APPLICATION FOR CERTIFICATE OF NEED
Health Care Facility Projects
(Excluding nursing home, hospital, or CCRC related projects)

Certificate of Need applications must be submitted with a fee in accordance with Washington Administrative Code (WAC) 246-310-990.

Application is made for a Certificate of Need in accordance with provisions in Revised Code of Washington (RCW) 70.38 and WAC 246-310, rules and regulations adopted by the Washington State Department of Health. I hereby certify that the statements made in this application are correct to the best of my knowledge and belief.

Signature and Title of Responsible Officer DocuSigned by: Rachel Todd Chief Executive Officer Puget Sound Gastroenterology, PS	Date 7/ 6/ 2018 Telephone Number (425)977-4655
Legal Name of Applicant Puget Sound Gastroenterology, P.S. d/b/a **Edmonds Endoscopy Center** Address of Applicant 19000 33rd Ave W, Suite 230 Lynnwood, WA 98036	Type of Application: [X] Ambulatory Surgical Facility [ ] Kidney Disease Treatment Center Type of Project (check all that apply) [ ] New Health Care Facility [ ] Capital expenditure over expenditure minimum [ ] Pre-development Expenditure [ ] Increase in the number of dialysis stations in a kidney disease center
Intended date of incurring contractual obligation to construct, acquire, lease or finance capital asset: Estimated capital expenditure: $0	Intended date of undertaking project: Upon Certificate of Need approval Intended date for beginning to offer services or operate completed project: Upon Certificate of Need approval Project Summary: To convert a Certificate of Need ("CN") exempt Ambulatory Surgery Center to a CN-approved Ambulatory Surgery Center

Application Instructions

The department will use the information in your application to determine if your project meets the applicable review criteria. These criteria are included in state law and rules. (RCW 78.38.115, WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, WAC 246-310-240. For kidney disease treatment centers-WAC 246-310-280 thru 289, and for ambulatory surgery centers- WAC 246-310-270.

General Instructions:

- Include a table of contents for major application sections and appendices
- Number **all** pages consecutively
- **Do not** bind or 3-hole punch the application.
- Make the narrative information complete and to the point.
- Cite all data sources.
- Provide copies of articles, studies, etc. cited in the application.
- Place extensive supporting data in an appendix.
- Provide detailed descriptions of assumptions used for all projections.
- Use **non-inflated** dollars for **all** cost projections
- **Do not** include a general inflation rate for these dollar amounts.
- **Do** include current contract cost increases such as union contract staff salary increases. You must identify each contractual increase in the description of assumptions included in the application.
- **Do not** include a capital expenditure contingency.

Submission Instructions:

- Number of Copies-Initial application:
    - original,
    - one electronic (pdf) version

- Number of Copies-all other submissions:
    - Original
    - one electronic (pdf) version

To be accepted, the application must include:

- A completed and signed Certificate of Need application face sheet
- The review fee of:
    - **$20,427** for Ambulatory Surgical Centers. Make check payable to **Department of Health**
    - **$25,054** for Kidney Disease Treatment Centers. Make check payable to **Department of Health**
- Send application to:

Mailing Address:
Department of Health
Certificate of Need Program
P O Box 47852
Olympia, Washington 98504-7852

Other Than By Mail:
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, Washington 98501

Puget Sound Gastroenterology, PS, d/b/a Edmonds Endoscopy Center
Certificate of Need Application
For
Existing Certificate of Need Exempt ASC
To Convert To
Certificate of Need Approved ASC

Section I
Applicant Description

a. Legal name(s) of applicant(s)

The legal name of applicant is Puget Sound Gastroenterology, PS. ("PSG")

b. Name and address of proposed/existing facility

The name of the Ambulatory Surgical Center is Puget Sound Gastroenterology, PS, doing business as Edmonds Endoscopy Center (the "ASC"). By this application, PSG is only proposing to convert its existing dedicated outpatient endoscopy ASC from a CN-exempt ASC to a CN-approved ASC. Nothing in this application seeks to change the physician staffing, ownership, operation of, or scope and type of services offered by, the ASC. The ASC will remain a dedicated outpatient endoscopy ASC.

The address of the ASC currently is and will continue be located at: 21600 Hwy. 99, Suite 260, Edmonds, WA 98026.

c. Type of ownership (public/private/corporation)

PSG is a Washington professional services corporation.

d. Name and address of owning entity at completion of project (unless the same as applicant)

Same as applicant.

e. Name, title, address and telephone number of the person to whom questions regarding this application should be directed.

Please direct all questions regarding this application to:
Rachel Todd
Chief Executive Officer
19000 33rd Ave W, Suite 230
Lynnwood, WA 98036
(425)977-4655

With a copy to:
Elana Zana
Ogden Murphy Wallace
901 5th Ave, Suite 3500
Seattle, WA 98164
(206)447-7000

f. Corporate structure and related parties. Attach chart showing organizational relationship to related parties.

Please see Exhibit A for an organizational chart specific to Edmonds Endoscopy Center. PSG is owned by its Members: Russ Arjal, MD, Crystal Bernstein, MD, Janelle Brown-Chang, MD, Cara Debley, MD, Gary Dines, MD, Sue Eng, MD, Alina Gavrila, MD, Michelle Gottschlich, MD, Jinfeng Jeff Guo, MD , Peter Justus, MD, David Lee, MD, Arnold Levin, MD, Steven Lewis, MD, Ronald Mason, MD, Gilbert Ong, MD, Alexandra Read, MD, Jason Schneier, MD, Thomas Sloane, MD, Wataru Tamura, MD, Darik Taniguchi, MD and Steven Wegley, MD.

PSG is designated as a "C" Corporation and is a professional services organization.

While PSG as an entity is owned by all partners across all locations, the physicians with privileges at the Edmonds Endoscopy Center are: Cara Debley, MD, Gary Dines, MD, Michelle Gottschlich, MD, Jinfeng Jeff Guo, MD, Gilbert Ong, MD, and Jason Schneier, MD.

g. Name and address of operating entity at completion of project (unless same as applicant).

Same as applicant

h. General description and address of each facility owned and/or operated by applicant.

A healthcare facility, per CN WAC 246-310-010(26) means a hospital, psychiatric hospital, nursing homes, kidney disease treatment centers including freestanding dialysis units, ambulatory surgical facilities, continuing care retirement communities, hospices and home health agencies. PSG owns and operates 4 ASCs and clinics in Fremont, Northgate, Edmonds and Kirkland. The currently CN-exempt outpatient endoscopy centers are all in contiguous space with the physician practices and are only used by PSG physicians.

ASCs owned and operated by PSG:

Seattle Endoscopy Center 11027 Meridian Ave N. Suite 100 Seattle, WA 98133	Fremont Endoscopy Center 501 N. 34th St, Suite 101 Seattle, WA 98103	Evergreen Endoscopy Center 11800 NE 128th St, Suite 100 Kirkland, WA 98034

i. Facility licensure/accreditation status.

The ASC is licensed as an Ambulatory Surgical Facility ("ASF") under WAC 246-330. The ASC is also Medicare certified.

j. Is applicant reimbursed for services under Title V, XVIII, and XIX of Social Security Act?

The ASC is currently and will continue to be reimbursed for services under Titles V, XVIII, and XIX of the Social Security Act. No change is anticipated if CN approval is obtained.

k. Geographic identification of primary service area.

The ASCs primary service area is the Southwest Snohomish Planning Area. The ASC also serves existing patients from North King County. Based on the zip codes of the Southwest Snohomish Planning area, 63.2% of patients who had procedures performed at the Edmonds Endoscopy Center originated from the Southwest Snohomish Planning Area and 36.8% of patients sourced from outside the Southwest Snohomish Planning Area.

PSG does not anticipate a change in patient origin as a result of this application.

Primary patient origin zip codes include: 98012 (Mill Creek/North Creek), 98020 (Edmonds/Woodway), 98021 (Bothell/North Creek), 98026 (Edmonds/Lynnwood), 98036 (Lynnwood), 98037 (Lynnwood), 98043 (Mountlake Terrace), 98087 (Martha Lake/North Lynnwood), 98133 (Seattle/Shorline), 98155 (Lake Forest Park/Shoreline/Kenmore), 98177 (Seattle/Shoreline), 98203 (Everett), 98204 (Everett), 98208 (Everett/Martha Lake), 98258 (Lake Stevens), 98275 (Mukilteo), and 98296. See also Exhibit B for further information related to patient origin.

l. List physician specialties represented on active medical staff and indicate number of active staff per specialty.

Any qualified, credentialed and privileged physician on PSG's medical staff will be able to use the proposed CN-approved facility. Table 1, below lists all physicians who are active medical staff with the ASC. All of them are board certified in gastroenterology. Table 1 also provides the professional license number, board certification, and whether the physician is an owner or employee. Table 2 provides Medicare and Medicaid provider numbers.

Table 1
Ambulatory Surgery Center
Active Medical Staff

Name	Professional License Number	Board Certified/Eligible	Owner/Employee
Cara K Debley, MD	MD00039774	Board Certified	Owner
Gary N Dines, MD	MD00025063	Board Certified	Owner
Michelle J Gottschlich, MD	MD60544549	Board Certified	Owner
Jinfeng Jeff Guo, MD	MD00038303	Board Certified	Owner
Gilbert K Ong, MD	MD00047300	Board Certified	Owner
Jason I Schneier, MD	MD00015865	Board Certified	Owner

Table 2
Ambulatory Surgery Center
Active Medical Staff – Medicare and Medicaid Numbers

Name	NPI Number	Medicare Provider Number	Medicaid Provider Number
Cara K Debley, MD	1265459135	G8859797	1006284
Gary N Dines, MD	1831110451	G8802900	1019957
Michelle J Gottschlich, MD	1225090566	G8941980	2043427
Jinfeng Jeff Guo, MD	1912924739	G8802898	1022096
Gilbert K Ong, MD	1740310283	G8948693	1031816
Jason I Schneier, MD	1174544712	G8802894	1004075

m. List all other generally similar providers currently operating in the primary service area.

Applicant is aware of the following physicians and facilities operating in the primary service area (Southwest Snohomish Planning Area):

- Swedish Edmonds Hospital has an outpatient endoscopy center with PSG physicians performing procedures along with Swedish employed colon-rectal surgeons.
- Virginia Mason has an outpatient endoscopy center in Lynnwood with gastroenterologists rotating through to perform procedures.
- The Everett Clinic currently has an ASC CN Application pending, within that application it lists gastroenterological procedures.[1]

The following is a list of all OR providers in the Southwest Snohomish County Planning Area

Table 3
Southwest Snohomish County Planning Area Hospitals and ASCs

Facility	Type	CN Approved
Swedish Medical Center - Edmonds	Hospital	Hospital
Baxter Plastic Surgery	ASC	Exempt
Edmonds Center of Outpatient Surgery	ASC	Exempt
Puget Sound Surgical Clinic PS dba EVIVA	ASC	Exempt
Virginia Mason Lynnwood Ambulatory Surgical Center	ASC	Exempt
Alderwood Surgery Center	ASC	Exempt
Cosmetic Surgical Arts	ASC	Exempt
Proliance Center for Outpatient Spine And Joint Surgery of Puget Sound	ASC	Exempt
Sound Urological Associates	ASC	Exempt
Urology Northwest Surgery Center	ASC	Exempt
Washington Spine Diagnostics and Treatment Center	ASC	Exempt

[1] According to the Everett Clinic's CN application, page 9, the expected volume of gastroenterology procedures in 2019 is 1,281.

n. For existing facilities, provide applicant's overall utilization for the last five years, as appropriate.

1. Ambulatory Surgical Facility – surgeries per year;
2. Kidney Disease Treatment Center – dialyses and/or transplants per year;

Table 4 below sets forth the ASC's annual procedures for the last six (6) years along with a projection for 2018. Using the volume for the past six (6) years (2012-2017), there is approximately a .94% growth rate each year, accordingly PSG applied a 1% growth rate to calculate its projected utilization for 2018.

Table 4
PSG (Edmonds Endoscopy Center)
Annual Procedures, 2012-2017

Year	EGD	Colon	Flex Sig	Total
2012	856	3630	75	4561
2013	1098	3214	79	4391
2014	1044	3425	93	4562
2015	985	3364	76	4425
2016	1099	3700	50	4849
2017	1183	3464	56	4703
2018 (projected)	1205	3528	57	4750

o. Describe the history of the applicant entity with respect to criminal convictions related to ownership/operation of a health care facility, license revocations, and other sanctions described in WA 246-310-230 (5)(a). If there have been no such convictions or sanctions, please state.

There have not been any convictions or sanctions related to ownership and/or operation of a health care facility, license revocations, or other sanctions described in the above noted WAC of any physician employed by PSG, nor have there been any convictions or sanctions of any physician owner of the same, or of PSG itself.

Section II
Project Description

a. Describe the project for which Certificate of Need approval is sought

The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. The Edmonds Endoscopy Center opened in 1998.

As of the time of this application, PSG Edmonds (Edmonds Endoscopy Center) includes six (6) physicians and is a long established group in the Southwest Snohomish Planning Area. The ASC provides valuable and necessary endoscopic services to a growing local population. PSG's expertise and focus on the patient experience is well known throughout the region.

The following procedures are performed at the Edmonds Endoscopy Center:
Colonoscopy
EGD (Esophagogastroduodenoscopy)
EGB (Esophagogastroduodenoscopy) with Bravo
Ileoscopy/Pouchoscopy
EGD (Esophagogastroduodenoscopy)/Colonoscopy
Flexible Sigmoidoscopy

b. Total estimated capital expenditures.

Applicant does not anticipate any capital expenditures over the next three (3) years associated with this conversion from an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. New equipment necessary for operations was recently leased and/or purchased.

c. Total estimated operation expense for the first and second years of operation (please show separately)

The total estimated operating expenses for the ASC for the first and second years of operation are as follows:

2018 (actuals & projections): $2,432,248.57
2019 (projected): $2,059,358.47
2020 (projected): $2,113,392.92

d. New services/changes in services represented in this project

No new services are proposed with this project; the ASC will continue to provide the same services it has provided in the past. The purpose of this application is simply to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.

e. General description of types of patients served by the project.

Patients needing outpatient endoscopic procedures will be served by this project. The Patient Admission Policy is attached as Exhibit C.

f. Projected utilization of service (s) for the first and second year of operation following project completion (please show separately). This should be expressed in appropriate workload unit measures.

Based on growth over the past six (6) years in procedure volume, applicant is conservatively projecting 1% growth in 2019 and 2020, respectively. Services offered at the ASC will likewise remain the same. The anticipated utilization is as follows:
2018 (actuals and projections): 4,750
2019 (projections): 4,798
2020 (projections): 4,846

g. A copy of the letter of intent, per WAC 246-310-080.

A copy of the letter of intent is attached as Exhibit D.

h. Sources of patient revenue (Medicare, etc.) with anticipated percentages of revenue from each source. Estimate the percentage of change for each of the courses of revenue by payer that will result from this project.

Current and projected sources of patient revenue are documented below. The anticipated percentage of revenue from each source is expected to remain the same.

Table 4
PSG (Edmonds Endoscopy Center) Sources of Patient Revenue

Payer	Percentage
Commercial/Contracted Insurances	89.84%
Medicare	9.27%
Medicaid	.13%
Private Pay/Self Pay	.23%
HMO	0%
Other Government	.53%

Source: Applicant

i. Sources of Financing.

There are no anticipated capital expenditures planned with this application and project and therefore there are no sources of financing. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.

j. Equipment proposed.

There is no new equipment proposed to be purchased nor is it anticipated that any equipment will need to be replaced during this application and project. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.

k. Drawings

a. Single line drawings, *at least approximately to scale*, of <u>current</u> locations which identify current department and services.

Attached as Exhibit E, are the single line drawings of the current facility.

b. Single line drawings, *at least approximately to scale*, of <u>proposed</u> locations which identify proposed services and departments.

The proposed location is the same as the current location, and there are no anticipated changes to the current location/facility. Therefore, attached as Exhibit E, are the single line drawings of the current facility.

c. Total net and gross square feet of project.

The total square footage of the ASC is approximately 1,480 and will not change with this project.

d. Describe any changes in dialysis station capacity as part of this project.

This question is not applicable to this application.

l. Anticipated dates of both commencement and completion of project.

The anticipated date of commencement of the ASC operating as a CN-approved ASC is the date the CN is approved. Because this is only an application to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC, with no new construction, completion of the project is anticipated to be the same date.

m. Describe the relationship of this project to the applicant's long range plan and long-range financial plan (if any).

Applicant is currently operating the ASC and anticipates continuing to run it as part of its long-range goals and commitment to providing necessary endoscopic services to the community.

n. Describe any of the following which would currently restrict usage of the proposed site and/or alternate site for the proposed project: (a) mortgages; (b) liens; (c) assessments; (d) mineral or mining rights; (e) restrictive clauses in the instrument of conveyances; (f) easements and right-of-ways; (g) building restrictions; (h) water and sewer access; (i) probability of flooding; (j) special use restrictions; (k) existence of access roads; (l) access to power and/or electricity sources; (m) shoreline management/environmental impact; (n) others (please explain).

The ASC is already in full operation at this site; none of these items listed above restrict the use of the site for this purpose in any way.

o. Provide documentation that the proposed site may be used for the proposed project. Documentation may include, but not limited to a letter from any appropriate municipal authority, zoning information, and signed letter from leasing agent or realtor attesting to appropriate usage.

The ASC is already operation at this time. Attached as Exhibit F is the existing Lease Agreement with amendments, the most recent dated September 25, 2017, which will remain in effect through June 30, 2024.

p. Provide documentation that the applicant has sufficient interest in the site or facility as proposed. *"Sufficient interest"* includes but not limited to one of the following:

- **a. Clear legal title to the proposed site;**
- **b. A lease for at least one year with, options to renew for not less than a total of five years;**
- **c. A draft lease for at least one year with, options to renew for not less than a total of five years. A draft is acceptable only if all parties identified in the**

draft agreement provide a signed "Letter of Intent to finalize" the agreement.

d. **An earnest money agreement provided all parties identified in the agreement and signed it.**
e. **A letter signed by a duly authorized representative of the property owner attesting to the property owner's intent to sale the site as represented in the application.**

Exhibit F is a copy of the existing Lease Agreement with amendments, the most recent dated September 25, 2017 which will remain in effect through June 30, 2024.

Section III
Rationale

A. Need (WAC 246-310-210)

1. **Identify and analyze the unmet health services needs and/or other problems toward which this project is directed.**
   - **Unmet health services needs of the defined populations should be differentiated from physical plant and operating (*service delivery)* deficiencies that are related to present arrangements.**
   - **The negative impact and consequences of unmet needs and deficiencies should be identified.**

PSG currently operates a two procedure endoscopy room utilized solely by PSG's physicians. PSG and its physicians have exclusively owned and used the ASC to treat outpatient endoscopy patients since 1998.

PSG's project is not aimed at meeting unmet healthcare needs, but rather is aimed at maintaining the status quo within the Southwest Snohomish Planning Area. PSG currently provides over 4700 procedures per year, making it one of the largest outpatient providers of endoscopy services in the Southwest Snohomish Planning Area. Further, PSG provides endoscopy services to Medicaid patients. PSG does not anticipate growth in market share as a result of this CN approval, but instead desires to continue operations and continuity of care for its patients. Failure to grant this CN could destabilize the healthcare market and availability of necessary endoscopic services that are provided in a high quality, low cost environment. The Edmonds Endoscopy Center is currently the only free standing endoscopic only ASC in the Southwest Snohomish Planning Area.

With regard to endoscopy, the CN program has traditionally excluded outpatient endoscopy ASCs from the numeric methodology in WAC 246-310-270(9):

The numeric portion of the methodology requires a calculation of the annual capacity of outpatient and inpatient existing ORs and it excludes specialized dedicated rooms. Examples of dedicated rooms are open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms. Given that

endoscopic rooms are specifically excluded from the utilization calculations and this project proposes to establish an ASC dedicated to endoscopic procedures, the numeric methodology is not suitable for projecting need for the ORs specific to this project. The department recognizes that dedicated outpatient endoscopy ASCs are deliberately excluded from the numeric methodology outlined in WAC 246-310-270(9)[2].

In the Mid-Columbia Endoscopy Center Evaluation, the Program granted the CN application even through there was a surplus of operating rooms because the addition of dedicated operating rooms "would not be counted in the OR supply and would have no impact on the need calculations or the future need for additional ORs in the planning area"[3]. PSG is asking the CN Program to do the same in this situation as well. Since the two existing rooms are dedicated for outpatient endoscopy, they should not be counted in the OR supply nor have an impact on the need calculations.

2. **Define the population that is expected to be served by this project. The specific manner of definition is of necessity based on the specific project proposed, and may require definitions for different elements of the project.**

In all cases, provide Office of Fiscal Management population forecasts for the next ten years, broken down into age and gender categories.

In the case of an existing facility, include a patient origin analysis for at least the most recent three-month period, if such data is maintained, or provide patient origin data from the last statewide patient origin study. Patient origin is to be indicated by zip code. Zip codes are to be group by city and county, and include a zip code map illustrating the service area.

The population expected to be served can be defined according to specific needs and circumstances of patients (e.g., alcoholism treatment, renal dialysis), or by the number of persons who prefer to receive the services of a particular recognized school or theory of medical care.

The ASC is located in the Southwest Snohomish Planning Area. Table 6 below lists the zip codes in the Southwest Snohomish Planning Area. Exhibit G includes the Planning Area map.

Table 6
SW Snohomish Secondary Health Service Area Zip Codes

Zip Code	City	Zip Code	City
98020	Edmonds	98036	Lynnwood
98043	Mountlake Terrace	98012	Bothell
98021	Bothell	98026	Edmonds
98037	Lynnwood	98087	Lynnwood

[2] See Evaluation of the Certificate of Need Application Submitted on Behalf of Mid-Columbia Endoscopy Center, LLC Proposing to Establish an Ambulatory Surgery Center in Benton County, 2017, page 8.
[3] Id. At page 10.

Primary patient origin zip codes include: 98012 (Mill Creek/North Creek), 98020 (Edmonds/Woodway), 98021 (Bothell/North Creek), 98026 (Edmonds/Lynnwood), 98036 (Lynnwood), 98037 (Lynnwood), 98043 (Mountlake Terrace), 98087 (Martha Lake/North Lynnwood), 98133 (Seattle/Shorline), 98155 (Lake Forest Park/Shoreline/Kenmore), 98177 (Seattle/Shoreline), 98203 (Everett), 98204 (Everett), 98208 (Everett/Martha Lake), 98258 (Lake Stevens), 98275 (Mukilteo), and 98296 (Snohomish/Maltby/Cathcart). Exhibit B is a zip code analysis for the ASC showing where patients have sourced from over the past two years (2016/2017 – sourcing from Centricity Practice Management System).

The ASC currently treats patients 15 years and older. Attached in Exhibit H is the population data is the OFM Snohomish County Population projections.

3. **Provide utilization forecasts for each service included in the project. Include the following:**
   a. **Utilization forecasts for at least five years following project completion.**

      Based on historical experience, the ASC has experienced a .94% growth rate over the last six (6) years. Accordingly, the ASC is assuming a 1% growth rate when projecting utilization for the next five (5) years.

      2018: 4,750
      2019: 4,798
      2020: 4,846
      2021: 4,894
      2022: 4,943
      2023: 4,993

   b. **The complete quantitative methodology used to construct each utilization forecast.**

      The calculations provided in the utilization forecast are based on a 1% year over year growth (based on the past 6 years of volume in the ASC).

   c. **Identify and justify all assumptions related to changes in use rate, market share, intensity of service, and others.**

      The calculations provided in the utilization forecast are based on a 1% growth rate year over year. Further, PSG believes that this is a conservative growth rate considering that the Snohomish County population is expected to grow by 5.6% by 2021.[4]

   d. **Evidence of the number of persons now using the service who will continue to use the service(s). Utilization experience for existing services involved in the project should be reported for up to the last ten years, as available. Such utilization should be reported in recognized units of measure appropriate to the service.**

[4] See Exhibit I with OFM GMA data projections – medium series.

The number of people currently using the services of the ASC will likely stay the same and a similar number of people will likely continue to use the services. Evidence that supports current and future volume numbers conservatively growing is that there is no indication of significant change in payer mix or referring providers based on the consistent healthcare job market in Southwest Snohomish County. Additionally, colonoscopies are recommended every 3-10 years for all adults age 50-75, dependent on family and personal history of polyps. Therefore, the number of persons now using the services of the current ASC will likely conservatively increase based on the Southwest Snohomish County population aging (resulting in more people between the ages of 50-75). In addition, PSG expects the usage of the ASC to grow following the recent article from the American Cancer Society (attached as Exhibit I) recommending screening at the age of 45, rather than 50.

e. Evidence of the number of persons who will begin using the service(s).

