667.67	$682.46	$474.51	$485.02	$197.44	141%
45330	Diagnostic Sigmoidoscopy	$500	$667.67	$682.46	$135.66	$138.66	$543.79	492%
45331	Sigmoidoscopy & Biopsy	$750	$667.67	$682.46	$361.01	$369.01	$313.45	185%
45335	Sigmoidoscope w/Submuc Ing	$825	$667.67	$682.46	$361.01	$369.01	$313.45	185%
45338	Sigmoidoscopy w/Removal of Tumor	$915	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45340	Sig w/Balloon Dilation	$825	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45378	Diagnostic Colonoscopy	$1,450	$667.67	$682.46	$361.01	$369.01	$313.45	185%
45379	Colonoscopy W/FB Removal	$1,510	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45380	Colonoscopy and Biopsy	$1,480	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45381	Colonoscope, Submucous Inj.	$1,525	$877.60	$897.04	$474.51	$485.02	$412.02	185%

45382	Colonoscopy/Control Bleeding	$1,880	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45385	Lesion Removal Colonoscopy	$1,745	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45386	Colonoscopy W/Dilation	$1,900	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45905	Dilation of Anal Sphincter	$500	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45910	Dilation of Rectal Narrowing	$500	$877.60	$897.04	$474.51	$485.02	$412.02	185%
45915	Removal Rectal Obstruction	$650	$877.60	$897.04	$474.51	$485.02	$412.02	185%
46221	Ligation of Hemorrhoids	$980	$667.67	$682.46	$176.93	$180.85	$501.61	377%
91035	Bravo 48 hr PH	$1,575	$415.87	$425.08	N/A	N/A	N/A	N/A
99214	HP Assessment	$175	N/A	N/A	N/A	N/A	N/A	N/A
30104	Colorectal Cancer Screening-Flex Sig	$1,450	N/A	N/A	N/A	N/A	N/A	N/A
30105	Colorectal Cancer Screening; Colonoscopy High Risk	$1,480	N/A	N/A	N/A	N/A	N/A	N/A
30121	Colorectal Cancer Screening, No High Risk	$1,450	N/A	N/A	N/A	N/A	N/A	N/A