Based on the past six (6) years of the ASC history of steadily increasing referrals along with an increasing local adult population, there is an assumption of increased referrals for routine and diagnostic gastrointestinal procedures.

4.

a. Provide information on the availability and the accessibility of similar services to the defined population expected to be served. This section should concentrate on other facilities and services that *"compete"* with the applicant.

i. Identify all existing providers of services similar to those proposed and include sufficient utilization experience of those providers that demonstrates that such existing services are not available in sufficient supply to meet all or some portion of the forecaster utilization.

ii. If existing services are available to the defined population, demonstrate that such services are not accessible to that population. Time and distance factors, among others, are to be analyzed in this section.

iii. If existing services are available and accessible to the defined population, justify why the proposed project does not constitute an unnecessary duplication of services.

Applicant is aware of other hospital/clinic employed physicians operating in the primary service area, but no other solely gastroenterological ASCs. Please see page 7 above regarding the list of existing providers.

This project proposes to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. The ASC is currently operating with the physicians listed above in the area, and PSG projects use of the ASC in the future to remain the same as it is now. Therefore, it can be assumed that there will not be unnecessary duplication of services. In fact, if this project is not approved, more than 4,700 procedures per year would need to be performed in other facilities and north King County and south Snohomish County residents

would experience reduced access to diagnostic and therapeutic endoscopy procedures.

1. **In the context of the criteria contained in WAC 246-310-210 (1) (a) and (b), document the manner in which:**
   i. **Access of low-income persons, racial and ethnic minorities, women, mentally handicapped persons, and other under-served groups to the services proposed is commensurate with needs for the health services.**

   PSG services patients regardless of income, race, ethnicity, sex, or disability and fully intends to continue observing the same policy.

   A copy of PSG's charity care policy is included within Exhibit J. Consistent with the requirements of WAC 246-310-270(7), PSG projects to provide the average charity care for Snohomish County. According to the 2016 Charity Care Report (issued February 2018) produced by the Department of Health, the three year charity care average for the Puget Sound Region is 1.16% of gross revenue and 3.21% of adjusted revenue.

   ii. **In the case of relocation of a facility or service, or the reduction or elimination of a service, the present needs of the defined population for that facility or service, including the needs of under-served groups, will continue to be met by the proposed relocation by alternative arrangements.**

   This sub-section is not applicable to the project.

Applicants should include the following:

- **Copy of admissions policy;**
- **Copy of community service policy;**
- **Copy of its charity care policy;**
- **Reference appropriate access problems and discuss how this project addresses such problems;**
- **As appropriate, reference health facility related access problems of under-served groups noted in social service plan documents;**
- **Other information as appropriate**

Attached as Exhibit K is a copy of PSG's Standard of Care Policy, which addresses patient rights and responsibilities (#22 of this policy addresses non-discrimination). Exhibit J contains the Charity Care Policy. Exhibit C contains the PSG Admissions Policy.

5. **As applicable, substantiate the following special needs and circumstances that the proposed project is to serve.**
   a. **The special needs and circumstances of entities such as medical and other health professions' schools, multi-disciplinary clinics, and specialty centers that provide a substantial portion of their services,**

resources, or both, to individuals residing in service areas in which entities are located or in adjacent health service areas.

b. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

c. The special needs and circumstances of osteopathic hospitals and non-allopathic services with which the proposed facility/service would be affiliated.

This question is not applicable to this project.

B. Financial Feasibility (WAC 246-310-220)

1. **Proposed capital expenditures should be broken out in detail and should account for at least the following:**
   - **Land acquisition;**
   - **Site survey, tests, inspections;**
   - **Construction contract;**
   - **Financial feasibility studies, architectural fees/engineering fees/consulting fees;**
   - **Fixed equipment (not in construction contract);**
   - **Movable equipment;**
   - **Freight and delivery charges;**
   - **Sales tax;**
   - **Cost of tuning up and trial runs;**
   - **Reconditioning costs (in case of used asset);**
   - **Cost of title investigations, legal feels, brokerage commissions;**
   - **Other activities essential to the acquisition, improvement, expansion, or replacement of plant and equipment due to the project; and**
   - **Financing costs, including interim interest expense, reserve account, interest expense, and other financing costs**

   There are no anticipated capital expenditures associated with this project. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.

2. **The method and sources for calculating construction costs and other estimated capital expenditures should be fully explain.**

   There are no anticipated capital expenditures associated with this project. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC.

3. **Documentation of project impact on (a) capital costs, (b) operating costs and charges for health services.**

   This project is not expected to have any impact on capital costs or operating costs and charges for the health services provided, as nothing is anticipated to change if CN approval is granted. The purpose of this application is to convert an existing

dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. Exhibit L (contains the 2019/2020 pro formas.

Table 6
PSG (Edmonds Endoscopy Center) Average Cost and Charge Per Surgery (2017)

	Amount
Average Charge/Surgery	**$3,403.04**
Average Reimbursement/Surgery	**$1,209.02**
Average Cost/Surgery	**$416.47**

4. **Source(s) of financing (loan, grant, gifts, etc.). Provide all financing costs, including reserve account, interest expense, and other financing costs. If acquisition of the asset is to be by lease, copies of any lease agreements, and/or maintenance repair contracts should be provided. The proposed lease should be capitalized with interest expense and the principal separated. For debt amortization, provide a repayment schedule showing interest and principal amount for each year over which the debt will be amortized.**

   No financing is required for this project.

5. **Provide a cost comparison analysis of the following alternative financing methods: purchase, lease, board-designated reserves, and interfund loan or bank loan. Provide the rationale for choosing the financing method selected.**

   Because no financing is required for this project, this section is not applicable.

6. **Provide a pro forma balance sheet and the accounting statement, statement of financial position of unrestricted funds and changes in components of working capital.**

   A proforma for the next 2 years (2019/2020) is attached in Exhibit L and the financial statements for PSG for the past 3 years (2015/2016/2017) are attached in Exhibit M. The purpose of this application is to convert an existing dedicated outpatient endoscopy CN-exempt ASC to a dedicated outpatient endoscopy CN-approved ASC. The ASC is currently operating and does not anticipate any expansion or financial changes in the next 3 years.

   The accounting for the ASC is on a cash basis from an accounting perspective, therefore the proforma financials do not show gross revenues but rather reflect expected cash receipts. The proforma financials reflect what expected actual collections will be (since all reporting is done based on a cash basis rather than an accrual basis) rather than showing gross revenue with corresponding contractual write offs.

   <u>Forecast Methodology</u>

   Utilization

   - The methodology used to estimate the ASC utilization projections is based on the growth rate over the past six (6) years of operation and taking into

consideration the expected population growth in Southwest Snohomish County.

Capital Expenditures

- As discussed above, there are no anticipated capital expenditures expected as a result of this project.

Revenues & Expenses

- Inflation of revenue is excluded from the pro forma.
- Average revenue per case was calculated using historical trends/data from 2017 and YTD 2018.
- The payer percentages for revenue are provided below (in Table 8)
- Since PSG is on a cash basis (from an accounting perspective), no bad debt percentage is assumed since it will just be part of the actual collections.
- Charity care is assumed constant at 1.16% of total revenue.
- Staffing requirements are based on current FTE counts for the ASC and adjusted in the forecast to reflect conservative volume increases in the facility. The current FTE counts are in Table 9 and the historical FTE counts are in Exhibit N.
- Wage and salary figures are specific to each group of FTEs, and are calculated on an hourly basis, based on current PSG estimates. It is assumed a FTE works 2,080 hours per year.
- Benefits are calculated as 24.5% of total wages and salaries, based on current PSG estimates.
- Supplies, purchased services, and other expenses were calculated on a per case basis, driven off of PSG actuals. Other expenses include recruitment, legal, and travel expenses, among others.
- Repairs and maintenance were calculated based on PSG actuals.
- Employee development, physician development, and dues/memberships/licenses are calculated by actuals per FTE and projected to adjust for any increases in FTEs.
- B&O taxes were calculated at 1.45% of net revenue.
- Lease equipment was based on PSG actuals.
- Projected rent expense was based on the lease (Exhibit F) with escalator as noted in the lease.
- Inflation of expenses is excluded from the pro forma.

7. **Provide a capital expenditure budget through the project completion and for the three years following completion of the project.**

   No capital expenditures are anticipated for the first three (3) years.

8. **The expected sources of revenues for the applicant's total operations (e.g. Medicaid, Blue Cross, Labor and Industries, etc.) with anticipated percentages of revenue from each source.**

Table 8
PSG (Edmonds Endoscopy Center) Expected Sources of Revenue

Payer	Percentage
Commercial/Contracted Insurances	89.84%

Medicare	9.27%
Medicaid	.13%
Private Pay/Self Pay	.23%
HMO	0%
Other Government	.53%

9. **Expense and revenue statements for the last three full years.**

   Financial statements for PSG for the last three (3) years are attached in Exhibit M. The financial statements are compilations for PSG as a corporation produced by Clark Nuber (the audit firm). Since PSG is on a cash basis from an accounting perspective, the financials are produced on a cash basis, therefore gross revenue is not reflected in the compilation financials. Top line revenue is based on actual collections (cash).

10. **Cash flow statements for the last three full years.**

    Financial statements for PSG for the last three (3) years are attached in Exhibit M.

11. **Balance sheets detailing assets, liabilities, and net worth of facility for the last three full fiscal years.**

    Financial statements for PSG for the last three (3) years are attached in Exhibit M.

12. **Indicate the reduction or addition in FTEs with the salaries, wages, employee benefits for each FTE affected.**

    PSG anticipates conservative growth in procedure volume, and therefore there is no anticipated increase in staffing. Exhibit N provides the historical FTE count for the last three years. Current and projected staffing is as follows in Table 9.

    There are two (2) types of Histology Technicians at PSG:
    - Certified Histology Technician – no licensure but Board Certified by the American Society of Clinical Pathology (ASCP)
    - Non Certified Histology Technician – No licensure and not Board eligible
    - The PSG Histology Lab has 3 Certified Histology Technicians and 1 Non Certified Histology Technician in the department

Table 9
PSG (Edmonds Endoscopy Center) FTEs

Position	FTEs
Endo Medical Director	1
Physicians	6
RN Nurse Manager	1
RN	7
LPN	1
Endoscopy Tech/CNA/CMA	4
PSR (Front Desk)	1
Histology Tech	1

Total	**22**

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Please document the following associated with structure and process of care.

1. **<u>The availability of sufficient numbers of qualified health manpower and management personnel.</u> If the staff availability is a problem, describe the manner in which the problem will be addressed.**

   The ASC is an existing facility and the number of staff noted in the answer to number 12 (above) has been sufficient for staffing needs. No change in staffing is anticipated as a result of CN approval.

2. **Identify the facility's Medical Director, Director of Nursing, and other key staff. For each provider their professional license number for Washington. If they are also licensed in other states, provider their license number for those states.**

   Medical Director/Endoscopy Supervisor: Jinfeng "Jeff" Guo, MD
   License # MD00038303
   Endoscopy Manager: Alaina Torzillo, RN
   License #RN00164072

3. **For the Medical Director indicate if he/she will be an employee of the facility or contractual. If performing his/her duties through a contract, provide a copy. A draft is acceptable only if all parties are identified in the draft agreement provide a signed "Letter of Intent to finalize" the agreement and all terms and costs are included.**

   Dr. Guo is an employee of PSG.

4. **<u>The relationship of ancillary and support services</u> to proposed services, and the capability of ancillary and support services to meet the service demands of the proposed project.**

   This project does not propose the addition of any new services. Existing ancillary and support services are already established and sufficiently meet the service demands of the existing ASC.

   The Edmonds Endoscopy Center typically sends patients needing imaging services to Swedish Radia and patients needing lab services to Swedish Edmonds Hospital. PSG has its own Histology Lab and Pathologist, so most pathology stays internal to PSG.

   The Patient Transfer Agreement between Edmonds Endoscopy Center (PSG) and Swedish-Edmonds Hospital is included in Exhibit O.

5. **The specific means by which the proposed project <u>will promote continuity</u> in the provision of healthcare to the defined population and <u>avoid unwarranted fragmentation</u> of services. This section should include the identification of**

existing and proposed formal working relationships with hospitals, nursing homes, and other health service resources serving your primary service area. This description should include recent, current, and pending cooperative planning activities, shared service agreements, and transfer agreements. Copies of relevant agreements and other documents should be included.

The ASC already exists; thus the continuation as a CN-approved facility will promote continuity in the provision of healthcare to the Southwest Snohomish population and avoid unwarranted fragmentation of services. If this project is not approved that continuity would be interrupted and fragmentation would occur.

6. **Fully describe any history of applicant identity with respect to the actions in Certificate of Need rules and regulations WAC 246-310-230 (5) (a). If there is such history, provide clear, cogent, and convincing evidence that the proposed project will be operated in a manner that ensures safe and adequate care to the public to be served and in conformance with applicable federal and state requirements.**

   PSG and the individual owners thereof have no history of a criminal conviction of any kind, nor have they received a denial or revocation of a license to operate a health care facility, to practice a health profession, or a decertification as a provider of services in the Medicare or Medicaid program.

7. **Services to be provided will be provided (a) in a manner that ensures safe and adequate care, and (b) in accord with applicable federal and state laws, rules, and regulations.**

   The ASC currently is and will continue to operate in a manner that ensures safe and adequate care, and in accord with applicable federal and state laws, rules, and regulations.

D. Cost Containment (WAC 246-310-240)

Please document the following associated with cost containment.

1. **Exploration of alternatives to the project you have chosen to pursue, including postponing action, shared service arrangements, merger, contract services, and different methods of service provision, including different special configurations you have evaluated and rejected. Each alternative should be analyzed by application of the following:**
   - **Decision making criteria (cost limits, availability, quality of care, legal restrictions, etc.):**
   - **Advantages and disadvantages , and whether the sum of either the advantages or the disadvantages outweigh each other by application of the decision-making criteria;**
   - **Capital costs;**
   - **Staffing impact**

   PSG currently operates the Edmonds Endoscopy Center in the Southwest Snohomish County Planning Area, the granting of this Certificate of Need should

have no impact on the current market share, utilization or effect on other providers in the Southwest Snohomish County Planning Area. The proposed project is aimed at promoting continuity of care to PSG's patients and the Southwest Snohomish County residents in an outpatient setting, which is a lower cost alternative for these patients.

PSG has provided endoscopic procedures for over 20 years and is a premier health care provider in Snohomish County. With over 4,700 annual procedures, denying a Certificate of Need will detrimentally impact planning area patients. Further, granting this Certificate of Need will have no impact on current planning area providers, as PSG is not a new entrant to the market and does not expect a noticeable market share shift as a result of Certificate of Need approval.

The PSG facility is fully built-out and operational. It has the specific surgical tools necessary to provide the specialized endoscopic services necessary to PSG patients. In addition, close to 90% of the ASC's patients state that they would recommend this facility to other patients.[5] A "do nothing" alternative will require patients needing these endoscopic and gastroenterological procedures to find other locations and physicians to provide these services, potentially in a more costly setting. This will create a burden on the patients and physicians and could jeopardize the continuity of care.

PSG weighed the following alternatives:

Alternative 1: Request approval of a CN – Proposed Project

PSG facility is fully built-out and operational. It has the endoscopic equipment, medical supplies and expertise to provide quality service to its patients. Since the ASC already exists there is no additional capital expenditure and PSG operates the Edmonds Endoscopy Center in a cost effective manner. PSG has 6 providers credentialed at this facility. It is committed to providing high quality patient services. Granting this Certificate of Need will enable the continuation of the valuable services PSG is currently providing in the Planning Area.

Alternative 2: Do Nothing

PSG does not believe a "do nothing" approach is realistic, considering its current services to the community, and the fact that PSG is the only free-standing solely endoscopic ASC in the Southwest Snohomish Planning Area. Without a CN, patients seeking endoscopic procedures will have to obtain these procedures either outside of the planning area or potentially in a costlier setting. A "do nothing" approach would be detrimental to the community, requiring patients to find alternative facilities and could potentially over burden existing providers, therefore increasing wait times. A "do nothing" approach deprives planning area residents of necessary services and therefore it was rejected.

2. **The specific ways in which the project will promote staff or system efficiency or productivity.**

[5] Internal PSG Press Ganey Survey.

The existing ASC uses staff and systems efficiently; PSG will continuously re-evaluate its methods to ensure the most efficient and productive use of resources. PSG will continue to do so if the ASC is granted a CN.

Further, access to free-standing ambulatory surgery centers enables patients to utilize lower cost alternatives to hospital based surgeries and procedures. This cost savings was acknowledged by the CN Program in its 2014 decision approving Providence Health Services' ASC in Spokane Valley:

"As a freestanding ASC, PHS-W would be precluded from including a hospital facility fee in its patient billing. As a result, PHS-W would be reimbursed at the ambulatory surgery rates, rather than hospital outpatient department rates. This action could reduce the overall costs of healthcare to the community. This conclusion is supported by a cost comparison review between ambulatory surgery and hospital outpatient department 2014 CMS rates. Using the CPT codes provided by Rockwood Health System to support its position that the procedures proposed to be provided by PHS-W in its 'procedure rooms' were surgical procedures, the comparison showed that ambulatory surgery reimbursement rates are lower, and in some cases, significantly lower, than hospital outpatient department reimbursement rates."[6]

3. **In the case of construction, renovation, or expansion, capital cost reductions achieved by architectural planning or engineering methods and methods of building design and construction. Include an inventory of net and gross square feet for each service and estimated capital cost for each proposed service. Reference appropriate recognized space planning guidelines you have employed in your space allocation activities.**

   No construction, renovation or expansion of the currently operating ASC is anticipated.

4. **If the case of construction, renovation or expansion, an analysis of the capital and operating costs or alternative methods of energy consumption. Including the rationale for choosing any method other than the least costly. For energy-related projects, document any efforts to obtain a grant under the National Energy Conservation Act.**

   No construction, renovation or expansion of the currently operating ASC is anticipated.

[6] *See Evaluation of the Certificate of Need Application Submitted on Behalf of Providence Health Services – Washington Proposing to Establish an Ambulatory Surgery Center in Spokane County, 2014, page 19.*

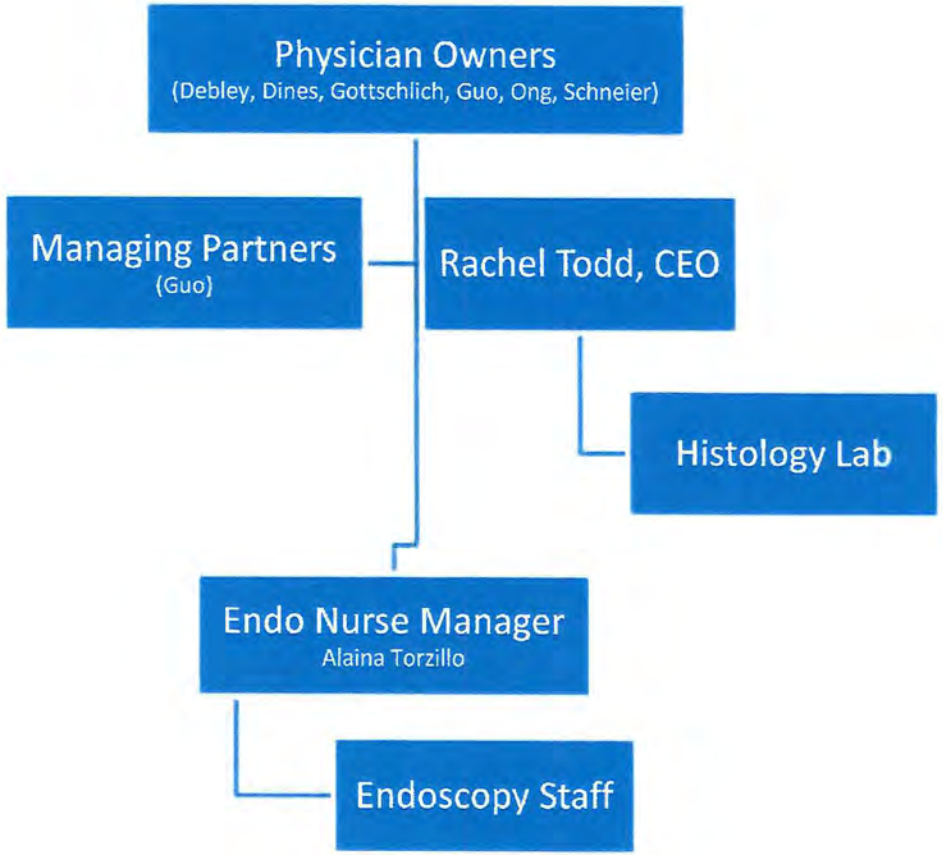
Exhibits to Certificate of Need Application

Edmonds Endoscopy Center

Exhibit Number	Exhibit Name / Description
A.	Organizational Chart
B.	Zip Code Analysis
C.	Patient Admission Policy
D.	Letter of Intent
E.	Single line drawings of the current facility
F.	• PSG/ Edmonds Endoscopy Seventh Amendment to Lease Agreement (dated September 2017) • PSG/ Edmonds Endoscopy Sixth Amendment to Lease Agreement (dated June 2015) • PSG/ Edmonds Endoscopy Fifth Amendment to Lease Agreement (dated January 2015) • PSG/ Edmonds Endoscopy Fourth Amendment to Lease Agreement (dated July 2014) • PSG/ Edmonds Endoscopy Third Amendment to Lease Agreement (dated October 2013) • PSG/ Edmonds Endoscopy Second Amendment to Lease Agreement (dated July 2012) • PSG/ Edmonds Endoscopy First Amendment to Lease Agreement (dated June 2011) • PSG/ Edmonds Endoscopy Lease Agreement
G.	Planning Area map
H.	Population Data
I.	American Cancer Society Screening Guidelines
J.	Charity Care Policy
K.	Standards of Care Policy
L.	Pro Forma (2019/2020)
M.	PSG Financial Statements
N.	Historical FTE Count
O.	Patient Transfer Agreement between Evergreen Health and Evergreen Endoscopy Center (PSG)

Exhibit A
Edmonds Endoscopy Center Organizational Chart

Puget Sound Gastroenterology, P.S. – Edmonds Endoscopy Center Organizational Chart



PSG
PUGET SOUND
Gastroenterology

Exhibit B

Zip Code Analysis

Edmonds Endoscopy Center - Patient Origin Analysis

2016-2017 Patient Origin Statistics by Zip Code		
Patient Residence - Zip code	**Patient Count**	**% of total**
98012 - Mill Creek/North Creek	720	7.96%
98020 - Edmonds	925	10.22%
98021 - Bothell/North Creek	156	1.72%
98026 - Edmonds/Lynnwood	1414	15.63%
98036 - Lynnwood	880	9.73%
98037 - Lynnwood	682	7.54%
98043 - Mountlake Terrace	454	5.02%
98087 - Martha Lake/North Lynnwood	487	5.38%
98133 - Seattle/Shoreline	221	2.44%
98155 - Lake Forest Park/Shoreline/Mountlake Terrace	298	3.29%
98177 - Seattle/Shoreline	171	1.89%
98203 - Everett	129	1.43%
98204 - Everett	297	3.28%
98208 - Everett/Martha Lake	441	4.87%
98258 - Lake Stevens	140	1.55%
98270 - Marysville	93	1.03%
98275 - Mukilteo	236	2.61%
98296 - Snohomish/Maltby/Cathcard	220	2.43%
All other Zip codes	1084	11.98%
Total	**9048**	**92.04%**

2016/2017 Patient Origin Statistics by Planning Area		
Patient residence	**Patient Count**	**% of Total**
SW Snohomish Planning Area	5718	63.20%
Outside of Planning Area	3330	36.80%
Total	**9048**	**100.00%**

2016/2017 Patient Origin Statistics by County		
Patient Residence	**Patient Count**	**% of Total**
Snohomish County	7703	85.13%
Outside of Snohomish County	1345	14.87%
Total	**9048**	**100.00%**

Exhibit C

Patient Admission Policy

ADMISSION / TREATMENT POLICY	PSG# 5500
SECTION V – ADMISSION / OFFICE	Page: 1 of 1
	EFFECTIVE: 07/22/1996
APPROVED BY:	REVIEWED: 7/1997, 7/1998, 6/1999, 9/2000, 5/2002, 8/2004, 6/2008, 2/2014
PSG Board	REVISED: 11/2017

POLICY

It is the policy of the Endoscopy Center to admit, treat, and provide services to all persons without regard to race, color, handicap, religious or fraternal organizations. All persons and organizations having occasion to refer persons for services or to recommend the Center are advised to do so without regard to the person's race, color, national origin, handicap, religious or fraternal organization.

Exhibit D

Letter of Intent

OGDEN MURPHY WALLACE

OGDEN MURPHY WALLACE, PLLC
901 FIFTH AVENUE, SUITE 3500
SEATTLE, WA 98164-2008

T 206.447.7000
F 206.447.0215

OMWLAW.COM

April 12, 2018

VIA FEDEX OVERNIGHT

Janis Sigman, Manager
Certificate of Need Program
Department of Health
111 Israel Rd. S.E.
Tumwater, WA 98501

Re: Letter of Intent – Puget Sound Gastroenterology, P.S. – Edmonds Endoscopy Center

Dear Ms. Sigman:

On behalf of my client, Puget Sound Gastroenterology, P.S. ("PSG"), and in accordance with WAC 246-310-080, PSG hereby submits this Letter of Intent proposing to operate PSG Edmonds Endoscopy Center located at 21600 Highway 99, Suite 260, Edmonds, WA 98026 as a certificate of need approved ambulatory surgery center in the Southwest Snohomish Planning Area. The PSG Edmonds Endoscopy Center is an existing facility with two (2) procedure rooms that has historically operated as a certificate of need exempt ASC.

Pursuant to WAC 246-310-080, PSG submits the following information:

1. Description of proposed services: PSG proposes to operate the PSG Edmonds Endoscopy Center as a two (2) operating room free-standing ambulatory surgical center.

2. Estimated cost of proposed project: There are no capital expenditures associated with this project. The PSF Edmonds Endoscopy Center is an existing facility and these operating rooms are fully built-out and operational.

3. Identification of service area: The service area is the SW Snohomish Planning Area.

Thank you for your assistance in this matter. If you have any questions, please contact me by phone at (206) 447-7212 or by email at dblack@omwlaw.com .

Very truly yours,

OGDEN MURPHY WALLACE, P.L.L.C.

Donald W. Black

DWB:ctb

cc: Rachel Todd, CEO, Puget Sound Gastroenterology *(Via Email - rtodd@psgastro.com)*

(DWB1707085.DOCX;1/14342.000003/)

Exhibit E

Single line drawings of the current facility

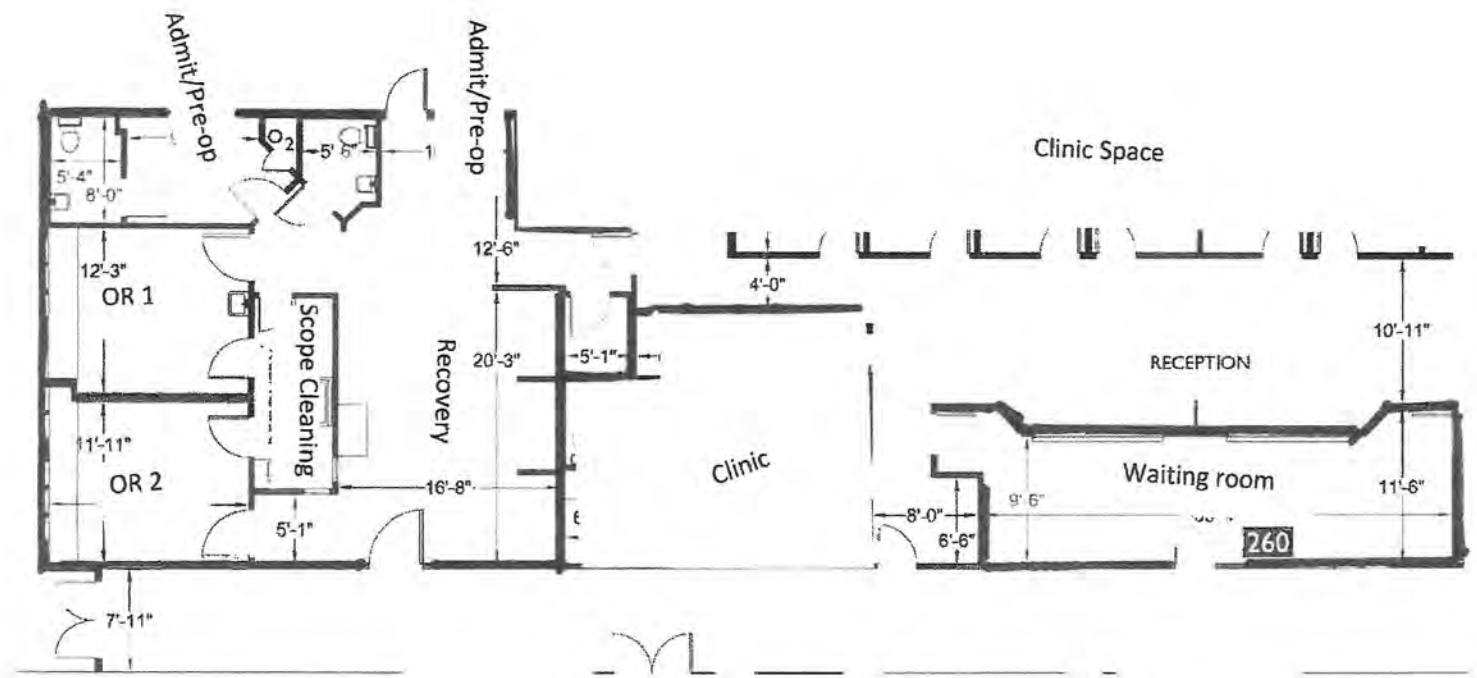

Admit/Pre-op
Admit/Pre-op
Clinic Space
5'-4"
8'-0"
12'-3"
OR 1
11'-11"
OR 2
Scope Cleaning
Recovery
12'-6"
20'-3"
5'-1"
16'-8"
5'-1"
4'-0"
Clinic
RECEPTION
10'-11"
Waiting room
11'-6"
8'-0"
6'-6"
260
7'-11"

Exhibit F

- **PSG/ Edmonds Endoscopy Seventh Amendment to Lease Agreement (dated September 2017)**
- **PSG/ Edmonds Endoscopy Sixth Amendment to Lease Agreement (dated June 2015)**
- **PSG/ Edmonds Endoscopy Fifth Amendment to Lease Agreement (dated January 2015)**
- **PSG/ Edmonds Endoscopy Fourth Amendment to Lease Agreement (dated July 2014)**
- **PSG/ Edmonds Endoscopy Third Amendment to Lease Agreement (dated October 2013)**
- **PSG/ Edmonds Endoscopy Second Amendment to Lease Agreement (dated July 2012)**
- **PSG/ Edmonds Endoscopy First Amendment to Lease Agreement (dated June 2011)**
- **PSG/ Edmonds Endoscopy Lease Agreement (dated April 2009)**

KRUGER CLINIC
SEVENTH AMENDMENT TO LEASE

Puget Sound Gastroenterology, P.S.

THIS SEVENTH AMENDMENT TO LEASE AGREEMENT (this "Amendment") is made effective as of this 25th day of September, 2017 (the "Effective Date") between SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission ("Landlord"), and PUGEST SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord (as successor in interest to GRE Kruger LLC, a Washington limited liability company) and Tenant are parties to that certain Lease dated April 28, 2009 (the "Original Lease"), as amended by a First Amendment thereto dated December 18, 2013 (the "First Amendment") and by a Second Amendment thereto dated June 8, 2011 (the "Second Amendment"), and by a Third Amendment thereto dated October 28, 2013 (the "Third Amendment"), and by a Fourth Amendment thereto dated July 28, 2014 (the "Fourth Amendment"), and by a Fifth Amendment thereto dated January 13, 2015 (the "Fifth Amendment"), and by a Sixth Amendment thereto dated June 1, 2015 (the "Sixth Amendment," and, collectively with the Original Lease, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, and the Fifth Amendment, the "Lease"), pursuant to which Tenant leases from Landlord certain premises commonly known as Suites 205, 210, 220 and 260 (collectively, the "Premises"), located on the Second Floor of the "Building" commonly known as the Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8,846 rentable square feet ("RSF") of space on real property more particularly described in the Lease. Tenant also currently occupies additional Storage Space pursuant to the Lease.

B. Landlord and Tenant desire to extend the term of the Lease and amend said Lease as set forth herein. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. Recitals. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. Amendment. By the terms of this Amendment, Landlord and Tenant hereby agree to amend the terms of the Lease, and the parties agree that the terms of this Amendment are incorporated into the Lease. In the event of a conflict between this Amendment and the Lease, the provisions of this Amendment shall prevail.

3. Extension of Term. The current Term of the Lease is scheduled to expire on December 31, 2022 (the "Expiration Date"). The Term of the Lease is hereby extended for a period of eighteen (18) months, so that the new Expiration Date shall be June 30, 2024 (the "Revised Expiration Date"). The period from January 1, 2023 through the Revised Expiration Date is hereby referred to hereinafter as the "Third Extended Term".

4. Minimum Rent. The Minimum Rent owing to Landlord from Tenant each month from the Effective Date through the end of the Third Extended Term shall be as follows:

Period	Total RSF of Premises	Annual Minimum Rent per PSF	Annual Minimum Rent	Monthly Minimum Rent
1/1/2018-12/31/2018	8,846	24.50	216,727.00	18,060.58
1/1/2019-12/31/2019	8,846	25.24	223,273.04	18,606.09
1/1/2020-12/31/2020	8,846	25.99	229,907.54	19,158.96
1/1/2021-12/31/2021	8,846	26.77	236,807.42	19,733.95
1/1/2022-12/31/2022	8,846	27.57	243,884.22	20,323.69
1/1/2023-12/31/2023	8,846	28.40	251,200.75	20,933.40
1/1/2024-6/30/2024*	8,846	29.25	258,736.77	21,561.40

* Partial Year

5. Miscellaneous.

a. No Brokers. Landlord and Tenant each represents and warrants to the other that it has not had any dealings with any realtors, brokers or agents in connection with the negotiation of this Amendment, and each party agrees to hold the other harmless from the failure to pay any realtors, brokers or agents and from any cost, expense or liability for any compensation, commission or changes claimed by any other realtors, brokers or agents claiming by, through or on behalf of it with respect to this Amendment and/or the negotiation hereof.

b. Full Force and Effect. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect.

c. Condition of Premises. Tenant acknowledges and agrees that its possession of the Premise after the Effect Date hereof is a continuation of Tenant's possession of the Premises under the Lease. Tenant is familiar with the condition of the Premises, and has accepted same in their existing condition "AS IS", without any further obligation of Landlord to remodel, improve, or alter the Premises, to perform any construction or work of improvement upon the Premises, or to provide Tenant with any additional construction or refurbishing allowance.

d. Status of Lease. As of the date hereof, Tenant acknowledges and agrees that Landlord has performed all obligations of Landlord under the Lease and that there are no offsets, counterclaims, remaining tenant improvement allowances, or defenses against Landlord, and that the Lease is in full force and effect. Tenant hereby confirms that all alterations, additions, improvements and tenant improvement allowances required to be performed or paid by Landlord pursuant to the Lease have been performed and/or paid by Landlord and were accepted by Tenant.

e. Counterparts. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission

By: _____
Name: ROBIN FENN
Its: SUPERINTENDENT
Date: 25 SEPT 2017

TENANT:

PUGET SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation

By: _____
Name: Rachel Todd
Its: CEO
Date: 9/19/17

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

I certify that I know or have satisfactory evidence that Robin Fenn is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Superintendent of SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 25th day of September, 2017.

(Signature of Notary)

Notary Public
State of Washington
JUDY POWELL
MY COMMISSION EXPIRES
FEBRUARY 5, 2019

Judy Powell
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at Snohomish
My appointment expires 2/5/19

STATE OF WASHINGTON)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Rachel Todd is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the CEO of PUGET SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 19th day of September, 2017.

(Signature of Notary)

CAROLYN HARRIS
Notary Public
State of Washington
My Appointment Expires
Jul 6, 2021

Carolyn Harris
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at Everett, WA
My appointment expires 7/6/2021

51033972.1

KRUGER CLINIC

SIXTH AMENDMENT TO LEASE

Puget Sound Gastroenterology

THIS SIXTH AMENDMENT TO LEASE AGREEMENT (this "Amendment") is made effective as of this 1st day of June, 2015 (the "Effective Date") between SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission ("Landlord"), and PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional services corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord and Tenant are the current parties to that certain Lease dated April 28, 2009, with all addenda, exhibits, and amendments thereto (collectively, the "Lease") demising certain premises (the "Premises") commonly known as 205, 210, 220 and 260 in the Building commonly known as Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, WA 98020, on real property more particularly described in the Lease. Tenant also currently occupies approximately 180 square feet of Storage Space basis for which it pays $75 per month.

B. The parties now wish to amend the Lease set forth hereinbelow to add additional Storage Space.

C. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. Recitals. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. Additional Storage Space. Effective as of the Effective Date, the Storage Space described in Paragraph W. of the Basic Lease Provisions is hereby increased by the addition of storage shelf, located in the file storage area of the Basement in the same room as the initial Storage Space currently used by Tenant, until **September 30th, 2015** for which Tenant shall pay as an additional Storage Fee the amount of $125 per month. Provided neither party has terminated this Contract in accordance with its terms prior to **September 30th,2015**, this Contract shall continue on a month to month basis following **September 30th,2015** until terminated by either party upon thirty (30) days prior written notice.

3. Miscellaneous. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect. Tenant acknowledges and agrees that there are no offsets, counterclaims or defenses of Tenant existing against Landlord. Tenant further acknowledges and agrees that no events have occurred that, with the passage of time or the giving of notice, or both, would constitute a basis for an offset, counterclaim, or defense against Landlord, and that the Lease is in full force and effect. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission

By: Carl J Zapora
Name: CARL J ZAPORA
Its: SUPERINTENDENT
Date: 5/15/15

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional services corporation

By: Rachel J Todd
Name: Rachel Todd
Its: CEO
Date: 5/15/15

STATE OF WASHINGTON)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Carl Zapora is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Superintendent of SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 15th day of May, 2015.

(Signature of Notary)

Karen Y. Goto
(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington,
residing at Mukilteo, WA
My appointment expires 4.8.2018

STATE OF WASHINGTON)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Rachel Todd is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the _____ of PUGET SOUND GASTROENTEROLOGY, P.S.., a Washington professional services corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 15th day of May, 2015.

(Signature of Notary)

Karen Y. Goto
(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington,
residing at Mukilteo, WA
My appointment expires 4.8.2018

KRUGER CLINIC

FIFTH AMENDMENT TO LEASE

Puget Sound Gastroenterology, P.S.

THIS FIFTH AMENDMENT TO LEASE AGREEMENT (this "Amendment") is made effective as of this 13th day of January, 2015 (the "Effective Date") between SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission ("Landlord"), and PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional services corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord (as successor in interest to GRE Kruger LLC, a Washington limited liability company) and Tenant are parties to that certain Lease dated April 28, 2009, as amended by that First Amendment to Lease Agreement dated June 8, 2011, that Second Amendment to Lease Agreement dated July 17, 2012, that Third Amendment to Lease Agreement dated October 28, 2013, and that certain Fourth Amendment to Lease dated July 28, 2014, and all exhibits thereto (collectively, the "Lease"), pursuant to which Tenant leases from Landlord certain premises commonly known as Suites 205, 210, 220 and 260 (collectively, the "Premises"), located on the Second Floor of the "Building" commonly known as the Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8,846 rentable square feet ("RSF") of space on real property more particularly described in the Lease.

B. The parties now wish to further amend the Lease as set forth hereinbelow.

C. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. Recitals. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. Deletion of Firewall and Fire Sprinkler Installation Requirements. The parties have agreed that neither a firewall nor a fire sprinkler system needs to be installed in the Premises, as was originally contemplated in Sections 5 and 7, respectively, of the Fourth Amendment. Therefore, the second paragraph of Section 5 and all of Section 7 are hereby deleted in their entirety and shall be of no further force or effect.

3. Miscellaneous. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

STATE OF WASHINGTON)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Carl J Zapora is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Superintendent of SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 20th day of February, 2014.

KAREN Y. GOTO NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 04-08-18

(Signature of Notary)

Karen Y. Goto

(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington, residing at Mukilteo, WA

My appointment expires 4.8.2018

STATE OF WASHINGTON)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Rachel Todd is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the CEO of PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional services corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 20th day of February, 2014.

KAREN Y. GOTO NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 04-08-18

(Signature of Notary)

Karen Y. Goto

(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington, residing at Mukilteo, WA

My appointment expires 4.8.2018

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

SNOHOMISH COUNTY PUBLIC HOSPITAL DISTRICT NO. 2, a Washington municipal corporation dba Verdant Health Commission

By: _____
Name: CARL J. ZAPORA
Its: SUPERINTENDENT
Date: 2/20/15

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional services corporation

By: _____
Name: _____
Its: CEO
Date: 2/20/15

KRUGER CLINIC
FOURTH AMENDMENT TO LEASE

Puget Sound Gastroenterology, P.S.

THIS FOURTH AMENDMENT TO LEASE (the "Fourth Amendment") is made and entered into this _____ day of July, 2014 (the "Effective Date"), by and between PUBLIC HOSPITAL DISTRICT NO. 2 OF SNOHOMISH COUNTY, D/B/A VERDANT HEALTH COMMISSION ("Landlord"), and PUGET SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation ("Tenant").

WITNESSETH

WHEREAS, Landlord (as successor in interest to GRE Kruger LLC, a Washington limited liability company) and Tenant are parties to that certain Lease dated April 28, 2009, as amended by that First Amendment to Lease Agreement dated June 8, 2011, that Second Amendment to Lease Agreement dated July 17, 2012, and that Third Amendment to Lease Agreement dated October 28, 2013, and all exhibits thereto (collectively, the "Lease"), pursuant to which Tenant leases from Landlord certain premises commonly known as Suites 205, 210, 220 and 260 (collectively, the "Premises"), located on the Second Floor of the "Building" commonly known as the Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8,846 rentable square feet ("RSF"), on real property more particularly described in the Lease;

WHEREAS, the parties desire to amend said Lease as set forth herein;

WHEREAS, capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein;

AGREEMENT

NOW THEREFORE, in consideration of the covenants and agreements contained herein, and for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby mutually agree as follows:

1. RECITALS. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. AMENDMENT. By the terms of this Fourth Amendment, Landlord and Tenant hereby agree to amend the terms of the Lease, and the parties agree that the terms of this Fourth Amendment are incorporated into the Lease. In the event of any conflict between this Fourth Amendment and the Lease, the provisions of this Fourth Amendment shall prevail.

3. EXTENSION OF TERM. The current Term of the Lease is scheduled to expire on December 31, 2016 (the "Expiration Date"). The Term of the Lease is hereby extended for a period of six (6) additional years, so that the new Expiration Date shall be December 31, 2022 (the "Revised Expiration Date"). The period from January 1, 2017 through the Revised Expiration Date is hereby referred to hereinafter as the "Second Extended Term").

4. MINIMUM RENT. The Minimum Rent owing to Landlord from Tenant each month from the Effective Date through the end of the Second Extended Term shall be as follows:

Period	Total RSF of Premises	Annual Minimum Rent Rate Per RSF	Annual Minimum Rent	Monthly Minimum Rent
Effective Date – 12/31/18	8,846	$24.50	$216,727.00	$18,060.58
1/1/19 – 12/31/19	8,846	$25.24	$223,273.04	$18,606.09
1/1/20 – 12/31/20	8,846	$25.99	$229,907.54	$19,158.82
1/1/21 – 12/31/21	8,846	$26.77	$236,807.42	$19,733.95
1/1/22 – 12/31/22	8,846	$27.57	$243,884.22	$20,323.69

5. TENANT IMPROVEMENTS. On or prior to December 31, 2014, Tenant shall complete a renovation of the Premises pursuant to a plan (including without limitation its construction plans) to be

presented by Tenant to Landlord, which shall be subject to Landlord's written consent, which consent shall not be unreasonably withheld, conditioned or delayed (such work based upon the approved plan shall be collectively referred to as the "Renovation Work"). Said Renovation Work shall include, without limitation, new building standard carpet and building standard paint throughout the Premises. Tenant shall proceed with due diligence and at its own expense to perform the Renovation Work. All entry into and onto the Premises and the Renovation Work done by Tenant shall be at Tenant's sole risk. All of the Renovation Work shall be performed in accordance with good construction practices, all applicable laws, insurance requirements, the terms of the Lease, and Landlord's reasonable rules and regulations. Tenant agrees that the Renovation Work shall not interfere with the access to or the quiet enjoyment of any other tenant of the Building. Tenant shall not erect any barricades in the common areas of the Building without Landlord's prior written consent.

As part of the Renovation Work, Tenant may install a firewall in one or more locations within the Premises in order to comply with applicable law as such pertains to Tenant's Use of the Premises (the "Firewall"). Tenant hereby agrees and acknowledges that installation of the Firewall, whether now or in the future, is solely the responsibility of Tenant (financial and otherwise), and should Tenant install such voluntarily, or should Tenant install such as a result of the direction of any governmental or quasi-governmental entity (whether such demand is made by said governmental or quasi-governmental entity against Tenant or Landlord), Tenant shall install such at its sole cost and expense, and Landlord shall have absolutely no duty or obligation to install such, nor pay for any portion thereof. Tenant hereby agrees and acknowledges that a portion of the Allowance described in Section 6 below was calculated based upon Tenant's future installation of the Firewall, and such funds shall constitute Landlord's sole financial involvement in connection therewith.

6. TENANT IMPROVEMENT ALLOWANCE. In consideration for Tenant's completion of the Renovation Work, Landlord shall provide Tenant a tenant improvement allowance in an amount not to exceed One Hundred One Thousand Four Hundred Sixty and No/100 U.S. Dollars ($101,460.00) (the "Allowance") [For purposes of clarification, the Allowance has been calculated based on approximately $13.27 RSF of the Premises, less the RSF in Suite 210 (1,200 RSF)]. The Allowance shall only be used to reimburse Tenant for its hard costs actually incurred for labor and materials to perform the Renovation Work. The Allowance shall be due to Tenant within thirty (30) days following the date (i) Tenant has opened for business to the public in the Premises, (ii) Tenant has provided Landlord with invoices substantiating that the work and materials used in connection with the Renovation Work equal or exceed $101,460.00, and (iii) Tenant has delivered to Landlord final lien waivers executed by Tenant's general contractor, all sub-contractors and all suppliers. Tenant represents and warrants to Landlord that the Allowance shall be used only for improvements in, to and for the Premises.

7. LANDLORD IMPROVEMENTS. Contemporaneously with Tenant's performance of the Renovation Work, Landlord shall, in those particular locations within the Premises as shown on Exhibit A attached hereto, install fire sprinklers, which sprinklers shall be in compliance with applicable law (the "Sprinkler System"). Landlord shall be solely responsible for the design and installation of the Sprinkler System, and shall be responsible for the costs of design and installation of the Sprinkler System, estimated to cost approximately $50,000.00. Landlord and Tenant hereby agree that each of their contractors shall work together in good faith so as not to unreasonably interfere with the construction work of the other. Further, Landlord and Tenant hereby agree and acknowledge that Landlords' work within the Premises in connection with the Sprinkler System shall not in any manner be construed as interfering with Tenant's quiet possession of the Premises, nor shall such form the basis for the abatement of any rent of any kind due and owing under the Lease.

8. LEASE OF TEMPORARY SPACE. Subject to the terms of this Fourth Amendment, and in addition to, and not in limitation of Tenant's lease of the Premises pursuant to this Lease, Tenant hereby leases, hires and takes from Landlord those certain premises within the Building totaling 752 RSF, commonly known as Suites 225 and 245, and as shown in Exhibit B to this Lease (the "Temporary Space"), for a period commencing on August 1, 2014, and terminating on October 31, 2014 (the "Temporary Space Term"). Tenant's lease of the Temporary Space shall be upon the same terms and conditions of this Lease as apply to the Premises, except for term, which shall be as specifically set forth in this Section 8 (the Temporary Space Term), and except that monthly Minimum Rent for the Temporary Space shall be in an amount equal to $10.00 per RSF. Tenant's Pro Rata Share for the Temporary Space towards Operating Expenses and Taxes shall be 1.79%. Tenant's rights to lease the Temporary Space are specifically limited to the terms set forth in this Section 8, and all of Tenant's rights to the Temporary Space shall terminate immediately upon the end of the Temporary Space Term. Nothing contained within this Section 8 shall in any way impact or lessen Tenant's obligations under the Lease

as such relates to the Premises, including without limitation, the payment of Minimum Rent, Additional Rent and all other monies due under the Lease.

9. HOLDOVER. Should Tenant hold over in all or any portion of the Temporary Space after the expiration of the Temporary Space Term, then in such case: (i) Minimum Rent for the Temporary Space shall increase to $19.00 per RSF; (ii) for each day from the end of the Temporary Space Term until the date possession of the Temporary Space has been returned to Tenant, Tenant shall pay Landlord an amount equal to $236.02 per day; and (iii) Tenant shall be unlawfully detaining the Temporary Space, and Landlord shall be entitled to any and all remedies available to it under the Lease or applicable law, including without limitation the right to bring an unlawful detainer action.

10. EFFECT OF AMENDMENT. Any and all terms and provisions of the Lease are hereby modified wherever necessary, and even though the same may not be specifically addressed herein, so as to conform to the amendment(s) set forth in the preceding paragraph(s) hereof.

11. NO WAIVER OF CLAIMS. The parties agree that the terms and conditions set forth in this Fourth Amendment shall not alter, waive or modify any rights, remedies or claims that Landlord or Tenant now has or may hereafter have under or arising out of the Lease, whether known or unknown, and whether relating to periods of time before or after the date of this Fourth Amendment, including, without limitation, any rights, remedies or claims of Landlord or Tenant based in whole or in part on a default by the other party of its obligations under the Lease, or the non-satisfaction or failure of any requirement or condition under the Lease.

12. CONSTRUCTION. Descriptive headings used herein are for convenience of reference only and shall not control or affect the meaning or construction of any provision set forth in this Fourth Amendment. Where required for proper interpretation, words used herein in the singular tense shall include the plural, and vice versa; the masculine gender shall include the neuter and the feminine, and vice versa. As used in this Fourth Amendment, the words "hereof," "herein," "hereunder" and words of similar import shall mean and refer to this entire Fourth Amendment and not to any particular section or paragraph of this Fourth Amendment, unless the context clearly indicates otherwise. If any provision hereof is for any reason unenforceable or inapplicable, the other provisions hereof will remain in full force and effect in the same manner as if such unenforceable or inapplicable provision had never been contained herein. This Fourth Amendment shall be construed without presumption of any rule requiring construction to be made against the party causing same to be drafted.

13. CORPORATE AUTHORITY. The individual executing this Fourth Amendment on behalf of Tenant represents and warrants to Landlord that: he/she has the authority to bind Tenant; Tenant is a valid and existing profession service corporation in the state of Washington; and that all things necessary to qualify Tenant to do business in the state of Washington have been accomplished prior to the date of the Lease.

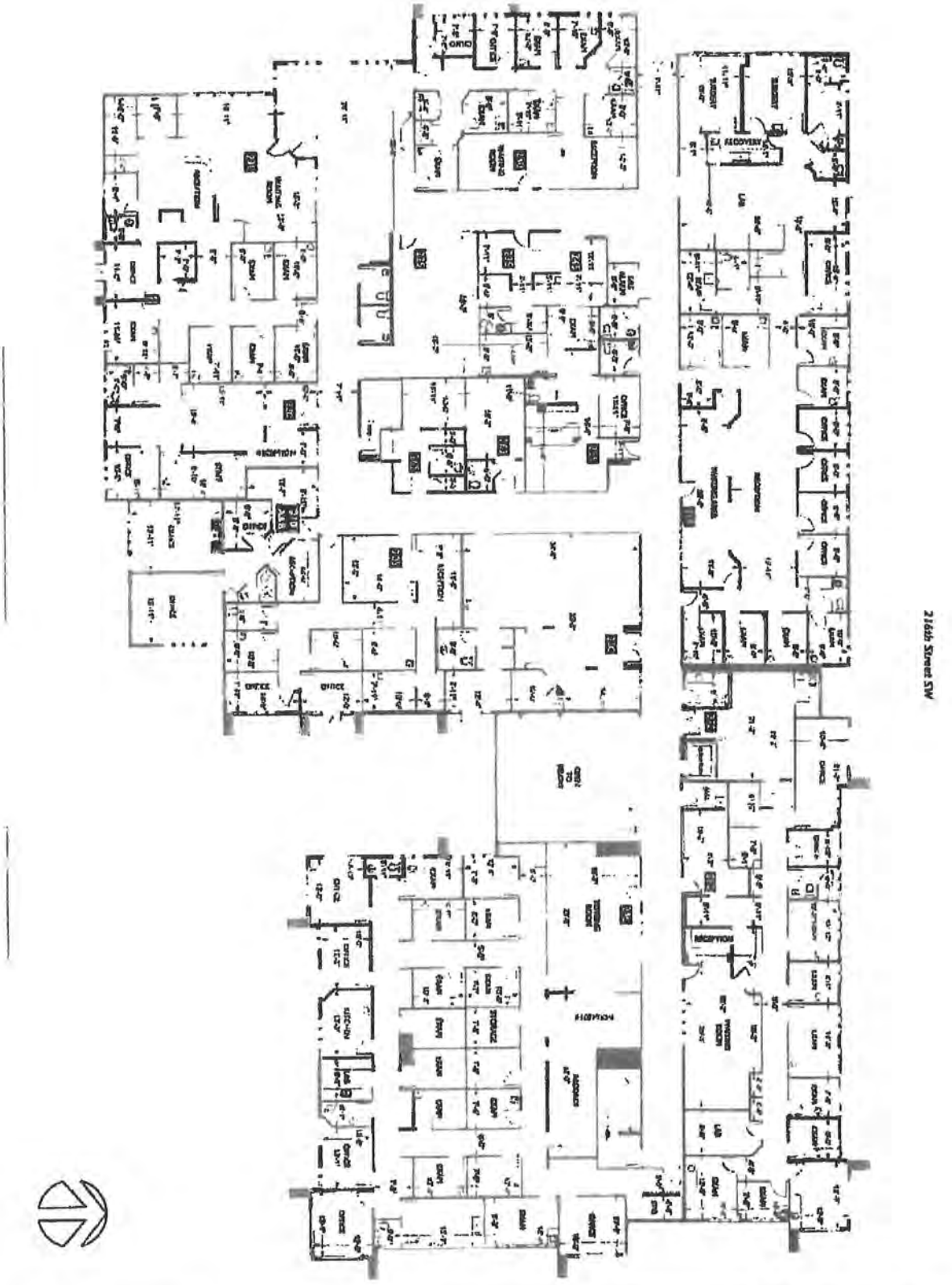
14. ENTIRE AGREEMENT. This Fourth Amendment contains all of the agreements of the parties hereto with respect to the matters contained herein, and no prior agreement, arrangement, or understanding pertaining to any such matters shall be effective for any purpose. Unless otherwise specified herein, the capitalized terms used in this Fourth Amendment shall have the same meaning as in the Lease. Except as expressly amended herein, all terms, covenants, and conditions of the Lease shall remain unchanged and in full force and effect.

15. MISCELLANEOUS. This Fourth Amendment shall be binding upon and inure to the benefit of the parties, their successors and assigns. Any modification of this Fourth Amendment must be in writing and signed by all parties hereto. This Fourth Amendment shall be construed in accordance with the laws of the state of Washington. Each party hereto shall be solely responsible for its own costs, expenses and attorneys in connection with the preparation of this Fourth Amendment. Further, no commission of any kind is due or owing to any agent, broker or third party in connection with this Fourth Amendment, and each party shall indemnify and hold the other harmless from and against any claim arising by or through it for a commission in connection with this Fourth Amendment. Tenant shall have absolutely no naming rights as to the Building, Property or any portion thereof, and Tenant agrees and acknowledges that Landlord shall have the absolute right to name and/or re-name the Building and/or the Property, or any portion thereof, as Landlord so desires.

16. FACSIMILE/COUNTERPART. This Fourth Amendment may be executed in counterparts and all such executed counterparts shall constitute a single agreement, binding on all of the parties hereto, their successors and assigns. Delivery by facsimile of an executed counterpart shall have the same effect as physical delivery of an original.

[Signature Page to Follow]

EXHIBIT D



Client	Kruger Clinic 21600 Highway 99 Edmonds, WA 98026 Subject	Floor Plan 2 Floor	Scale 2-D FLOOR PLANS 3DFLOORPLANS.COM 206-328-7410 fax 206-328-4764 1700 21st Avenue South Suite 100 Seattle, WA 98144 Measured: September 2009 Project: C12-491

IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment to Lease Agreement as of the day and year first above written.

LANDLORD:

PUBLIC HOSPITAL DISTRICT NO. 2
OF SNOHOMISH COUNTY, d/b/a
Verdant Health Commission

By: _____
Carl J. Zapora, Its Superintendent
Date: _____

TENANT:

PUGET SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation

By: _____
(Print Name) _____
Its: _____
Date: 7-16-14

STATE OF WASHINGTON)
) ss.
COUNTY OF KING)

I certify that I know or have satisfactory evidence that CARL J. ZAPORA is the person who appeared before me, and said person acknowledged that he signed this instrument, on oath stated that he was authorized to execute the instrument and acknowledged it as the **Superintendent** of **PUBLIC HOSPITAL DISTRICT NO. 2 OF SNOHOMISH COUNTY, d/b/a Verdant Health Commission**, to be the free and voluntary act of such party for the uses and purposes mentioned in the instrument.

Dated: _____, 2014.

_____
_____ (Name)
NOTARY PUBLIC in and for the State of Washington, residing at _____
My commission expires _____

STATE OF Washington)
) ss.
COUNTY OF Snohomish)

I certify that I know or have satisfactory evidence that Lisa Barg is the person who appeared before me, and said person acknowledged that he/she signed this instrument, on oath stated that he/she was authorized to execute the instrument and acknowledged it as the COO of PUGET SOUND GASTROENEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such party for the uses and purposes mentioned in the instrument.

Dated: July 16, 2014.

Tracy Lynn Kish
_____ (Name)
NOTARY PUBLIC in and for the State of WA, residing at Snohomish County
My commission expires 6/27/2016

TRACY LYNN KISH
Notary Public
State of Washington
My Commission Expires
June 27, 2016

KRUGER CLINIC
THIRD AMENDMENT TO LEASE

Puget Sound Gastroenterology, P.S.

THIS THIRD AMENDMENT TO LEASE AGREEMENT (this "Amendment") is made effective as of this 28th day of October, 2013 (the "Effective Date") between GRE KRUGER LLC, a Washington limited liability company ("Landlord"), and PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord and Tenant are the parties to that certain Lease dated April 28, 2009, with all addenda, exhibits, and amendments thereto (collectively, the "Lease") demising certain premises (the "Original Premises") commonly known as Suites 205, 220, 225, 245, 260, and 263 located on the Second Floor of the Building commonly known as the Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8,715 rentable square feet ("RSF"), on real property more particularly described in the Lease.

B. The parties now wish to amend the Lease set forth herein below, effective as of November 1, 2013 (the "Effective Date"), to extend the Term, vacate and return portions of the Original Premises, add additional space to the Original Premises, and to make certain other changes to the terms and conditions of the Lease as more specifically set forth below.

C. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. Recitals. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. Extension of Term. The current Term of the Lease is scheduled to expire on December 31, 2014 (the "Expiration Date"). The Term of the Lease is hereby extended for a period of two (2) additional years, so that the new Expiration Date thereof shall be December 31, 2016. The period from December 1, 2013 through and including the new Expiration Date is hereby referred to hereinafter as the "Extended Term."

3. Changes to Original Premises. Pursuant to this Amendment, the Original Premises is being revised by (i) the expansion thereof into Suite 210 containing approximately 1,200 RSF of space (collectively, the "Expansion Space"), and vacating Suites 225, 245, 263 containing approximately 1,069 RSF (collectively, the "Give Back Space"), as depicted on the diagram attached as Exhibit "A" attached hereto, under the terms and conditions set forth below.

a. Expansion Space. Effective on the "Effective Date", the Premises shall be deemed amended to be a revised total of 8,846 RSF (the "Premise') all inclusive by the addition of the Expansion Space and reduction by the Give Back Space. On or before the "Effective Date", Tenant shall provide updated insurance certificates as required by the Lease, acknowledging the revised Premises.

4. Minimum Rent. On and after the Effective Date, the Minimum Rent payable by Tenant under the Lease is hereby revised as follows:

Period	Total RSF of Premises	Annual Minimum Rental Rate Per RSF	Annual Rent	Monthly Minimum Rent
12/01/13 – 12/31/14	8,846	$24.50	$216,727.00	$18,060.58
01/01/15 – 12/31/15	8,846	$24.50	$216,727.00	$18,060.58
01/01/16 – 12/31/16	8.846	$24.50	$216,727.00	$18,060.58

5. Tenant's Pro Rata Share. Tenant's Pro Rata Share shall be amended to be 21.00%.

6. Tenant Improvements. Landlord shall build out Suite 210 per the attached plan depicted on Exhibit "B" herein, pending structural feasibility and including new building standard carpet and building standard paint throughout. Landlord shall also enclose existing server equipment located in Suite 225 providing hallway access and a ventilation fan where permitted. Landlord shall also build one (1) 4ft long x 1.5ft deep MA computer shelf, with one (1) duplex outlet and one (1) data pull string box. Otherwise Tenant accepts space as is where is condition and the Landlord shall have no other obligation to perform any other work or improvements hereto in connection with Tenant's occupancy or otherwise.

7. Security Deposit. The existing Security Deposit is hereby confirmed to be $17,459.20 per the terms of Article 11 of the Lease.

8. Miscellaneous.

a. Brokers. Landlord and Tenant each represents and warrants to the other that it has not had any dealings with any realtors, brokers or agents in connection with the negotiation of this Amendment, except that Goodman Real Estate represented the Landlord and Cavan O'Keefe and Scott Barber at CBRE, Inc., represented the Tenant in connection with this Amendment (collectively the "Brokers") and each party agrees to hold the other harmless from the failure to pay any realtors, brokers or agents (other than Brokers) and from any cost, expense or liability for any compensation, commission or changes claimed by any other realtors, brokers or agents (other than Broker) claiming by, through or on behalf of it with respect to this Amendment and/or the negotiation hereof.

b. Full Force and Effect. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect.

c. Counterparts. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

GRE KRUGER LLC, a Washington limited liability company

By: [signature]
Name: Kelli Jo Norris
Its: Authorized Signatory
Date: 11/11/13

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation

By: [signature]
Name: JACQUELYN TILLINGER
Its: CEO
Date: 11-9-13

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that [illegible] is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Authorized Signatory of GRE KRUGER LLC, a Washington limited liability company, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 11th day of November, 2013.

Raymond H. Warrick
(Signature of Notary)

Raymond H. Warrick
(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington,
residing at Seattle
My appointment expires 12/02/15

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that Jacquelyn Tillinger is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the CEO of PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 4th day of November, 2013.

Tracy Lynn Kish
(Signature of Notary)

Tracy Lynn Kish
(Legibly Print or Stamp Name of Notary)

Notary public in and for the state of Washington,
residing at Snohomish County
My appointment expires June 27, 2016

TRACY LYNN KISH
Notary Public
State of Washington
My Commission Expires
June 27, 2016

EXHIBIT A

DIAGRAM OF PREMISE

Existing (Suite 205 – 1,605 RSF) (Suite 220 – 1,119 RSF) (Suite 260 – 4,922 RSF)

Give Back (Suite 225 – 612 RSF) (Suite 245 – 140 RSF) (Suite 263 – 317 RSF)

Expansion (Suite 210 – 1,200 RSF)

EXHIBIT B

Suite 210 Tenant Improvement

51117252.1

KRUGER CLINIC
SECOND AMENDMENT TO LEASE
Puget Sound Gastroenterology, P.S.

THIS SECOND AMENDMENT TO LEASE AGREEMENT (this "Amendment") is dated as of this 17th day of July, 2012 between GRE KRUGER LLC, a Washington limited liability company ("Landlord"), and PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord and Tenant are the parties to that certain Lease dated April 28, 2009, with all addenda, exhibits, and amendments thereto (collectively, the "Lease") demising certain premises (the "Original Premises") commonly known as Suites 205, 220, 225, 260, and 263 located on the Second Floor of the Building commonly known as the Kruger Clinic, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8.575 rentable square feet ("RSF"), on real property more particularly described in the Lease.

B. The parties now wish to amend the Lease set forth hereinbelow, effective as of January 1, 2012 (the "Effective Date"), to extend the Term and add additional space to the Original Premises, and to make certain other changes to the terms and conditions of the Lease as more specifically set forth below.

C. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. . The foregoing recitals are incorporated herewith as if fully set forth herein.

2. . The current Term of the Lease is scheduled to expire on December 31, 2012 (the "Expiration Date"). The Term of the Lease is hereby extended for a period of two (2) additional years, so that the new Expiration Date thereof shall be December 31, 2014. The period from January 1, 2012 through and including the new Expiration Date is hereby referred to hereinafter as the "Extended Term." Tenant has no further right or option to extend or renew the Term of the Lease, and Paragraph K of the Basic Lease Provisions and Sections 3.2 and 3.3 of the Lease are hereby deleted in their entirety.

3. . Pursuant to this Amendment, the Original Premises is being revised by (i) the expansion thereof into Suite 245 containing approximately 140 RSF of space (collectively, the "Expansion Space"), as depicted on the diagram attached as Exhibit "A" attached hereto, under the terms and conditions set forth below.

a. Effective on the Effective Date, the Premises shall be deemed increased to a total of 8,715 RSF by the addition of the Expansion Space. Tenant shall provide updated insurance certificates as required by the Lease, acknowledging the addition of the Expansion Space to the Premises.

4. On and after the Effective Date, the Minimum Rent payable by Tenant under the Lease is hereby revised as follows:

Period	Total RSF of Premises	Monthly Minimum Rent NNN	Annual Rent NNN	Annual Minimum Rental Rate Per RSF NNN
1/1/12 – 12/31/13	8,715	$16,950.68	$203,408.16	$23.34
1/1/14 – 12/31/14	8,715	$17,459.20	$209,510.40	$24.04

5. Tenant's Pro Rata Share shall be amended to be 20.69%.

6. Upon Tenant's execution hereof, Tenant shall deposit with Landlord a Security Deposit equal to $17,459.20 per the terms of Article 11 of the Lease.

7. In connection with the foregoing changes to the Original Premises, the Carpet and Paint Allowance and Tenant Improvement Allowance described in Paragraphs R and S, respectively, of the Basic Lease Provisions in the Lease, as well as Exhibits "B" and "C" to the Lease, are hereby deleted in their entirety and replaced as follows: Tenant shall be entitled to reimbursement of its hard costs for materials related to improvements, up to $5.00 ($5.00 x 8,715 = $43,575.00) per RSF, (the "Tenant Improvement Allowance"), under the conditions set forth in Second Amendment Exhibit B attached hereto.

8.

a. Landlord and Tenant each represents and warrants to the other that it has not had any dealings with any realtors, brokers or agents in connection with the negotiation of this Amendment, except that Goodman Real Estate represented Landlord and Cavan O'Keefe and Scott Barber at CB Richard Ellis, Inc., represented Tenant in connection with this Amendment (the "Broker") and each party agrees to hold the other harmless from the failure to pay any realtors, brokers or agents (other than Broker) and from any cost, expense or liability for any compensation, commission or changes claimed by any other realtors, brokers or agents (other than Broker) claiming by, through or on behalf of it with respect to this Amendment and/or the negotiation hereof.

b. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect.

c. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

GRE KRUGER LLC, a Washington limited liability company

By:
Name: Kelli Jo Norris
Its: Authorized Signatory
Date: 7/27/2012

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation

By:
Name: JACQUELYN A TILLINGER
Its: CEO
Date: 7.29.12

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that Kelly J. Noble is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Authorized Signatory of GRE KRUGER LLC, a Washington limited liability company, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 27th day of July, 2012.

RAYMOND H. WARRICK NOTARY PUBLIC STATE OF WASHINGTON Commission Expires 12-07-2013

Raymond H. Warrick
(Signature of Notary)

Raymond H. Warrick
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at Seattle
My appointment expires 12/07/2013

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that Jacquelyn Tillinger is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the CEO of PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 24th day of July, 2012.

CATHERINE L. RICHARDSON NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 9-29-13

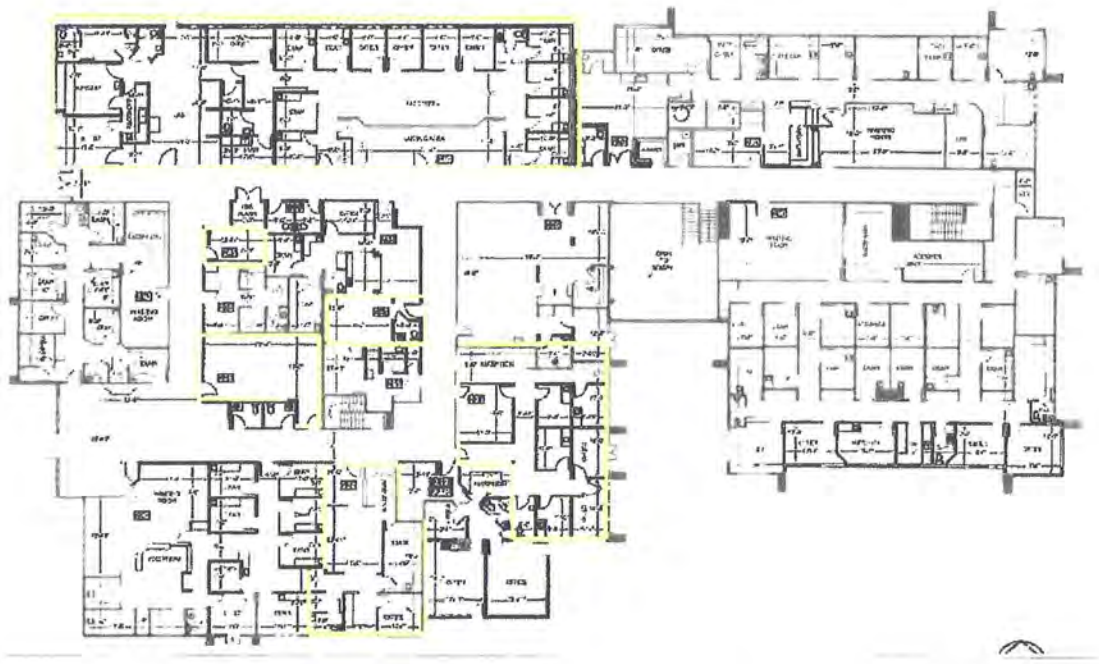
Catherine L. Richardson
(Signature of Notary)

Catherine L. Richardson
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at Kirkland
My appointment expires 09-29-2013

51117232.1

SECOND AMENDMENT
EXHIBIT A

DIAGRAM OF ORIGINAL PREMISES and EXPANSION SPACE



51117232.1

SECOND AMENDMENT
EXHIBIT B

WORK LETTER AGREEMENT

1. . Tenant shall accept the Premises "as-is" and Landlord shall have no obligation to perform any further work or improvements thereto in connection with Tenant's occupancy or otherwise. Tenant shall perform all work required to improve the Premises for Tenant's use ("Tenant's Work"), at Tenant's sole cost and expense.

Tenant may provide the Tenant Improvements described and defined below. All work shall require prior written approval by Landlord, and shall be building standard quality.

2. . Tenant shall be entitled to reimbursement of its hard costs actually incurred for labor and materials to perform the Tenant Improvements, up to a maximum total of $5.00 ($5.00 x 8,715 = $43,575) (collectively, the **"Tenant Improvement Allowance"**), under the conditions set forth below, but payment or nonpayment thereof shall not relieve Tenant of its responsibility and payment for all costs thereof. If Tenant is not then in uncured default under this Lease, Landlord shall reimburse the Tenant Improvement Allowance within thirty (30) days after final completion of the work and receipt by Landlord of lien releases from all contractors and suppliers whom Tenant has contracted with in connection with such work. If Tenant fails to request the Tenant Improvement Allowance after satisfaction of the preconditions set forth above by January 31, 2013, Tenant shall be conclusively deemed to have waived any right to receive the Tenant Improvement Allowance.

3. . Any work proposed by Tenant (the **"Tenant Improvements"**) shall be subject to Landlord's reasonable prior approval and shall be subject to the other terms and conditions of this Exhibit. All architectural, engineering and other design fees shall be paid by Tenant. Tenant shall use its architect, engineers and other design professionals, all of whom shall comply with any applicable licensing or governmental requirements of the city, county, and/or state having jurisdiction. Tenant shall provide to Landlord its plans for any desired Improvements in form suitable for permit application (collectively, the **"Working Drawings"**). The Working Drawings shall include architectural, structural, plumbing, mechanical, electrical, and fire protection drawings as required. Working Drawings, and all changes thereto, shall be subject to Landlord's reasonable written approval. If Landlord denies its approval, it shall specify the reasons for doing so in reasonable detail.

4. . All contractors and subcontractors participating in construction of the Tenant Improvements shall be reputable and shall meet all licensing and insurance requirements of the state in which the Property is situated, and be reasonably satisfactory to Landlord. Tenant's choice of subcontractors shall not materially affect any guaranties or warranties relating to the Building or Building systems. Tenant shall utilize contractors from a list previously approved by Landlord; use of any contractor not previously approved by Landlord shall be subject to Landlord's express prior approval. All Tenant Improvements shall be completed under the same general contractor (**"Contractor"**) unless otherwise agreed by Tenant. All contracts between Tenant and Tenant's Contractor(s) for the Improvements shall contain a provision requiring the Contractor to notify Landlord immediately in writing if Tenant fails to pay such Contractor according to the terms of the contract. Tenant shall obtain at its sole cost and provide to Landlord payment and performance bonds for all Improvements prior to the commencement of construction, and shall further provide Landlord with:

(a) Contractor's state contractor registration numbers;
(b) Complete list of subcontractors with name, telephone number, address and contact name;
(c) A set of Working Drawings approved by the municipality issuing the Building permit;
(d) A copy of the Building permit; and
(e) Copies of bonds in place, if required by Landlord.

Prior to the commencement of construction, Tenant and Tenant's Contractor shall attend a preconstruction meeting with Landlord's Construction Representative and/or Property Manager.

5. . Tenant will provide a draft Work Schedule to Landlord seven (7) days prior to commencement of construction. The Work Schedule is subject to Landlord's reasonable approval.

6. . Tenant shall cause the approved Working Drawings to be submitted to the appropriate governmental agencies for plan review and building permit. Revisions which may be required by governmental agencies as a result of the plan review process shall be reviewed by Tenant and Landlord and modifications reflecting same shall be mutually agreed upon in a timely manner. Tenant shall diligently pursue issuance of all permits and approvals required for the Tenant Improvements.

7. . Tenant shall complete all Tenant Improvements at Tenant's sole risk, cost and expense, including without limitation the costs of changes, code compliance work, and upgrades to the base, shell & core of the Building or to any major Building systems such as fire, life safety, electrical, mechanical, and structural, as may be required by the Working Drawings or applicable permitting authorities, and whether or not such changes or upgrades are due to the fact that such work is prepared on an unoccupied basis. The construction shall be performed in a good and workmanlike manner and in compliance with all applicable rules, laws, codes and regulations, including all applicable safety procedures established by Landlord's Construction Representative. All construction of the Tenant Improvements shall be coordinated through Landlord's Construction Representative. Tenant shall obtain Landlord's written approval prior to the performance of any additional Tenant Improvement work, such approval not to be unreasonably withheld, delayed, or conditioned. If, at any time prior to completion of the Improvements, Tenant or Tenant's Contractor requests a change order or orders, which in the aggregate, exceed ten percent (10%) of the amount of any payment and performance bond required by Landlord, Tenant or Tenant's Contractor shall obtain Landlord's written approval prior to the performance of the additional work contemplated by such change order or orders. Landlord's consent shall not be unreasonably withheld, but in any event, Tenant shall cause the amount of the bonds to be increased to cover the cost of the additional work. If Tenant or Tenant's Contractor fails to obtain Landlord's consent for the additional work, Tenant shall be in default under the Lease and Tenant's Contractor shall be deemed to have waived and released its lien rights for the additional work for which no consent was obtained. The following conditions during construction of the Tenant Improvements shall apply to Tenant and Tenant's Contractor.

(a) Tenant's Contractor shall diligently perform all work in a manner and at times that do not impede or delay Landlord in the completion of any other work being performed by Landlord or its contractors to the Building or any other portion of the Building or Property.

(b) Tenant's Contractor shall provide written notice to Landlord's Construction Representative of any work to be done on weekends or other than normal job hours, and Landlord shall provide keys and/or security access cards for needed after-hours access.

(c) All deliveries shall be through service entries except as pre-scheduled for oversized items. Contact Landlord's Property Manager for authorization to route any large equipment or materials through non service areas.

(d) Use of building elevators for delivery of materials shall be arranged through Landlord's Property Manager. Elevator pads shall be used at all times during construction. In buildings with service elevators, movement of all tools, materials and equipment shall be in service elevators only.

(e) Use of Building or Property utilities shall be arranged through Landlord's Property Manager and Landlord reserves the right to charge Tenant the costs therefor.

(f) Common Areas shall be kept clean at all times. The Premises shall be maintained in a clean and orderly condition.

(g) Tenant's Contractor to coordinate all interruptions to the fire alarm and sprinkler systems with Landlord's Construction Representative twenty-four (24) hours prior to interruption of service. Only Landlord's Construction Representative may request interruption of service.

(h) Tenant's Contractor shall obtain written approval from Landlord's Construction Representative prior to any penetration of the floor slab. Landlord's approval shall not relieve Tenant or Tenant's Contractor from responsibility for damage to Landlord's and/or other Tenant's premises because of such penetration. Tenant's Contractor shall accept the Premises prior to starting any trenching operations. Any roof penetration or modification to the Building structure shall be completed by the Landlord's designated contractor at the Tenant's expense and only after receiving prior written approval from the Landlord's Construction Representative. Landlord's approval shall not relieve Tenant or Tenant's Contractor from responsibility for damage to Landlord's and/or other tenant's premises because of such work.

(i) Tenant's Contractor shall store all construction materials and contain all operations within the Premises and such other space as Landlord's Construction Representative may direct from time to time, following reasonable prior notice. With regard to space outside of the Premises, Landlord's Construction Representative shall have the right to reassign such space and require Tenant's Contractor to move its materials and/or operations to such other space as directed from time to time. Tenant shall promptly move to such other space as directed and shall take all steps necessary to avoid interference or delays with other work. All trash, construction debris and surplus construction materials shall be promptly removed from the Building Site.

(j) Security of tools, equipment and materials is the responsibility of the Tenant's Contractor.

(k) Tenant's Contractor, subcontractors and suppliers shall park in areas as designated by the Landlord's Property Manager.

(l) Tenant's Contractor or subcontractors shall not post signs on any part of the Building, Building Site or the Premises.

(m) During construction of the Tenant Improvements, the Premises shall be open during working hours for inspection by the Landlord's Construction Representative and Property Manager. Upon completion of the Tenant Improvements, the Landlord's Construction Representative and Property Manager shall perform a final inspection for conformance of the Improvements to the Building Standards.

(n) Any and all work performed by Tenant's Contractor shall be performed in a manner to avoid any labor dispute which results in a stoppage or impairment of work, deliveries or any other service in the building. If there shall be any such stoppage or impairment as the result of any such labor dispute, Tenant shall immediately undertake such action as may be necessary to eliminate such dispute or potential dispute, including, without limitation, (a) removing all disputants from the job site until such time as the labor dispute no longer exists, (b) seeking a temporary restraining order and other injunctive relief with regard to illegal union activities or a breach of contract between Tenant and Tenant's Contractor, and (c) filing appropriate unfair labor practice charges.

8. . Tenant shall keep the Premises and the Building free and clear of liens of any kind. If any such liens are filed, Tenant shall have thirty (30) days from the receipt of notice from Landlord informing Tenant of such filing to either remove such liens or to provide a bond (or other security acceptable to Landlord and its lender) in the amount of 150% of the lien claim (or a greater amount, if so required by Landlord's lender) indemnifying Landlord as security for the removal or certification thereof. Tenant agrees to hold harmless and indemnify Landlord in the event of any breach of Tenant's obligations, and upon completion of the Tenant Improvements, shall provide written lien releases from all contractors, suppliers, and laborers, mechanics, or other materialmen providing materials, labor, or services toward such Tenant Improvements.

9. . During construction, Tenant or its Contractor shall procure and maintain in effect the following insurance coverages with an insurance company or companies authorized to do business in the State in which the Property is situated:

(a) Workmen's Compensation - Statutory Limits for the State in which the Property is situated, together with "ALL STATES," "VOLUNTARY COMPENSATION" AND "FOREIGN COMPENSATION" coverage endorsements;

(b) Employer's Liability (Stop Gap) Insurance with a limit of not less than $500,000.00;

(c) Commercial General Liability - at least $1,000,000 Combined Single Limit, including Personal Injury, Contractual and Products/Completed Operations Liability naming Landlord and Tenant as additional insured. Coverage must be primary and non-contributing and include the following:

(i) Premises - Operations
(ii) Elevators and Hoists
(iii) Independent Contractor
(iv) Contractual Liability assumed under the construction contract
(v) Completed Operations - Products
(vi) Explosion, Underground and Collapse (XUC) Coverage

(d) Automobile Liability - Including Owned, Hired and Non-owned licensed vehicles used in connection with performance of the construction work of at least: $1,000,000 per occurrence, $3,000,000 general aggregate (including umbrella limits). Coverage must include the following:

(i) Owned vehicles
(ii) Leased vehicles
(iii) Hired vehicles
(iv) Non-owned vehicles

(e) Procure or cause contractor to procure and maintain installation floater insurance to protect against the risk of physical damage until acceptance of the construction work;

(f) Furnish the Landlord with certificates of insurance evidencing such coverage prior to the commencement of the construction work. All insurance shall be carried in companies reasonably acceptable to the Landlord;

(g) The following statement shall appear in each certificate of insurance provided Landlord by Tenant hereunder:

"It is agreed that in the event of any material change in, cancellation or non-renewal of this policy, the Company shall endeavor to give ten (10) days prior notice to [Landlord]."

(h) During construction of the Tenant Improvements, both parties shall give prompt notice to the other of all losses, damages, or injuries to any person or to property of Tenant, Landlord or third parties. Landlord or Tenant shall promptly report to the other all such claims of which that party has notice, whether related to matters insured or uninsured. No settlement or payment for any claim for loss, injury or damage or other matter as to which one party may have an obligation for any payment or reimbursement, shall be made by the other without the written approval of the affected party;

(i) The carrying of any of the insurance required hereunder shall not be interpreted as relieving the insuring party of any responsibility to the other party, and the other party does not waive any rights that it may have against the other party and/or its representatives for any expense and damage to persons and property (tangible and intangible) from any cause whatsoever with respect to the insuring party's work; and

(j) Landlord and Tenant shall assist and cooperate with any insurance company in the adjustment or litigation of all claims arising under the terms of this Section.

10. . Tenant hereby appoints _____ to act on its behalf and represent its interests with respect to all matters requiring Tenant action in this Exhibit. All matters requiring the consent, authorization or other actions by Tenant with respect to matters set forth in this Section shall be in writing and signed by the aforementioned person. No consent, authorization, or other action by Tenant with respect to the matters set forth in this Exhibit shall bind Tenant unless in writing and signed by the aforementioned person. Landlord hereby appoints Goodman Real Estate to act on its behalf and represent its interests with respect to all matters requiring Landlord action in this Exhibit. All matters requiring the consent, authorization or other actions by

Landlord with respect to matters set forth in this Section shall be in writing and signed by the aforementioned person. No consent, authorization, or other action by Landlord with respect to the matters set forth in this Exhibit shall bind Landlord unless in writing and signed by the aforementioned person.

11. . Upon the expiration or termination of this Lease, Landlord may elect to require Tenant to restore, at Tenant's sole cost, the Premises to its condition existing as of the date hereof, unless Landlord states at the time in approves the Working Drawings that all or portions of the Tenant Improvements shall remain on the Premises following such expiration or earlier termination.

12. . Upon completion of the Tenant Improvements, Tenant's Contractor shall submit to Landlord's Construction Representative: (i) copies of all as-built Construction Documents and specifications (or marked-up construction drawings) indicating reconfiguration of the Premises, including changes to the mechanical, electrical, architectural, plumbing, cabling, sprinkler and fire alarm, as applicable; and (ii) original permit with inspector(s) final acceptance.

13. . Legal title to all Tenant Improvements shall immediately vest in Landlord upon substantial completion thereof.

14. . The Landlord shall not be liable for any injury, loss or damage to any person (including death) or property on or about the Building or Premises during the performance of the work, unless caused by the Landlord, its employees or agents, and Tenant shall indemnify and hold the Landlord harmless against and from any such liability, and any costs or charges (including, without limitation, reasonable attorney's fees and court costs) which the Landlord may incur on account of any such injury, loss or damage. Tenant's Contractor shall carry commercial general liability insurance which shall include coverage of the foregoing contractual liability. Landlord's collection rights to any amounts due shall be deemed the same as for additional rent under the Lease.

KRUGER CLINIC
FIRST AMENDMENT TO LEASE AGREEMENT

Puget Sound Gastroenterology, P.S.

This FIRST AMENDMENT TO LEASE AGREEMENT (this "Amendment") is made effective as of June 8, 2011 (the "Effective Date") by and between GRE KRUGER LLC, a Washington limited liability company ("Landlord"), and PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation ("Tenant"), with reference to the following:

RECITALS

A. Landlord and Tenant are the parties to that certain Kruger Clinic Lease Agreement dated April 28, 2009, with all addenda, exhibits, and amendments thereto (collectively, the "Lease") demising certain premises (the "Original Premises") commonly known as Suites 205, 220, 225, 260, and 263, as depicted on the diagram attached as Exhibit "A-1" attached hereto, located on the Second Floor of the Building commonly known as the Kruger Clinic Building, having a street address of 21600 Highway 99, Edmonds, Snohomish County, Washington, which Premises contain approximately 8,575 rentable square feet ("RSF"), on real property more particularly described in the Lease.

B. The parties now wish to amend the Lease set forth hereinbelow, effective as of the Effective Date, to extend the Initial Term and to make certain other changes to the terms and conditions of the Lease as more specifically set forth below.

C. Capitalized terms used herein shall have their meanings set forth in the Lease, except as otherwise defined herein.

Accordingly, in consideration of the foregoing and the mutual covenants herein contained, it is hereby agreed as follows:

AGREEMENT

1. Recitals. The foregoing recitals are incorporated herewith as if fully set forth herein.

2. Negotiation of Further Changes to Lease. The parties are currently negotiating certain changes to the Original Premises, a further extension of the Term, and certain other changes to the terms and conditions of the Lease. From and after the date hereof, the parties contemplate continuing such negotiations. Each party shall be entitled to negotiate such revised terms in its sole discretion; however, the parties agree to respond promptly and in good faith to proposals and negotiations, and shall reasonably cooperate to achieve the following milestones:

DATE	ACTION
Final approval of Space Plan for TI's to the expansion space and the original Premises.	August 15, 2011
Final approval of any required structural work for TI's	September 15, 2011
Final approval of Working Drawings for TI's	October 15, 2011
Final Pricing of Working Drawings for TI's	October 31, 2011
Final approval of detailed Lease Amendment terms and conditions relating to proposed changes to the original Premises (e.g., expansion/contraction of space; rent; term extension and additional extension options; terms of a Right of First Offer for Suite 240; expansion space and TI delivery schedules, and allocation of cost responsibility for planned new TI's).	November 15, 2011
Final Amendment executed	December 15, 2011

3. Extension of Initial Term. The current Initial Term of the Lease is scheduled to expire on December 31, 2011 (the "Expiration Date"). The Initial Term of the Lease is hereby extended for a period of one (1) additional year, so that the new Expiration Date is December 31, 2012. There shall be no change to the Minimum Rent or Additional Rent payable by Tenant during such one-year extension.

4. Miscellaneous.

a. Brokers. Landlord and Tenant each represents and warrants to the other that it has not had any dealings with any realtors, brokers or agents in connection with the negotiation of this Amendment, except that Cavan O'Keefe and Scott Barber at CB Richard Ellis, Inc., represented Tenant in connection with this Amendment (the "Broker") and each party agrees to hold the other harmless from the failure to pay any realtors, brokers or agents (other than Broker) and from any cost, expense or liability for any compensation, commission or changes claimed by any other realtors, brokers or agents (other than Broker) claiming by, through or on behalf of it with respect to this Amendment and/or the negotiation hereof.

b. Full Force and Effect. Except as expressly amended herein, the Lease is unmodified and remains in full force and effect.

c. Counterparts. This Amendment may be executed in counterparts, each of which, when combined, shall constitute one single, binding agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment the day and year first above written.

LANDLORD:

GRE KRUGER LLC, a Washington limited liability company

By: [signature]
Name: Kelly Downs
Its: Authorized Signatory
Date: 6/23/11

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation

By: [signature]
Name: [illegible] MD
Its: CEO
Date: 6-16-11

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that Kelly Johnson is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Authorized Signer of GRE KRUGER LLC, a Washington limited liability company, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 23rd day of June, 2011.

Raymond H. Warrick
(Signature of Notary)

RAYMOND H. WARRICK
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at SEATTLE
My appointment expires 12/07/2013

RAYMOND H. WARRICK Commission Expires NOTARY PUBLIC 12-07-2013 STATE OF WASHINGTON

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that JACQUELYN ACCETTULLO is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the CEO of PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such entity for the uses and purposes mentioned in the instrument.

Dated this 16th day of JUNE, 2011.

Bianca T. Williams
(Signature of Notary)

BIANCA T. WILLIAMS
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at 9223 SAND POINT WAY NE SEATTLE WA 98115
My appointment expires 12/29/12

BIANCA T. WILLIAMS Commission Expires NOTARY PUBLIC 12-29-12 STATE OF WASHINGTON

KRUGER CLINIC
LEASE AGREEMENT

BETWEEN

GRE KRUGER LLC,

LANDLORD

AND

PUGET SOUND GASTROENTEROLOGY, P.S.

TENANT

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Page

KRUGER CLINIC LEASE AGREEMENT
(NNN)

Landlord hereby leases to Tenant and Tenant hereby leases and accepts from Landlord the premises hereinafter described in the terms and conditions set forth in this Lease Agreement, hereinafter called "this Lease."

BASIC LEASE PROVISIONS

A.	Lease Date:	April 28, 2009
B.	Landlord:	GRE KRUGER LLC
C.	Tenant:	Puget Sound Gastroenterology, P.S.
D.	Reserved.	
E.	Property/Building:	The project including existing parking areas on property particularly described and depicted on **Exhibit "A"** (the **"Property"**), commonly known as the Kruger Clinic Building; (the "**Building**"), located at 21600 Highway 99, Edmonds, Snohomish County, Washington 98026.
F.	Premises Rentable Area:	The area shown on **Exhibit "B,"** containing approximately 8,575 rentable square feet (**"RSF"**), known as Suites 205, 220, 225, 260 and 263 located on the 2nd floor of the Building.
G.	Building Rentable Area:	42,121RSF.
H.	Tenant's Pro Rata Share:	4.91%
I.	Permitted Use:	Solely for use as a gastroenterology clinic; and as an ambulatory surgery center available for use only by physicians employed by Tenant; and for no other use or purpose.
J.	Initial Term:	Two (2) years, commencing on the Lease Commencement Date and terminating on the Expiration Date (the **"Initial Term"**).
K.	Extension Option(s):	Three (3) options, as follows: The First Extended Term option shall be for a period of five (5) years; the Second Extended Term Option shall be for a period of five (5) years; and the Third Extended Term Option shall be for a period of five (5) years (the **"Extended Terms"**). The Initial Term, together with any Extended Terms duly exercised by Tenant, are referred to collectively in this Lease as the **"Lease Term."**
L.	Possession Date:	The Lease Commencement Date.
M.	Lease Commencement Date:	January 1, 2010
N.	Expiration Date:	11:59 p.m. on the day prior to the second (2nd) anniversary of the Commencement Date.

O. Minimum Rent Commencement Date: The Lease Commencement Date

P. Minimum Rent:

Lease Year	Minimum Annual Rent/RSF (NNN)	Minimum Monthly Rent (NNN)
1	$23.00	$16,435.42
2	$23.69	$16,928.48
First Extended Term:		
1	$23.34	$16,678.38
2	$24.04	$17,178.73
3	$24.76	$17,694.09
4	$25.50	$18,224.91
5	$26.27	$18,771.66
Second Extended Term	Fair Market Rental Value (See **Section 3.3**)	
Third Extended Term	Fair Market Rental Value (See **Section 3.3**)	

Q. Security Deposit: $2,191.37 (already on deposit with Landlord).

R. Carpet and Paint Allowance: Maximum of $5.00 per RSF of the Premises.

S. Tenant Improvement Allowance: $241,172.00 (the "**Basic Allowance**") and $144,703.00 (the "**Additional Allowance**") and, together with the Basic Allowance, the "**Tenant Improvement Allowance**") (both of the foregoing shall be payable only if Tenant duly exercises the First Extended Term Option).

T. Right of First Opportunity: See **Section 1.4** below.

U. Landlord's Address for Notices: c/o Goodman Real Estate, Inc.
509 Olive Way, Suite 1062
Seattle, WA 98101
Attention: Serena Dickerson

V. Landlord's Address for Rent Payments: c/o Goodman Real Estate, Inc.
509 Olive Way, Suite 1062
Seattle, WA 98101
Attention: Serena Dickerson

W. Tenant's Address for Notices: The Premises

X.	Landlord's Broker:	Paul Carr & Steve Perovich, CB Richard Ellis, Inc.
Y.	Tenant's Broker:	Cavan O'Keefe, CB Richard Ellis, Inc.

ARTICLE 1

PREMISES

1.1 Construction; Suitability. Landlord shall have no obligation to perform any construction or other work to the interior or exterior of the Premises or elsewhere at the Property; provided that nothing herein shall be construed to limit Landlord's obligation to provide the Carpet and Paint Allowance as more specifically described in **Exhibit "C"** attached hereto. Except as expressly provided herein, Tenant acknowledges that neither Landlord, nor any agent or representative of Landlord, has made any representation or warranty with respect to the suitability of the Premises for the use set forth in the Basic Lease Provisions, and that Tenant has entered into this Lease based solely upon its own investigation and inspection of the Property and the Premises. Landlord does not represent, and Tenant does not rely on the fact that any specific tenant or tenants will occupy space in the Property during the Term of this Lease. Landlord reserves and excepts from the Premises the roof and exterior walls of the Building of which the Premises are a part.

1.2 Location. The parties acknowledge that **Exhibit "A"** describes the current perimeter of the Property and sets forth a general layout of the Property, and shall not be deemed a representation by Landlord that the Property shall always be constructed as indicated thereon or that any tenants or occupants designated by name or nature of business thereon shall conduct business in the Property during the Term of this Lease; and, subject to compliance with all applicable laws and governmental requirements and provided that there is reasonable access to the Premises, Landlord may in its sole discretion increase, decrease or change the number, location, and dimensions of the buildings, the premises therein, driving lanes, driveways, walkways, parking places and other improvements shown on **Exhibit "A,"** and Landlord reserves the right to make additions and alterations, including the addition of pay telephones, to all buildings constructed in the Property, and to change the name of the Building, the Property, or any of the other buildings thereon from time to time. References to "this Lease" include all exhibits and matters incorporated by reference as part of this Lease. In the event a portion of the Premises, Building, or Property is damaged or any other event or change occurs which alters the RSF of any or all of the foregoing, Landlord shall appropriately adjust the foregoing areas and Tenant's Pro Rata Share thereof. Landlord reserves the right to remeasure the Premises and the Building in accordance with provisions of the Standard Method for Measuring Floor Area in Office Buildings published by the Building Owners and Managers Association (ANSI/BOMA Z65.1-1996) applicable to multi-tenant office buildings, or any other method selected by Landlord, to establish the RSF thereof, and appropriate adjustments (if any) shall be made to Minimum Monthly Rent, Tenant's Pro Rata Share, and other terms of this Lease dependent on the RSF of the Premises and/or Building. Tenant shall be deemed to have accepted any such remeasurement and/or adjustment unless Tenant objects to same within thirty (30) days after receipt of notice thereof from Landlord.

1.3 Termination of Prior Leases. The parties hereby confirm that, effective as of the Lease Commencement Date hereof, the prior Leases for Suite 205 dated December 20, 2000, for Suite 220 dated May 1, 2004, for Suite 225 dated September 11, 1996, for Suite 260 dated November 15, 2001, and for Suite 263 dated October 1, 2006, between Landlord's predecessor in interest and Tenant, are hereby deemed terminated and of no further force and effect. The parties shall have no further obligations or liabilities thereunder except as may have already accrued.

1.4 Right of First Offer. Landlord hereby grants Tenant a one-time right of first offer ("**ROFO**") to lease replacement premises if, during the Term hereof, Landlord ever elects in its sole discretion to either (i) renovate all or substantially all of the Building, (ii) demolish the Building, or (iii) construct a new medical office building adjacent to the Building (each of which, a "**New Development**"). Tenant's ROFO shall become effective only when Landlord elects to proceed with any such New Development. Tenant acknowledges that Landlord may give Landlord's Notice (described below) at any time. Before Landlord makes any written proposal to any other third party for space in any New Development, Landlord shall give Tenant written notice ("**Landlord's Notice**") that such space may become available, and the terms and conditions under which Landlord is willing to offer such space. Tenant shall have twenty (20) business days after Landlord gives Landlord's Notice (the "**Election Period**") in which to give Landlord written notice ("**Election Notice**") of Tenant's election to exercise its ROFO to lease space comparable in size to the Premises in the New Development. In the event Tenant duly and timely delivers its Election Notice to Landlord, the space shall be leased by and to Tenant upon and subject to the same terms and conditions contained in Landlord's Notice. Within a reasonable period after receipt of the Election Notice, Landlord shall prepare an amendment to this Lease or a new Lease, as Landlord reasonably deems required, to document the foregoing election by Tenant, and Tenant shall promptly execute same after receipt thereof. However, if Tenant fails to so execute such amendment, Landlord shall have the right (but not the obligation) to treat such failure as Tenant's election not to lease such space. If Tenant either fails or elects not to exercise its ROFO by not giving its Election Notice within the Election Period, then in any such event Tenant's ROFO shall be null and void and at any time thereafter Landlord shall be free to lease space in the New Development to any third party on any terms and conditions whatsoever. This ROFO is personal to Tenant and may not be used by, and shall not be transferable or assignable (voluntarily or involuntarily) to any other person or entity, and notwithstanding anything to the contrary, Tenant shall remain liable for all obligations under the Lease.

1.5 Exhibits. The following drawings and special provisions are attached as exhibits and made a part of this Lease:

Exhibit "A" – Legal Description
Exhibit "B" – Space Plan
Exhibit "C" – Allowances
Exhibit "D" – Rules and Regulations

ARTICLE 2

BUSINESS RIGHTS AND RESTRICTIONS

2.1 Use. The Premises shall be used solely for the Permitted Use set forth in the Basic Lease Provisions and under the Trade Name set forth in the Basic Lease Provisions and for no other purpose or use whatsoever.

2.2 Restrictions. Tenant shall not, without Landlord's prior written consent, which consent Landlord may withhold in its sole discretion: (a) conduct any auction or bankruptcy sales; (b) conduct any fire sale; (c) conduct any close-out sale except at the expiration of the Lease Term; (d) sell any so-called "surplus," "Army and Navy," or "secondhand" goods, as those terms are generally used at this time and from time to time hereafter; (e) permit anything to be done on the Premises which will in any way obstruct, interfere with or infringe on the rights of other occupants or invitees of the Property; (f) install or erect any satellite dish or other roof- or building-mounted equipment; (g) install any automated teller or cash machines ("**ATMs**"), appliances, video games, arcade games, pinball machines, or pay telephones in or about the Premises; or (h) bring or keep on the Premises any item or thing or permit any act thereon which is prohibited by any law, statute, ordinance or governmental regulation now

in force or hereinafter enacted or promulgated, or which is prohibited by any Standard form of fire insurance policy.

ARTICLE 3

TERM

3.1 Duration. The Term hereof shall commence on the Lease Commencement Date defined in the Basic Lease Provisions and shall terminate on the Expiration Date defined in the Basic Lease Provisions, unless earlier terminated or extended as set forth elsewhere herein.

3.2 Options to Extend. Provided that Tenant is not in default at the time of Tenant's exercise notices described below, or at the time of commencement of each Extended Term defined below, Tenant shall have the right to extend the term of this Lease for the Extended Terms described in the Basic Lease Provisions. Tenant may exercise an extension option by delivering to Landlord written notice of Tenant's intention to exercise such option (the **"Option Notice"**) not later than twelve (12) months prior to the Expiration Date of the then-effective Term. Each such Extended Term shall be on all of the terms and conditions contained in this Lease, except (i) Minimum Monthly Rent during the First Extended Term shall be as set forth in the Basic Lease Provisions; (ii) Minimum Monthly Rent during the Second and Third Extended Terms shall be Fair Market Rental Value as described below; (iii) at the commencement of the First Extended Term if duly exercised by Tenant, Tenant shall be entitled to the Allowances described in **Exhibit "C"** attached hereto; and (iv) there shall be no free rent periods, tenant improvement allowances (except as specifically set forth above) or further extension options. The options to extend the Term of this Lease are exercisable only by the original Tenant which is named in the Basic Lease Provisions, and an assignee or sublessee pursuant to a Permitted Transfer, and are not assignable or transferable. Once delivered, an Option Notice cannot be cancelled or revoked.

3.3 Minimum Monthly Rent During Second and Third Extended Terms. Minimum Monthly Rent during the Second and Third Extended Terms shall be Fair Market Rental Value. The term **"Fair Market Rental Value"** shall be the rental rate that comparable medical office space for the same term of the Extended Term would command on the open market at the time of commencement of the Extended Term, determined in the manner set forth below. For purposes hereof, the term "comparable Premises" shall mean medical office space similar in size and location to the Premises, in comparable buildings, with comparable views, and with similar improvements and amenities. Provided, however, in no event shall the Minimum Monthly Rent during the applicable Extended Term be less than the Minimum Monthly Rent in effect during the last year of the previously-effective Term.

(i) If Landlord and Tenant cannot agree upon the Fair Market Rental Value of the Premises within twenty (20) days after Landlord's receipt of the applicable Option Notice, then Landlord and Tenant shall agree within ten (10) days thereafter on one real estate appraiser (who shall be a Member of the American Institute of Real Estate Appraisers or equivalent) who will determine the Fair Market Rental Value of the Premises. If Landlord and Tenant cannot mutually agree upon an appraiser within said ten (10) day period, then one M.A.I. qualified appraiser shall be appointed by Tenant and one M.A.I. qualified appraiser shall be appointed by Landlord within ten (10) days of notice by one party to the other of such disagreement. The two appraisers shall determine the Fair Market Rental Value of the Premises within twenty (20) days of their appointment; provided, however, if either party fails to appoint an appraiser within such ten (10) day period, then the determination of the appraiser first appointed shall be used. The appraisers appointed shall proceed to determine Fair Market Rental Value within twenty (20) days following such appointment. If said appraisers should fail to agree, but the difference in their conclusions as to Fair Market Rental Value is ten percent (10%) or less of the lower of the two appraisals, the Fair Market Rental Value shall be deemed the average of the two.

(ii) If the two appraisers should fail to agree on the Fair Market Rental Value, and the difference between the two appraisals exceeds ten percent (10%), then the two appraisers thus appointed shall appoint a third M.A.I. qualified appraiser, and in case of their failure to agree on a third appraiser within ten (10) days after their individual determination of the Fair Market Rental Value, either party may apply to the Presiding Judge of the Superior Court for Snohomish County, Washington, requesting said Judge to appoint the third M.A.I. qualified appraiser. The third appraiser so appointed shall promptly determine the Fair Market Rental Value of the Premises and the average of the appraisals of the two closest appraisers shall be used. The fees and expenses of said third appraiser or the one appraiser Landlord and Tenant agree upon, shall be borne equally by Landlord and Tenant. Landlord and Tenant shall pay the fees and expenses of their respective appraiser if the parties fail to agree on a single appraiser. All M.A.I. appraisers appointed or selected pursuant to this subsection shall have at least ten (10) years experience appraising commercial properties in Edmonds/South Snohomish County area.

(iii) The determination of Fair Market Rental Value pursuant to this paragraph shall be final, conclusive and binding upon both parties.

ARTICLE 4

RENT

4.1 Payment. Tenant shall pay to Landlord without prior demand, abatement, deduction, set-off, counter claim or offset (except as otherwise expressly permitted elsewhere in this Lease), for all periods during the Lease Term, all sums provided in this **Paragraph 4.1** and all other additional sums as provided in this Lease, at the address set forth in the Basic Lease Provisions, payable in lawful money of the United States of America on the first day of each month, except that the Minimum Monthly Rent due for the first month (or first partial month) shall be prepaid on the date of execution of the Lease by Tenant. All sums of money required to be paid pursuant to the terms of this Lease are hereby defined as **"rent"** or **"Rent,"** including all sums as provided in **Paragraphs 4, 5, 6, 7, 8,** and **9** and provided elsewhere in this Lease, whether or not the same are designated as such. All Rent other than Minimum Monthly Rent is sometimes referred to herein as **"Additional Rent."** Landlord's acceptance of Tenant's bank check or other funds shall not be deemed a waiver of Landlord's right to thereafter demand and receive timely payment in immediately available funds.

(a) Minimum Monthly Rent. Commencing on the Rent Commencement Date, Tenant shall pay to Landlord Minimum Monthly Rent on a triple-net basis at the monthly rate with applicable increases as provided in the Basic Lease Provisions.

(b) Late Fee. If Tenant shall fail to pay when due any installment of Minimum Monthly Rent or any other sums due under this Lease, a late charge equal to the greater of (i) Five Hundred Dollars ($500), or (ii) five percent (5%) of the overdue amount shall be payable by Tenant to reimburse Landlord for costs relating to collecting and accounting for said late payment(s).

4.2 Lease Year. The term **"Lease Year"** shall mean each period of twelve (12) or less consecutive months which ends on December 31 of each calendar year during the Lease Term or any Extended Term, and the period from the last December 31 during the Lease Term or any Extended Term to and including the last day of the Lease Term or any Extended Term during the next calendar year. The first and last Lease Years may be less than twelve (12) months.

ARTICLE 5

COMMON AREA

5.1 Definition. The **"Common Area"** is that area within the Property which is neither occupied by buildings (excluding roof overhangs and canopies, columns supporting roof overhangs and canopies, and subsurface foundations) nor devoted permanently to the exclusive use of a particular tenant, except that areas containing pylon signs and buildings or subsurface utilities which are used with respect to the operation of the Common Area shall be deemed to be a part of the Common Area. The Common Area includes each area designated as a building area on **Exhibit "A"** until such time as it is improved with a building.

5.2 Use. During the Term hereof, Tenant, its subtenants, concessionaires, licensees, invitees, customers, and employees shall have the nonexclusive right to use the Common Area with Landlord, other owners of portions of the Property, other tenants, and their respective subtenants, concessionaires, licensees, invitees, customers, and employees, subject to the provisions of this Lease.

5.3 Maintenance and Operation. **"Operating Expenses"** shall include, but not be limited to, the costs and expenses of operating, managing, lighting, repairing, replacing (when repairing will be uneconomic), painting, and maintaining the Common Areas and the remainder of the Property in reasonably good and sanitary order, condition, and repair, including without limitation, the costs and expenses of the following: (l) property management fees; (2) cleaning and removing rubbish and dirt, and recycling expenses; (3) labor costs for personnel performing services in connection with the operation, repair and maintenance of the Common Area or Property and the payroll taxes and fringe and other benefits related thereto; (4) all utility services utilized in connection with the Common Area and Property which are not separately metered to the tenants, including but not limited to heating, ventilation, and air conditioning (**"HVAC"**), if any; as well as electricity, gas, water charges, sewer charges, hook-up fees, and cost of installing, maintaining and repairing the Property's intrabuilding network cabling, repair and/or installation of any fire protection systems, security alarm systems, lighting systems, electrical systems and any other utility systems; (5) cleaning, maintaining, repairing, replacing, and re-marking paved and unpaved surfaces, curbs, signs, landscaping, lighting and electrical facilities, drainage, elevators, escalators, meters, breakers, security systems, life safety systems, irrigation systems, window, fences and gates, wiring, and repairs, modifications, additions and replacements to the foregoing whether or not necessitated by any present or future law, statute, regulation, or directive of any governmental agency, and other similar items; (6) all premiums on, deductibles, retentions, and claims not covered by, worker's compensation, casualty, public liability, property damage, loss of rent, fire and extended coverage, and other insurance on the Common Area and Property obtained by Landlord pursuant to **Article 9**, or otherwise; (7) rental of or cost of tools, machinery, and equipment used in connection with managing, repairing, cleaning and maintaining the Common Area; (8) the cost of all janitors, gardeners, security personnel and equipment performing services on the Common Area; (9) any regulatory fee or surcharge or similar imposition imposed by governmental requirements based upon or measured by the number of parking spaces, commuter trips, or the areas devoted to parking in the Common Area; (10) the cost of other capital improvements to the Common Area; (11) all costs and expenses incurred in connection with the management, maintenance, repair, operation, and replacement of all landscaping and parking facilities serving the Property; (12) the Property's portion of the cost of any easements or other agreements maintained for the benefit of the Property or the Property's tenants and occupants; (13) license, permit, and inspection fees associated with the ongoing operation, maintenance, and repair of the Common Area; and (14) the Property's portion of accounting (i.e., the salary and associated expenses of Property accounting) and legal services directly attributable to the Property, but excluding all such services in connection with negotiations and disputes with specific tenants unless the matter involved affects all tenants of the Property. Notwithstanding the foregoing, following shall be excluded from

Operating Expenses: depreciation and amortization, except as provided herein and except on materials, tools, supplies and vendor-type equipment purchased by Landlord to enable Landlord to supply services Landlord might otherwise contract for with a third party where such depreciation and amortization would otherwise have been included in the charge for such third party's services and when depreciation or amortization is permitted or required, the item shall be amortized with interest over its reasonably anticipated useful life; and the costs of construction of any New Development. Notwithstanding the foregoing, costs of a capital nature, including, without limitation, capital improvements, capital replacements, capital repairs, capital equipment and/or capital tools, Tenant's share of which would exceed Five Thousand Dollars ($5,000), shall be amortized over the useful live thereof as reasonably determined by Landlord, and Tenant shall reimburse Landlord only for the annual amortized portions of the useful life thereof falling within the Lease Term.

5.4 Records. Landlord shall keep accurate records showing in reasonable detail all expenses incurred for such maintenance. These records shall, upon at least thirty (30) days' request, be made available during business hours at the offices of Landlord for inspection by Tenant. Any such inspection by Tenant shall take place within one (1) year following the date of the annual reconciliation statement (as defined in **Paragraph 5.5** below) setting forth such expenses, or else any disagreements or claims by Tenant in connection therewith shall be deemed forever waived.

5.5 Tenant's Contribution. From and after the Lease Commencement Date, and during the entire Initial Lease Term and all Extended Terms, Tenant shall pay to Landlord on the first day of each month, Tenant's Pro Rata Share of all Operating Expenses, based on, at Landlord's election, either: (a) the amount of such expenses actually incurred during the billing period; or (b) equal periodic installments which have been estimated in advance by Landlord for a particular period. Landlord may revise such estimates upward or downward at any time with reasonable prior notice to Tenant. If Landlord elects to bill Tenant based upon estimates, Landlord shall, within one hundred twenty (120) days after the end of the calendar year, or as soon thereafter as possible, forward to Tenant a written statement (the **"annual reconciliation statement"**) which adjusts the estimated expenses to reflect the actual expenses incurred for such year. If the annual reconciliation statement shows the actual expenses to have exceeded the estimated expenses, then Tenant's share of such additional amount shall be paid by Tenant to Landlord within ten (10) days of receipt of the annual reconciliation statement; if the annual reconciliation statement shows the actual expenses to have been less than the estimated expenses, Landlord shall at its election pay the amount to Tenant or credit Tenant's share against the sums next due hereunder from Tenant to Landlord (or against any outstanding sums then due). Landlord shall notify Tenant of its election to pay or credit the amount due Tenant with the annual reconciliation statement.

5.6 Operation and Control. Landlord shall have control and non-exclusive possession of the entire Common Area and may from time to time adopt rules and regulations pertaining to the use thereof. Landlord shall, except as otherwise provided herein, operate and maintain the Common Area during the Lease Term. Landlord reserves the right to use the Common Area for such promotions, exhibitions and similar uses as Landlord reasonably deems in the best interests of the Property and its tenants. Landlord may temporarily close parts of the Common Area for such periods of time as may be necessary for (i) temporary use as a work area in connection with the construction of buildings or other improvements within the Property or contiguous property; (ii) repairs or alterations in or to the Common Area to any utility facilities; (iii) preventing the public from obtaining prescriptive rights in or to the Common Area; (iv) emergency or added safety reasons; (v) temporary use of the Common Area for entertainment, performance or shopping events; or (vi) performing such other acts as in Landlord's reasonable judgment are appropriate for the proper operation or maintenance of the Property. Landlord shall have the sole and exclusive control of the Common Area. Landlord's rights shall include, but not be limited to, the right to (vii) restrain the use of the Common Area by unauthorized persons; (viii) utilize from time to time any portion of the Common Area for promotional, entertainment and related matters; (ix) place permanent or

temporary kiosks, displays, carts and stands in the Common Area and to lease same to tenants; (x) temporarily close any portion of the Common Area for repairs, improvements or alterations, to discourage non-customer use, to prevent dedication or an easement by prescription, or for any other reason deemed sufficient in Landlord's judgment; and (xi) change the shape and size of the Common Area, add, eliminate or change the location of improvements to the Common Area, including, without limitation, buildings, lighting, parking areas, roadways and curb cuts, and construct buildings on the Common Area. Landlord may determine the nature, size and extent of the Common Area and whether portions of the same shall be surface, underground or multiple-deck; as well as make changes to the Common Area from time to time which in Landlord's opinion are deemed desirable for the Property. The manner in which the Common Area shall be operated and maintained and the expenditures therefor shall be at Landlord's sole discretion. Landlord reserves the right to appoint a substitute operator, including but not limited to, any tenant in the Property, to carry out any or all of Landlord's rights and duties with respect to the Common Area as provided in this Lease; and Landlord may enter into a contract either by a separate document or in a Lease agreement with such operator on such terms and conditions and for such period as Landlord shall deem proper. Notwithstanding any other provision contained herein, in the event that any portion of the Common Area becomes, for a period longer than thirty (30) days, inaccessible, unusable or dedicated solely and exclusively to Landlord's use, including without limitation use related to any New Development, such portion shall no longer be considered a Common Area or included in the calculation of Tenant's Pro Rata Share of the Common Area Operating Expenses.

5.7 Obstructions. No fence, wall, structure, division, rail or obstruction shall be placed, kept, permitted or maintained upon the Common Area or any part thereof by Tenant. Tenant shall not conduct any sale, display, advertising, promotion, or storage of merchandise or any business activities of any kind whatsoever in or upon the Common Area without Landlord's prior written consent. Tenant shall not use the Common Area for solicitations, demonstrations or any other activities that would interfere with the conduct of business in the Property, or which might tend to create civil disorder or commotion.

5.8 Allocation of Expenses: Gross Up. Those Operating Expenses, Taxes, and insurance costs that Landlord reasonably determines should be allocable to all tenants of the Property shall be considered to be Property Operating Expenses, Taxes, and insurance costs, respectively, and those Operating Expenses, Taxes and insurance costs that Landlord reasonably determines should be allocable only to specific tenants shall be shared among only those tenants. Landlord also reserves the right to create, as appropriate, new categories of Operating Expenses, Taxes, and insurance costs, if certain Operating Expenses, Taxes, and/or insurance costs are reasonably allocable only to Tenant and not to all tenants of the Building. In such case, Tenant's Pro Rata Share shall be established for such separately-categorized Operating Expenses, Taxes, and/or insurance costs, and Tenant shall be responsible for paying the costs and expenses of installing meters or other devices to determine the actual cost or expense of such separately categorized Operating Expenses, Taxes, or insurance costs on a pro rata basis with those other tenants, if any, that are responsible for paying a portion of such separately-categorized Operating Expenses, Taxes and insurance costs, as applicable. If less than an average of ninety-five percent (95%) of the rentable area of the Property is occupied by tenants during all or any portion of a lease year, Landlord shall make an appropriate adjustment of those Operating Expenses and insurance costs that vary by occupancy, including for purposes of calculating Tenant's estimated payments thereof, employing sound accounting and property management principles, to determine the amount of Operating Expenses and taxes that would have been expended or incurred had ninety-five percent (95%) of the rentable area of the Property been occupied during the entire year.

ARTICLE 6

TAXES

6.1 Personal Property Taxes. Tenant shall pay before delinquency all license fees, public charges, taxes and assessments on the furniture, fixtures, equipment, inventory and other personal property of or being used by Tenant in the Premises, whether or not owned by Tenant.

6.2 Real Property Taxes.

(a) Definition: Payment. Tenant shall pay to Landlord as Additional Rent, in the manner set forth in **Paragraph 5.5**, Tenant's Pro Rata Share of all **"Taxes"** (as defined below). As used herein, Taxes shall mean all real property taxes, excises, license and permit fees, utility levies and charges, business improvement districts, transport fees, trip fees, monorail and other light rail fees or assessments, transportation management program fees, school fees, fees assessed by air quality management districts or any governmental agency regulating air pollution or commercial rental taxes, and other governmental charges and assessments, general and special, ordinary and extraordinary, unforeseen as well as foreseen, of any kind and nature whatsoever, and installments thereof (including any business and occupation tax imposed on Landlord, the Building or the Property, and any tax imposed on the rents collected therefrom or on the income generated thereby, whether or not substituted in whole or in part for real property taxes, as well as assessments and any license fee imposed by a local governmental body on the collection of rent), which shall be levied or assessed against all or any portion of the Premises, or imposed on Landlord for any period during the Term of this Lease. Said Taxes attributable to the years that this Lease commences and terminates shall, if necessary, be prorated and apportioned between Landlord and Tenant to coincide with the commencement and expiration of the Lease Term.

(b) Separate Tax Bill. If the Premises are separately billed pursuant to a segregation, Tenant shall pay such Taxes as Additional Rent, at Landlord's election, either (i) at least thirty (30) days prior to delinquency, directly to the tax collector, or (ii) together with Tenant's Pro Rata Share of monthly Operating Expenses, to Landlord, or (iii) twice each year within ten (10) days after delivery of Landlord's written statement which shall be accompanied by a copy of the tax bill, to Landlord. Each party shall furnish the other upon written request, evidence of payment of such Taxes.

(c) Tenant's Use. Notwithstanding any other provisions of this **Paragraph 6.2**, in the event that Tenant's use of the Premises or any action undertaken by Tenant causes an increase in Taxes assessed against the Property or the Premises as a result of any tax reassessment or reappraisal, Tenant shall be solely liable for, and shall pay, in addition to all other sums payable under this **Paragraph 6.2** or elsewhere in the Lease, the entire amount of the increase in Taxes over the amount of Taxes for the Property or the Premises had such reassessment or reappraisal not occurred.

6.3 Business Taxes. Tenant shall also pay Tenant's Pro Rata Share of: (a) all special taxes and assessments or license fees now or hereafter levied, assessed or imposed by law or ordinance, by reason of Tenant's use of the Premises; (b) all business and occupation tax and any tax, assessment, levy or charge assessed on the Rent paid under this Lease; and (c) metropolitan improvement and other business improvement district fees.

6.4 Substitute and Additional Taxes. If, at any time during the Term, the methods of taxation prevailing on the execution date hereof shall be altered so that in lieu of, or as a supplement to or as a substitute for, the whole or any part of the Taxes now levied, assessed or imposed on the Premises or the Property, there shall be levied, assessed or imposed a tax, assessment, levy, imposition or charge, wholly or partially as a capital levy or otherwise, on the rents received therefrom, or a tax, assessment, levy

(including but not limited to any municipal, state, or federal levy), imposition or charge measured by or based in whole or in part upon the Premises and imposed upon Landlord, or a license fee measured by the rent payable under this Lease or by expenditures made by Tenant on Landlord's behalf in connection which this Lease, then all such taxes, assessments, levies, impositions, charges of the part thereof so measured or based, shall be deemed to be included within the term "Taxes" as defined in **Article 6** hereof, and Tenant shall pay and discharge the same in the manner provided for the payment of Taxes herein, it being the intention of the parties hereto that the rent to be paid hereunder shall be paid to Landlord absolutely net, without deduction of any kind or nature whatsoever.

6.5 Commercial Rent Tax. Tenant shall pay to Landlord, in addition to and together with any and all installments of Minimum Monthly Rent, Additional Rent and other charges payable pursuant to this Lease, the excise, transaction, sales, privilege, or other tax (other than net income and/or estate taxes) now or in the future imposed by the city, county, state or any other government or governmental agency upon Landlord and attributable to or measured by the Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges or prorations payable by Tenant pursuant to this Lease.

ARTICLE 7

UTILITIES AND SERVICES

7.1 Utilities and Services. Provided that Tenant is not in default under this Lease, Landlord will provide the following services:

7.1.1 Maintain normal business hours at the Building, Monday through Friday from 7:00 a.m. to 6:00 p.m.

7.1.2 Furnish utilities to provide for lighting, convenience power, and heat and air conditioning capable of maintaining a temperature in accordance with applicable energy code requirements. Landlord shall cause the Premises to be supplied with electricity for standard power usage. As used herein, **"standard power usage"** means use of electricity for building standard lighting and office standard machines used in quantities and for amounts of time typically used by tenants in the building for ordinary medical/dental office use and in no event exceeding 3.5 watts per RSF of the Premises and all operating on 110 volt circuits. High power usage equipment includes without limitation machines that operate on 220-volt circuits. Tenant shall not install or operate high power usage equipment on the Premises without Landlord's prior written consent, which may be refused unless Tenant confirms in writing its obligation to pay the additional charges necessitated by such equipment. Electricity used by Tenant in the Premises shall, at Landlord's option, be paid for by Tenant either: (i) through inclusion in Operating Expenses (except as otherwise provided herein for excess usage); (ii) by a separate charge payable by Tenant to Landlord within 30 days after billing by Landlord; or (iii) by separate charge billed by the applicable utility company or reseller and payable directly by Tenant. Electrical service to the Premises may be furnished by one or more companies providing electrical generation, transmission and distribution services, and the cost of electricity may consist of several different components or separate charges for such services, such as generation, distribution and stranded cost charges. Landlord shall have the exclusive right to select any company providing electrical service to the Premises, to aggregate the electrical service for the Property, any Buildings and the Premises with other Buildings, to purchase electricity through a broker and/or buyers group and to change the providers and manner of purchasing electricity. Landlord shall be entitled to receive a fee (if permitted by law) for the selection of utility companies and the negotiation and administration of contracts for electricity. Whenever heat generating machines or equipment or lighting other than building standard lights in excess of Tenant's requirements described herein are used in the Premises by Tenant which affect the temperature otherwise maintained by the air cooling system, Landlord shall have the right to install

supplementary air cooling units in the Premises, and the cost thereof, including the cost of installation and the cost of operation and maintenance thereof, shall be paid by Tenant upon billing. Landlord may impose a reasonable charge for utilities and services, including without limitation, air cooling, electric current and water, required to be provided the Premises by reason of, (a) any substantial recurrent use of the Premises at any time other than the hours of 7:00 a.m. to 6:00 p.m., Monday through Friday, and 8:00 a.m. to 12:00 p.m. Saturday (b) any use beyond what Landlord agrees to furnish as described above, (c) electricity used by equipment designated by Landlord as high power usage equipment, or (d) the installation, maintenance, repair, replacement or operation of supplementary air cooling equipment, additional electrical systems or other equipment required by reason of special electrical, heating, cooling or ventilating requirements of equipment used by Tenant at the Premises. In no event shall Tenant install portable low voltage A/C units anywhere within the Premises. At Landlord's option, separate meters for such utilities and services may be installed for the Premises and Tenant upon demand therefor, shall pay within 30 business days for the actual cost of the installation, maintenance, repair and replacement of such meters.

7.1.3 Provide non-attended passenger elevator facilities during all working days (Saturday, Sunday and holidays, one elevator subject to call).

7.1.4 If Landlord provides janitorial services generally to the tenants of the Building, provide such services similar to that furnished in comparable general office space in the vicinity of the Building. Any and all additional janitorial service desired by Tenant shall be contracted for by Tenant directly with Landlord's janitorial agent.

7.1.5 Provide water for drinking, lavatory and toilet purposes drawn through fixtures installed by Landlord.

7.1.6 Maintain the Property and Common Area in reasonably good condition, and in compliance with all governmental codes, rules and regulations.

7.1.7 If Landlord replaces light bulbs generally for tenants of the Building, replace burned out fluorescent tubes in light fixtures that are standard for the Building. Burned out bulbs, tubes or other light sources in fixtures that are not standard for the Building will be replaced by Landlord, but at Tenant's expense.

7.1.8 Perform snow and debris removal from the parking areas and maintain lighting in such areas per applicable codes and industry standards.

7.2 Payment. Costs for all services rendered under this paragraph shall be included in Operating Expenses unless specifically excluded above or in **Article 5** of this Lease.

7.3 Interruptions. It is understood that Landlord does not warrant that any of the services referred to above will be free from interruption by virtue of a strike or a labor trouble or any other cause beyond Landlord's reasonable control. Such interruption of service shall never be deemed an eviction or disturbance of Tenant's use or possession of the Premises, or any part thereof, nor shall it render Landlord liable to Tenant for damages, by abatement or reduction of rent or otherwise, nor shall it relieve Tenant from performance of Tenant's obligations under this Lease, nor shall Tenant be relieved from the performance of any covenant or agreement in this Lease because of such failure or interruption; provided that Tenant's responsibility for Minimum Monthly Rent shall abate beginning on the fourth business day after the interruption caused by the gross negligence or intentional misconduct of Landlord or its agents or employees which renders all or a portion of its Premises untenantable (in proportion to the amount of Tenant's space rendered untenantable), and continuing until the interrupted service or utility no longer

renders a significant portion of the Premises untenantable. Landlord reserves the right to stop service of the elevator, plumbing, HVAC and electrical systems, when necessary, by reason of accident or emergency, or for repairs, alterations or improvements, which are in the reasonable judgment of Landlord desirable or necessary, until said repairs, alterations or improvements shall have been completed; provided, Landlord shall use its good faith efforts to try to minimize interruption to Tenant's business operations.

ARTICLE 8

REPAIRS AND ALTERATIONS

8.1 Landlord's Repairs. Landlord shall keep in good condition and repair the structure, foundation, bearing walls, roof system, and exterior utility lines serving the Building, the costs of which shall be included in Operating Expenses pursuant to **Paragraph 5.4**, and paid by Tenant in accordance with **Paragraph 5.5**, but which shall be paid solely by Tenant in the event that the repair or replacement relates solely to the Premises or is necessitated by Tenant's actions, or if not, which shall be pro rated and paid by Tenant in accordance with **Paragraph 5.5**), provided further that Landlord shall not be required to make any such repairs or replacements occasioned by the act or negligence of Tenant, its agents, employees, invitees, licensees, representatives or contractors. Nothing contained in this **Paragraph 8.1** shall limit Landlord's right to reimbursement from Tenant for maintenance, repair costs and replacement costs provided elsewhere in this Lease.

8.2 Tenant's Repairs. Except as expressly provided in **Paragraph 8.1**, Tenant shall, at its sole cost, keep in first-class appearance, in a condition at least equal to that which existed when Tenant initially began operating at the Premises, and in good order, condition, cleanliness and repair, the exterior and interior of the Premises and every part thereof, including without limitation, the interior surfaces of the walls and ceilings (including all interior painting thereof), all doors, door frames, door checks, interior relites and other glass, storefronts (if any), grease traps, all plumbing, HVAC, and sewage facilities serving the Premises, including free flow up to the main sewer line, trade fixtures, floor coverings (including periodic shampooing of all carpets), maintenance, repair and light bulb replacement for all non-Building standard lighting fixtures, and any mechanical systems or equipment installed for the sole use by Tenant. All equipment, facilities or fixtures shall, at Tenant's sole expense, be kept, repaired, maintained, replaced or added to by Tenant at all times in accordance with all governmental requirements. Tenant shall cause all grease traps, if any, serving the Premises to be cleaned and serviced as often as may be required by law, ordinance or regulation or in order to keep the grease traps safe, sanitary and in good working order, and shall, within five (5) days of receipt, furnish to Landlord true copies of all receipts or other evidence of service from outside vendors who empty, clean or service the grease traps. In the event that Tenant fails to comply with the obligations set forth in this **Paragraph 8.2**, Landlord may, but shall not be obligated to, perform any such obligation on behalf of, and for the account of Tenant, and Tenant shall reimburse Landlord for all costs and expenses paid or incurred on behalf of Tenant in connection with performing the obligations set forth herein. Tenant expressly waives the right to make repairs at Landlord's expense under any law, statute or ordinance now or hereafter in effect.

8.3 Alterations.

(a) Tenant's Alterations. Tenant shall not make any alterations, decorations, changes, installations or improvements (collectively, "**Tenant Changes**") in, to, or about the interior or exterior of the Premises without obtaining the prior written consent of Landlord. Tenant's request for Landlord's consent to perform any Tenant Changes which may affect the HVAC system or cause penetration through the roof of the Building, must be accompanied by plans and specifications (to be prepared by Tenant at Tenant's sole cost) for the proposed Tenant Change in detail reasonably satisfactory to Landlord, together

with notice of the identity of the licensed contractor which Tenant has or will engage to perform such work, plus a review fee not to exceed Three Hundred Dollars ($300).. Landlord shall grant or withhold its approval of such plans and specifications within fifteen (15) business days after Tenant makes request therefor in the manner provided herein; provided, however, if Landlord needs to consult with an outside consultant or expert with respect thereto, Landlord's consent shall be granted or denied not later than within a reasonable time after the expiration of such 15-day period. All such work shall be accomplished at Tenant's sole risk and expense, and Tenant shall indemnify, defend and hold harmless Landlord from and against any and all loss, cost, liability and expense (including consequential damages) relating to or arising from the Tenant Changes. All Tenant Changes shall become a part of the realty upon installation thereof.

(b) Approval Not Required. Notwithstanding **Paragraph 8.3(a)**, with respect to carpeting and painting of the interior portions of the Premises and other Tenant Changes which (i) are non-structural in nature (i.e., do not involve changes to or penetrations of any portion of the Building or the Property); (ii) do not involve changes to the building's systems, including without limitation, the roof, electrical, plumbing, and HVAC systems (the Tenant Changes described in clauses (i) and (ii) hereof are collectively called **"Non-Structural Changes"**); and (iii) in the aggregate would not cost in excess of Three Thousand Dollars ($3,000) when added together with the cost of all other Non-Structural Changes made by or for Tenant during the prior twelve (12) month period, Tenant need not obtain Landlord's prior written consent, but must notify Landlord in writing within ten (10) days prior to the commencement of such Non-Structural Changes. Landlord may elect upon expiration or termination of this Lease to require Tenant, at Tenant's sole cost, to remove all Tenant Changes installed by Tenant pursuant to this paragraph and to restore the Premises to substantially their condition prior to the installation thereof.

8.4 General Conditions. Tenant shall at all times comply with the following requirements when performing any work pursuant to **Paragraphs 8.2** or **8.3**:

(a) Contractors. Tenant shall use the contractors and mechanics then appearing on Landlord's approved list if the Tenant Changes involve changes to the Building's systems and/or structural elements. With respect to Non-Structural Changes, Tenant shall use such contractors and mechanics which Landlord approves of in writing prior to their use, which approval shall not be unreasonably withheld. All contractors used by Tenant shall be licensed contractors who are experienced in the type of work to be performed, and shall provide to Landlord certificates of liability insurance evidencing coverage in force from insurance and with liability limits reasonably acceptable to Landlord, and naming Tenant, Landlord and the Property Manager as additional insureds.

(b) Compliance With Laws. All Tenant Changes shall at all times comply with all laws, rules, orders and regulations of governmental authorities having jurisdiction thereof and all insurance requirements of this Lease, shall comply with the rules and regulations for the Property now or hereafter in existence, and shall comply with the plans and specifications approved by Landlord.

(c) Tenant's Responsibility. All Tenant Changes shall be made and completed at Tenant's sole cost and expense, and the Property and the Premises shall be kept lien-free at all times by Tenant.

8.5 Americans with Disabilities Act Compliance Landlord and Tenant acknowledge that, in accordance with the provisions of the Americans with Disabilities Act of 1990, together with its implementing regulations and guidelines (collectively, the **"ADA"**), responsibility for compliance with the terms and conditions of Title III of the ADA may be allocated as between the parties. Notwithstanding anything to the contrary contained in the Lease, Landlord and Tenant agree that the responsibility for compliance with the ADA (including, without limitation, the removal of architectural and communications barriers and the provision of auxiliary aids and services to the extent required) shall

be allocated as follows: (i) Tenant shall be responsible for compliance with the provisions of Title III of the ADA for any construction, renovations, alterations and repairs made within the Premises if such construction, renovations, alterations and repairs are made by Tenant at its expense without the assistance of the Landlord; (ii) Tenant shall be responsible for compliance with the provisions of Title III of the ADA for all construction, renovations, alterations and repairs Landlord makes within the Premises, whether at Landlord's or Tenant's expense; and (iii) Landlord shall be responsible for compliance with the provisions of Title III of the ADA for all Landlord's Work (if any) and for exterior and interior areas of the Building not included within the Premises. Landlord and Tenant each agree that the allocation of responsibility for ADA compliance shall not require either party to supervise, monitor or otherwise review the compliance activities of the other party with respect to its assumed responsibilities for ADA compliance as set forth in this paragraph.

ARTICLE 9

INSURANCE

9.1 Use Rate. Tenant shall not carry any stock of goods or do anything in or about the Premises which will cause an increase in insurance rates on the building in which the Premises are located. In no event shall Tenant perform any activities which would invalidate any insurance coverage on the Property or the Premises. Tenant shall pay on demand any increase in premiums that may be charged as a result of Tenant's use or activities or vacating or otherwise failing to occupy the Premises, but this provision shall not be deemed to limit in any respect Tenant's obligations under **Article 14**. In no event shall the limits of insurance required to be maintained by Tenant pursuant to this Lease be deemed to limit the liability of Tenant hereunder.

9.2 Liability Insurance. Tenant shall, during the Lease Term, at its sole expense, maintain in full force a policy or policies of Commercial general liability (CGL) insurance including contractual, on an occurrence basis, with coverage at least as broad as the most commonly available ISO Commercial General Liability policy CG 00 01, at least Two Million Dollars ($2,000,000) per occurrence limit, Two Million Dollars ($2,000,000) general aggregate limit, including any necessary and appropriate extensions to comply with the additional requirements of this Lease. Tenant shall also maintain Commercial Automobile coverage, One Million Dollars ($1,000,000) combined single limit/per accident, covering injury (or death) and property damage arising out of the ownership, maintenance, or use of any private passenger or commercial vehicles and of any other equipment required to be licensed for road use. Such limits may be achieved through the use of umbrella liability insurance otherwise meeting the requirements of this paragraph. Such insurance shall also cover independent contractors liability, products and completed operations liability, and personal injury liability.

9.3 Worker's Compensation Insurance. Tenant shall at all times maintain worker's compensation insurance in compliance with federal, state and local law including Employer's Liability coverage (contingent liability/stop gap) in the amount of One Million Dollars ($1,000,000) each accident; One Million Dollars ($1,000,000) bodily injury by disease policy limit; and One Million Dollars ($1,000,000) bodily injury each employee.

9.4 Property Insurance/Business Income.

(a) Landlord's Insurance. Landlord shall pay for and shall maintain in full force and effect during the Term of this Lease property insurance with respect to the Property as it may require and as may be required by its lender, which coverage may include at Landlord's option special extended coverage, earthquake and sprinkler leakage coverage, boiler and machinery, difference in conditions, business income and extra expense, building ordinance, terrorism, and excess rental value endorsements,

along with rent loss insurance. Tenant shall pay Tenant's Pro Rata Share for the costs incurred by Landlord for such insurance in accordance with the payment provisions set forth in **Paragraph 5.5** above.

(b) Tenant's Insurance. Tenant shall pay for and shall maintain in full force and effect during the Term of this Lease property insurance covering its leasehold improvements to the Premises, furniture, fixtures, equipment, inventory and other personal property located on the Premises in an amount of not less than one hundred percent (100%) insurable replacement value with no more than a Twenty Thousand Dollar ($20,000) deductible and no coinsurance penalty, **"Special Form—Causes of Loss,"** with flood insurance and earthquake insurance if Landlord or its lender deems such insurance to be necessary or desirable), with an Ordinance or Law endorsement, and replacement cost coverage to protect against loss of owned or rented equipment and tools brought onto or used at the Property by Tenant. Tenant shall also obtain and maintain Business Income and Extra Expense coverage for a period of not less than twelve (12) months.

9.5 Waiver of Subrogation. Except for the waiving party's deductible amount, each party hereby waives, and each party shall cause their respective property insurance policy or policies to include a waiver of such carrier's, entire right of recovery (i.e., subrogation) against the other party, and the officers, directors, agents, representatives, employees, successors and assigns of the other party, for all claims which are covered or would be covered by the property insurance required to be carried hereunder or which is actually carried by the waiving party.

9.6 General Requirements. All policies of insurance required to be carried hereunder by Tenant shall be evidenced by an appropriate evidence of insurance (ACORD Form 28), which evidences must contain the following additional clause:

> "It is agreed that this insurance will not be canceled, not renewed, or the limits of coverage in any way reduced without at least thirty (30) days' advance written notice [ten (10) days for nonpayment of premiums] sent by certified mail, return receipt requested, to _____ [Insert Landlord's name and address]"

(a) Licensed in State. Be written by companies reasonably satisfactory to Landlord and licensed to do business in the state of in which the Premises are situated. All policies of insurance required to be maintained by Tenant shall be issued by insurance companies with an A.M. Best's financial strength rating of "A-" or better and an A.M. Best's Financial Size Category of Class "IX" or higher, and shall not contain a deductible greater than Two Thousand Five Hundred Dollars ($2,500) or any self-insured retention unless expressly approved in writing by Landlord.

(b) Primary. Contain a clause that such policy and the coverage evidenced thereby shall be primary and non-contributing with respect to any policies carried by Landlord, and that any coverage carried by Landlord shall be excess insurance. All insurance coverage must be on an **"occurrence basis"**; **"claims made"** forms of insurance are not acceptable, and shall contain a severability of interests endorsement.

(c) Additional Named Insured. Liability policies shall name Landlord, Landlord's property manager, and such other parties reasonably selected by Landlord as additional insureds utilizing ISO Endorsement CG 20-11-01-96 or its equivalent ("certificate holder" status is not acceptable). Landlord shall be listed as a "loss payee" on property policies as its interests may appear.

(d) Notice of Cancellation. Not be subject to cancellation or reduction in coverage except upon at least thirty (30) days prior written notice to each additional insured. The policies of insurance containing the terms specified herein, or duly executed certificates evidencing them, together with

satisfactory evidence of the payment of premiums thereon, shall be deposited with Landlord prior to the Possession Date and thereafter not less than thirty (30) days prior to the expiration of the original or any renewal term of such coverage.

(e) Failure of Tenant to Obtain Insurance. If Tenant fails to acquire or maintain any insurance or provide any policy or evidence of insurance required by this Article, and such failure continues for three (3) days after written notice from Landlord, Landlord may, but shall not be required to, obtain such insurance for Landlord's benefit and Tenant shall reimburse Landlord for the costs of such insurance upon demand. Such amounts shall be additional rent payable by Tenant hereunder and in the event of non-payment thereof, Landlord shall have the same rights and remedies with respect to such non-payment as it has with respect to any other non-payment of rent hereunder.

9.7 Blanket Insurance. Each party shall be entitled to fulfill its insurance obligations hereunder by maintaining a so-called "blanket" policy or policies of insurance. Such policy shall contain an endorsement that names the other party as an additional insured, references the Premises, and guarantees a minimum limit of coverage available for the obligations under this Lease at least equal to the insurance amounts required hereunder. Tenant's right to fulfill its insurance obligations hereunder through a "blanket" policy shall be subject to approval of such policy by Landlord and Landlord's lender(s).

ARTICLE 10

DAMAGE AND RESTORATION

10.1 Damage and Destruction of the Premises. If the Premises are at any time destroyed or damaged by a casualty insured against by Landlord pursuant to **Article 9** hereof or otherwise insured against by Landlord, and if as a result of such occurrence:

(a) the Premises are rendered untenantable only in part, this Lease shall continue in full force and effect and, provided Tenant shall have been operating in the Premises for the Permitted Use set forth in the Basic Lease Provisions at the time of the casualty and shall covenant in writing to Landlord that Tenant shall reopen the Premises for such permitted use and will comply with the provisions of **Paragraph 10.3** below upon completion of Landlord's reconstruction, rebuilding or repair of the Premises, Landlord shall, subject to the provisions of **Paragraph 10.4** below, commence diligently to reconstruct, rebuild or repair the Premises to substantially their condition immediately prior to the casualty not later than six (6) months after the date of the casualty, subject to extension due to force majeure or if the required repairs and restoration cannot reasonably be completed within such 6-month period as long as Landlord is diligently prosecuting such repairs and restoration to completion (as so extendable, the "**Restoration Deadline**") (Landlord shall have no obligation to construct any Tenant Alterations). In such event, Minimum Monthly Rent shall abate proportionately to the portion of the Premises rendered untenantable (including to the extent Tenant's reasonable use of and access to the Premises are impaired due to damage to the Common Areas) from the date of the destruction or damage until the entire Premises and those Common Areas required for reasonable use of and access to the Premises have been restored by Landlord to the extent required above;

(b) the Premises are rendered totally untenantable, provided Tenant shall have been operating in the Premises for the Permitted Use set forth in the Basic Lease Provisions at the time of the casualty and shall covenant in writing to Landlord that Tenant shall reopen the Premises for such use and will comply with the provisions of **Paragraph 10.3** below upon completion of Landlord's reconstruction, rebuilding or repair of the Premises, Landlord shall, subject to **Paragraph 10.4** hereof, commence diligently to reconstruct, rebuild or repair the Premises to substantially their condition immediately prior to the casualty by the Restoration Deadline (Landlord shall have no obligation to perform any Tenant

Alterations). In such event, Minimum Monthly Rent shall abate entirely from the date of the destruction or damage until the Premises and any damaged Common Areas reasonably required for use of and access to the Premises have been restored by Landlord to the extent required above.

10.2 Damage or Destruction of Property.

(a) If 25% or more of the Leasable Area of the Property or 25% or more of the Common Area of the Property is at any time destroyed or damaged (including, without limitation, by smoke or water damage) as a result of fire, the elements, accident, or other casualty, whether or not the Premises are affected by such occurrence, Landlord may, at its option, to be exercised by written notice to Tenant within ninety (90) days following any such occurrence, elect to terminate this Lease. In the case of such election, the Term and tenancy created hereby shall expire on the thirtieth (30th) day after such notice is given, without liability or penalty payable or any other recourse by one party to or against the other; and Tenant shall, within such 30-day period, vacate the Premises and surrender them to Landlord. All rent shall be due and payable without reduction or abatement subsequent to the destruction or damage and until the date of termination, unless portions of the Premises or Common Areas reasonably required for the use of and access to the Premises shall have been destroyed or damaged, in which event the terms of **Paragraph 10.1(a)** or **(b)**, as applicable, of this Lease shall apply to determine the extent of any abatement of Minimum Monthly Rent to which Tenant may be entitled as a result thereof.

(b) If Landlord does not elect to terminate this Lease in accordance with the terms of **Paragraph 10.2(a)**, Landlord shall, following such destruction or damage, commence diligently to reconstruct, rebuild, or repair, if necessary, that part of the Property which is necessary, in Landlord's sole judgment, to create an economically viable unit and otherwise to substantially its condition immediately prior to the casualty by the Restoration Deadline. However, if Landlord elects to repair, reconstruct, or rebuild the Property, or any part thereof, Landlord may use plans, specifications, and working drawings other than those used in the original construction of the Property, so long as the Premises are restored to substantially their condition immediately prior to the casualty.

10.3 Tenant's Work. If this Lease has not been terminated after damage or destruction as provided above, then all proceeds of Tenant's insurance relating to reconstruction of the remainder thereof following substantial completion of Landlord's repair and restoration work as may be required hereby shall be applied by Tenant toward Tenant's repair and restoration work as required hereby. Upon receipt by Tenant of written notice that Landlord's Work has been substantially completed, Tenant shall forthwith complete all work required to fully restore the Premises for business fully fixturized, stocked, and staffed.

10.4 Limitation of Obligations. Notwithstanding anything set forth to the contrary herein, in the event the Premises or Property are damaged as a result of any cause in respect of which there are no insurance proceeds available to Landlord, or the proceeds of insurance are insufficient in Landlord's commercially reasonable judgment to pay for the costs of repair or reconstruction, or any mortgagee or other person entitled to the proceeds of insurance does not consent to the payment to Landlord of such proceeds to fully restore the Premises or Property, or if the Premises or Property cannot be fully restored to its prior condition under land use, zoning, and building codes in force at the time a permit is sought for repair or reconstruction, then Landlord may, without obligation or liability to Tenant, terminate this Lease on thirty (30) days' written notice to Tenant and all rent shall be adjusted as of the effective date of such termination, and Tenant shall vacate and surrender the Premises on the date set forth in Landlord's termination notice.

10.5 Damage or Destruction at End of Term. Notwithstanding anything to the contrary contained herein, Landlord shall not have any obligation to repair, reconstruct, or restore the Premises or Property

when the damage or destruction occurs during the last eighteen (18) months of the Term of this Lease. Furthermore, if the damage or destruction occurs during last six (6) months of the Term of this Lease, Tenant shall have the right to terminate this Lease by written notice given to Landlord within thirty (30) days from the date of the damage or destruction, whether or not Landlord elects to rebuild and restore the damage.

10.6 Tenant's Remedies for Landlord's Failure to Timely Commence or Complete Restoration. Notwithstanding anything to the contrary contained herein, if Landlord fails to commence repairs and restoration promptly upon receipt of required permits (if any) and applicable insurance proceeds, or fails to substantially complete its repair and restoration obligations by the Restoration Deadline, Tenant shall in either case as its sole remedy have the right to terminate this Lease upon thirty (30) days' written notice to Landlord, unless Landlord promptly commences repairs and restoration or substantially completes same, as applicable, within such 30-day period.

10.7 Waiver. Tenant hereby waives any statutory and common law rights of termination which may arise by reason of any partial or total destruction of the Premises which Landlord is obligated to restore or may restore under any of the provisions of this Lease.

ARTICLE 11

SECURITY DEPOSIT

Tenant has deposited with Landlord the Security Deposit set forth in the Basic Lease Provisions above, to be held by Landlord during the Term as set forth below. The Security Deposit shall be held by Landlord without liability for interest and as security for the performance by Tenant of Tenant's covenants and obligations hereunder, it being expressly understood that the Security Deposit shall not be considered as a measure of Tenant's damages in case of default by Tenant. Landlord may, in its sole discretion, from time to time without prejudice to any other remedy, use the Security Deposit to the extent necessary to make good any default under this Lease or to satisfy any other covenant or obligation of Tenant hereunder. Following any such application of the Security Deposit, Tenant shall pay to Landlord on demand the amount so applied in order to restore the Security Deposit to its original amount. If Tenant is not in default at the termination of this Lease, the balance of the Security Deposit remaining after any such application shall be returned to Tenant within a reasonable period after such termination, after deducting therefrom any unpaid obligation of Tenant to Landlord as may arise under this Lease, including, without limitation, the obligation of Tenant to restore the Premises upon termination of this Lease. If Landlord transfers its interest in the Premises during the Term of this Lease, Landlord may assign the Security Deposit to the transferee provided that such transferee accepts, in writing, to be bound by the terms of this Lease as the landlord hereunder.

ARTICLE 12

EMINENT DOMAIN

12.1 Definition. If there is any taking or condemnation of or transfer in lieu thereof for a public or quasi-public use of all or any part of the Property or the Premises or any interest therein because of the exercise or settlement due to threatened exercise of the power of eminent domain or inverse condemnation, whether by condemnation proceedings or otherwise (all of the foregoing being hereinafter referred to as "taking") before or during the Term hereof, the rights and obligations of the parties with respect to such taking shall be as provided in this **Article 12**.

12.2 Total Taking. If there is a taking of all of the Premises, this Lease shall terminate as of the date of such taking. All Minimum Monthly Rent and other amounts due under this Lease shall be paid by Tenant to the date of such termination.

12.3 Partial Taking of Premises. If any part of the Premises shall be taken, and a part thereof remains which is reasonably susceptible of occupation hereunder for the use permitted herein, this Lease shall, as to the part so taken, terminate as of the date title shall vest in the condemnor or transferee, and the Minimum Monthly Rent payable hereunder shall be reduced by the proportion which the floor area taken from the Premises bears to the total Floor Area of the Premises immediately before the taking; but in such event Landlord shall have the option to terminate this Lease as of the date when title to the part so condemned vests in the condemnor or transferee. All Minimum Monthly Rent and other amounts due under this Lease shall be paid by Tenant to the date of any such termination.

12.4 Common Area Taking. If so much of the Common Area is taken that in the commercially reasonable judgment of Landlord the Property will be rendered unsuitable for the continued use thereof for the purposes for which it was intended, Landlord may elect to terminate this Lease by giving Tenant written notice of such election within sixty (60) days after the date that title to the portion so taken vests in the condemnor or transferee. If Landlord fails to give such notice, this Lease shall remain in full force and effect. If any part of the Property is taken, but no part of the Premises is taken, and Landlord does not elect to terminate this Lease, the rent payable hereunder shall not be reduced, nor shall Tenant be entitled to any part of the award made therefor. In the event of termination, all Minimum Monthly Rent and other amounts due under this Lease shall be paid by Tenant to the date of such termination.

12.5 Repair and Restoration. If this Lease is not terminated as provided in this **Article 12**, Landlord shall, at its sole expense, restore with due diligence the remainder of the improvements occupied by Tenant so far as is practicable to a complete unit of like quality, character, and condition as that which existed immediately prior to the taking, provided that the scope of the work shall not exceed the scope of the work to be done by Landlord originally in construction of the Premises, and further provided that Landlord shall not be obligated to expend an amount greater than that which was awarded to Landlord for such taking. Tenant, at its sole cost and expense, shall restore its furniture, fixtures and other allowed leasehold improvements to their condition immediately preceding such taking.

12.6 Award. In the event of any taking, Landlord shall be entitled to the entire award of compensation or settlement in such proceedings, whether for a total or partial taking or for diminution in the value of the leasehold or for the fee. Any such amounts shall belong to and be the property of Landlord. Without in any way diminishing the rights of Landlord under the preceding sentence, Tenant shall be entitled to recover from the condemnor such compensation as may be separately awarded by the condemnor to Tenant or recoverable from the condemnor by Tenant in its own right for the taking of trade fixtures and equipment owned by Tenant (meaning personal property, whether or not attached to real property, which may be removed without injury to the Premises) and for the expense of removing and relocating them, and for loss of goodwill, but only to the extent that the compensation awarded to Tenant shall be in addition to and shall not diminish the compensation awarded to Landlord as provided above.

12.7 Waiver. Tenant hereby waives any statutory and common law rights of termination which may arise by reason of any partial taking of the Premises under the power of eminent domain.

ARTICLE 13

INDEMNITY; WAIVER

13.1 Indemnification and Waivers.

(a) Indemnity by Tenant. Except as specifically set forth herein, to the fullest extent permitted by law, and commencing on the first day Tenant or any of its employees, agents, or contractors first enters onto the Property for any reason relating to this Lease or the Premises, Tenant shall, at Tenant's sole cost and expense, Indemnify Landlord Parties against all Claims arising from (i) any Personal Injury, Bodily Injury or Property Damage whatsoever occurring in or at the Premises; (ii) any Bodily Injury to an employee of a Tenant Party arising out of and in the course of employment of the employee and occurring anywhere in the Property; (iii) the use or occupancy, or manner of use or occupancy, or conduct or management of the Premises or of any business therein; (iv) subject to the waiver of subrogation provisions of this Lease, any act, error, omission or negligence of any of the Tenant Parties in, on or about the Premises or the Property; (v) the conduct of Tenant's business; (vi) any alterations, activities, work or things done, omitted, permitted or allowed by Tenant Parties in, at or about the Premises or Property, including the violation of or failure to comply with, or the alleged violation of or alleged failure to comply with any applicable laws, statutes, ordinances, standards, rules, regulations, orders, or judgments in existence on the date of the Lease or enacted, promulgated or issued after the date of this Lease including Hazardous Materials Laws (defined below); (vii) any breach or default by Tenant in the full and prompt payment of any amount due under this Lease, any breach, violation or nonperformance of any term, condition, covenant or other obligation of Tenant under this Lease, or any misrepresentation made by Tenant or any guarantor of Tenant's obligations in connection with this Lease; (viii) all damages sustained by Landlord as a result of any holdover by Tenant or any Tenant Party in the Premises including, but not limited to, any claims by another tenant resulting from a delay by Landlord in delivering possession of the Premises to such tenant; (ix) any liens or encumbrances arising out of any work performed or materials furnished by or for Tenant; (x) commissions or other compensation or charges claimed by any real estate broker or agent with respect to this Lease by, through or, under Tenant or, (xi) any matter enumerated in **Paragraph 13(c)** below.

(b) Indemnity by Landlord. Notwithstanding the foregoing, Landlord shall defend, indemnify and hold Tenant harmless against all liabilities, damages, costs and expense, including attorney's fees, for personal injury, bodily injury (including death) or property damage arising from the gross negligence or intentional misconduct of Landlord or any of its agents. Landlord shall use legal counsel reasonably acceptable to Tenant in defense of any action within Landlord's defense obligation.

(c) Waivers. Except as specifically set forth herein, to the fullest extent permitted by law, Tenant, on behalf of all Tenant Parties, Waives all Claims against Landlord Parties arising from the following: (i) any Personal Injury, Bodily Injury, or Property Damage occurring in or at the Premises; (ii) any loss of or damage to property of a Tenant Party located in the Premises or other part of the Property by theft or otherwise; (iii) any Personal Injury, Bodily Injury, or Property Damage to any Tenant Party caused by other tenants of the Property, parties not occupying space in the Property, occupants of property adjacent to the Property, or the public or by the construction of any private, public, or quasi-public work occurring either in the Premises or elsewhere in the Property; (iv) any interruption or stoppage of any utility service or for any damage to persons or property resulting from such stoppage; (v) business interruption or loss of use of the Premises suffered by Tenant; (vi) any latent defect in construction of the Building; (vii) damages or injuries or interference with Tenant's business, loss of occupancy or quiet enjoyment and any other loss resulting from the exercise by Landlord of any right or the performance by Landlord of Landlord's maintenance or other obligations under this Lease, or (viii) any Bodily Injury to an employee of a Tenant Party arising out of and in the course of employment of the employee and occurring anywhere in the Property.

(d) Definitions. For purposes of this **Article 13**: (i) the term "**Tenant Parties**" means Tenant, and Tenant's officers, members, partners, agents, employees, sublessees, licensees, guests, customers, invitees and independent contractors, and all persons and entities claiming through any of these persons or entities; (ii) the term "Landlord Parties" means Landlord and the members, partners,

venturers, trustees and ancillary trustees of Landlord and the respective officers, directors, shareholders, members, parents, subsidiaries and any other affiliated entities, personal representatives, executors, heirs, assigns, licensees, invitees, beneficiaries, agents, servants, employees and independent contractors of these persons or entities; (iii) the term **"Indemnify"** means indemnify, defend (with counsel reasonably acceptable to Landlord) and hold free and harmless for, from and against; (iv) the term **"Claims"** means all liabilities, claims, damages (including consequential damages), losses, penalties, litigation, demands, causes of action (whether in tort or contract, in law or at equity or otherwise), suits, proceedings, judgments, disbursements, charges, assessments, and expenses (including attorneys' and experts' fees and expenses incurred in investigating, defending, or prosecuting any litigation, claim, or proceeding); (v) the term **"Waives"** means that the Tenant Parties waive and knowingly and voluntarily assume the risk of; and (vi) the terms **"Bodily Injury"**, **"Personal Injury"** and **"Property Damage"** will have the same meanings as in the form of commercial general insurance policy issued by Insurance Services Office, Inc. most recently prior to the date of the injury or loss in question.

(e) Scope of Indemnities and Waivers. Except as provided in the following sentence or above in **Paragraph 13.1(b)**, the indemnities and waivers contained in this **Article 13** shall apply regardless of the active or passive negligence or sole, joint, concurrent, or comparative negligence of any of the Landlord Parties, and regardless of whether liability without fault or strict liability is imposed or sought to be imposed on any of the Landlord Parties. The indemnities and waivers contained in this **Article 13** shall not apply to the extent of the percentage of liability that a final judgment of a court of competent jurisdiction establishes under the comparative negligence principles of the state in which the Premises are situated, that a Claim against a Landlord Party was proximately caused by the willful misconduct or gross negligence of that Landlord Party, provided, however, that in such event the indemnity or waiver will remain valid for all other Landlord Parties.

(f) Duty to Defend. Tenant's duty to defend Landlord Parties is separate and independent of Tenant's duty to Indemnify Landlord Parties. Tenant's duty to defend includes Claims for which Landlord Parties may be liable without fault or may be strictly liable. Tenant's duty to defend applies regardless of whether issues of negligence, liability, fault, default or other obligation on the part of Tenant Parties have been determined. Tenant's duty to defend applies immediately, regardless of whether Landlord Parties have paid any sums or incurred any detriment arising out of or relating, directly or indirectly, to any Claims. It is the express intention of Landlord and Tenant that Landlord Parties will be entitled to obtain summary adjudication regarding Tenant's duty to defend Landlord Parties at any stage of any Claim within the scope of this **Article 13**.

(g) Obligations Independent of Insurance. The indemnification provided in this **Article 13** shall not be construed or interpreted as in any way restricting, limiting or modifying Tenant's insurance or other obligations under this Lease, and the provisions of this **Article 13** are independent of Tenant's insurance and other obligations. Tenant's compliance with the insurance requirements and other obligations under this Lease does not in any way restrict, limit or modify Tenant's indemnification obligations under this Lease.

(h) Waiver of Immunity. EACH OF LANDLORD AND TENANT HEREBY WAIVES ITS IMMUNITY WITH RESPECT TO THE PARTIES INDEMNIFIED UNDER THE PRECEDING PARAGRAPHS UNDER THE APPLICABLE STATE INDUSTRIAL INSURANCE ACTS AND EXPRESSLY AGREES TO ASSUME POTENTIAL LIABILITY FOR ACTIONS BROUGHT AGAINST AN INDEMNIFIED PARTY BY THE INDEMNIFYING PARTY'S EMPLOYEES. THIS WAIVER HAS BEEN SPECIFICALLY NEGOTIATED BY THE PARTIES TO THIS LEASE AND EACH PARTY HAS HAD THE OPPORTUNITY TO, AND HAS BEEN ENCOURAGED TO, CONSULT WITH INDEPENDENT COUNSEL REGARDING THIS WAIVER.

(i) Survival. The provisions of this **Article 13** will survive the expiration or earlier termination of this Lease until all Claims against Landlord Parties involving any of the indemnified or waived matters are fully and finally barred by the applicable statutes of limitations.

ARTICLE 14

OPERATION OF BUSINESS

Tenant shall (a) keep the Premises and exterior and interior portions of windows, doors and all other glass or plate glass fixtures in a neat, clean, sanitary and safe condition; (b) refrain from burning any papers or refuse of any kind in the Property; (c) store in the area designated by Landlord all trash and garbage in neat and clean containers so as not to be visible to members of the public and arrange for the regular pick-up and cartage of such trash or garbage at Tenant's expense, or cooperate in the employment of a trash removal contractor designated by Landlord, if Landlord deems it desirable to have all waste materials removed by one contractor; (d) observe and promptly comply with all governmental requirements and insurance requirements affecting the Premises or any part of the Common Area which is under Tenant's exclusive control and promulgated during the Term of this Lease; (e) not use or suffer or permit the Premises or any part thereof to be used for any use other than the Permitted Use set forth in the Basic Lease Provisions or in any manner that will constitute a nuisance or unreasonable annoyance to the public, to other occupants of the Property or to Landlord, or that will injure the reputation of the Property, or for any extra hazardous purpose or in any manner that will impair the structural strength of the Building; (f) not add, remove, or change any locks on any doors to or in the Premises, or add, remove, or change any plumbing or wiring therein; and (g) not cause or permit any waste to be committed on the Premises or the Property

ARTICLE 15

SIGNS AND ADVERTISING

15.1 General. Tenant may at its own expense erect and maintain upon the interior areas of the Premises all signs and advertising matter customary and appropriate in the conduct of Tenant's business, subject to Landlord's right to remove any signs or advertising matter which violates **Article 14** or this **Article 15**. The Tenant shall not affix or maintain upon the glass panes and supports of windows and doors, or within twelve inches (12") of the show windows and doors, any signs, advertising placards, names, insignia, trademarks, descriptive material or any other such like item or items except such as shall have first received the written approval of the Landlord as to size, type, color, location, copy, nature and display qualities. All signs, decorations and advertising media shall conform in all respects to the sign criteria established by Landlord for the Property from time to time, and shall be subject to the prior written approval of Landlord as to construction, method of attachment, size, shape, height, lighting, color and general appearance. Without limiting the generality of the foregoing, neon signage shall not be permitted without Landlord's express prior approval. All signs and other advertising media shall comply with all applicable governmental requirements. Except for signs which comply with the terms of this Article, Tenant shall not erect, place, paint, or maintain in or on the Premises, any sign, exterior advertising medium, or any other object of any kind whatsoever, whether an advertising device or not, visible or audible from outside the Premises. Tenant shall not change the color, size, location, composition, wording or design of any sign or advertisement on the Premises that may have been theretofore approved by Landlord, without the prior written approval of Landlord and the applicable governmental authorities. Tenant shall at its own expense maintain and keep in good repair all installations, signs, and advertising devices which it is permitted or required by Landlord to maintain.

15.2 Directory Board. Landlord shall, throughout the Term of this Lease, maintain a directory board in the main lobby of the Building that shall list Tenant. The cost of said designation shall be at Tenant's expense and shall be limited to Tenant's corporate or entity name only, and shall not include additional individual designations.

15.3 Elevator Lobby; Suite Entry Signage. Landlord shall provide Building-standard elevator lobby signage on the floor on which the Premises are located. Tenant shall be required to provide at its sole expense suite entry signage, subject to Landlord's prior review, not to be unreasonably withheld.

ARTICLE 16

LIENS

Tenant will not permit any mechanic's liens or other liens to be placed upon the Premises, the Building, or the Property and nothing in this Lease shall be deemed or construed in any way as constituting the consent or request of Landlord, express or implied, by inference or otherwise, to any person for the performance of any labor or the furnishing of any materials to the Premises, the Building, or the Property or any part thereof, nor as giving Tenant any right, power, or authority to contract for or permit the rendering of any services or the furnishing of any materials that would give rise to any mechanic's or other liens against the Premises, the Building, or the Property. In the event any such lien is attached to the Premises, the Building, or the Property, then, in addition to any other right or remedy of Landlord, Landlord may, but shall not be obligated to, discharge the same. Any amount paid by Landlord for any of the aforesaid purposes including, but not limited to, reasonable attorneys' fees, shall be paid by Tenant to Landlord promptly on demand as Additional Rent. Tenant shall within ten (10) days of receiving such notice of lien or claim (a) have such lien or claim released or (b) deliver to Landlord a bond in form, content, amount and issued by surety, satisfactory to Landlord, indemnifying, protecting, defending and holding harmless Landlord and the Property against all costs and liabilities resulting from such lien or claim and the foreclosure or attempted foreclosure thereof.

ARTICLE 17

RIGHT OF ENTRY

Landlord and its authorized agents and representatives shall be entitled to enter the Premises at all reasonable times to inspect them, to make the repairs which Landlord is obligated to make under this Lease, to show them to prospective tenants, purchasers or lenders, to cure a default of Tenant, to post any notice provided by law that relieves a landlord from responsibility for the acts of a tenant, to comply with any governmental requirements or insurance requirements, to post ordinary signs advertising the Premises for sale or for lease, to install utilities, lines, chases, and conduit serving other portions of the Property through the Premises so long as the RSF of the Premises is not thereby materially reduced, and for any other lawful purpose relating to Landlord's rights and obligations under this Lease. Nothing in the preceding sentence shall imply or impose a duty to make repairs which Tenant has agreed to make hereunder. Landlord may erect scaffolding and other necessary structures where reasonably required by the character of the work to be performed, provided that the entrance to the Premises shall not be unreasonably blocked. Landlord shall have the right to use any means which Landlord may deem proper to enter the Premises in an emergency. Landlord's entry to the Premises shall not under any circumstances be construed to be a forcible or unlawful entry into the Premises or an eviction of Tenant from the Premises. Notwithstanding the foregoing, Landlord acknowledges that information maintained by the Tenant on the premises, including patient health information is confidential. Landlord shall not access, use or disclose any such information without Tenant's written permission and shall ensure that its employees and other agents are bound by this confidentiality provision.

ARTICLE 18

DELAYING CAUSES

If either party is delayed in the performance of any covenant of this Lease because of any of the following causes (referred to elsewhere in this Lease as a "delaying cause"): acts of the other party, action of the elements, war, riot, labor disputes, inability to procure or general shortage of labor or material in the normal channels of trade, delay in transportation, delay in inspections, or any other cause beyond the reasonable control of the party so obligated, whether similar or dissimilar to the foregoing, financial inability excepted, then, such performance shall be excused for the period of the delay; and the period for such performance shall be extended for a period equivalent to the period of such delay, except that the foregoing shall in no way affect Tenant's obligation to pay rent or any other amount payable hereunder, or the length of the Term of this Lease.

ARTICLE 19

ASSIGNMENT AND SUBLEASE

19.1 Consent Required. Notwithstanding anything to the contrary contained in this Lease, Tenant shall not assign this Lease or any interest herein or any right or privilege appurtenant hereto or sublet, license, grant any concessions, or otherwise give permission to anyone other than Tenant to use or occupy all or any part of the Premises (hereinafter sometimes referred to as a **"Transfer"**), without the prior written consent of Landlord, which consent Landlord shall not unreasonably withhold. Without limiting the generality of the foregoing, it shall be deemed reasonable for Landlord to withhold such consent if (i) the proposed Transferee does not have a tangible net worth and credit standing, calculated in accordance with generally accepted accounting principles consistently applied, that is comparable to the tangible net worth and credit standing of tenants then being considered by Landlord for space in the Building, (ii) the number of years of business experience or the business reputation of the proposed Transferee is not comparable to that of tenants then being considered by Landlord for space in the Building, (iii) there if then in existence an Event of Default with respect to any obligation of Tenant under the Lease, (iv) the proposed Transferee or an affiliate thereof is an existing tenant in the Property or is or has been, within the six-month period prior to the date Tenant requests Landlord's consent, in discussions with Landlord regarding space at the Property, or (v) the proposed Transferee proposes to change the use of the Premises to a use that is inconsistent with the character of the Building and/or will interfere with Landlord's existing or desired tenant mix for the Property. Furthermore, if the then-existing Security Deposit is less than or equal to one (1) month's Minimum Monthly Rent at the then-applicable rate, Landlord may further condition its consent to the Transfer on an increase in the Security Deposit to not less than one (1) month's Minimum Monthly Rent and the then-applicable rate. Any actual or attempted Transfer without the Landlord's prior written consent or otherwise in violation of the terms of this Lease shall, at Landlord's election, be void and shall confer no rights upon any third person, and shall be a non-curable default under this Lease which shall entitle Landlord to terminate this Lease upon ten (10) days' written notice to Tenant at any time after such actual or attempted Transfer without regard to Landlord's prior knowledge thereof. The acceptance of rent by Landlord from any person or entity shall not be deemed to be a waiver by Landlord of any provision of this Lease or a consent to any Transfer. A consent by Landlord to one or more Transfers shall not be deemed to be a consent to any subsequent Transfer. In addition, any option to extend or renew the Term hereof, to terminate this Lease early, or to expand or contract the size of the Premises shall be personal to Tenant, and shall not be Transferred without the prior written consent of Landlord in accordance with the terms of this **Article 19**.

19.2 Request For Consent. If Tenant shall desire Landlord's consent to any Transfer, Tenant shall notify Landlord in writing, which notice shall include: (a) the proposed effective date (which shall

be not less than forty-five (45) days nor more than one hundred eighty (180) days after Tenant's notice); (b) the portion of the Premises subject to the Transfer; (c) all of the terms of the proposed Transfer and the consideration therefor; (d) the name and address of the proposed transferee; (e) a copy of the proposed sublease, instrument of assignment and all other documentation pertaining to the proposed Transfer; (f) current financial statements of the proposed transferee certified by an officer, partner or owner thereof; (g) any information reasonably requested by Landlord to enable Landlord to determine the financial responsibility, character, and reputation of the proposed transferee and the nature of such transferee's business and the proposed use the Premises; and (h) such other information as Landlord may reasonably request, together with the nonrefundable sum of Seven Hundred Fifty Dollars ($750), which shall be applied towards Landlord's review and processing expenses. Such amount shall be subject to change without prior notice from Landlord.

19.3 Recapture. Upon receipt of Tenant's request for consent to any Transfer, Landlord may elect, by written notice given to Tenant within thirty (30) days after receipt of the information required pursuant to **Paragraph 19.2** above, to recapture the affected space by terminating this Lease as to that portion of the Premises covered by the proposed sublease or assignment, effective upon a date specified by Landlord, which date shall not be earlier than thirty (30) days nor later than sixty (60) days after Tenant's request for consent, with a proportionate reduction of all rights and obligations of Tenant hereunder that are based on the area of the Premises. However, if Landlord exercises its recapture right set forth herein, Tenant may void such recapture election by rescinding its request for Landlord's consent by written notice of such rescission given to Landlord within fifteen (15) days after receipt of Landlord's notice of recapture.

19.4 General Conditions. If Landlord does not elect to recapture the affected Premises or deny its consent to a Transfer, the granting of such consent shall be subject to the following conditions, which the parties hereby agree are reasonable:

(a) Payment of Transfer Premium. Tenant shall pay to Landlord one-half of any Transfer Premium derived by Tenant from such Transfer. **"Transfer Premium"** shall mean all rent and any other consideration payable by such transferee in excess of the Minimum Monthly Rent payable by Tenant under this Lease (on a per square foot basis, if less than all of the Premises is Transferred), after deducting therefrom any brokerage commissions in connection with the Transfer actually paid by Tenant to an unaffiliated broker. If any part of the consideration for such Transfer shall be payable other than in cash, Landlord's share of such non-cash consideration shall be in such form as is reasonably satisfactory to Landlord. The Transfer Premium payable hereunder shall be due within ten (10) days after Tenant receives such payments.

(b) Continued Liability of Tenant. Tenant shall remain primarily liable on its covenants hereunder unless released in writing by Landlord. In the event of any assignment or sublease which is consented to by Landlord, the transferee shall agree in writing to perform and be bound by all of the covenants of this Lease required to be performed by Tenant.

19.5 Transfer to a Subsidiary. The sale, assignment, transfer or disposition within a three (3)-year period, whether or not for value, by operation of law, gift, will, or intestacy, of (a) fifty percent (50%) or more of the issued and outstanding stock of Tenant if Tenant is a corporation, or (b) the whole or a partial interest of any general partner, joint venturer, associate or co-tenant who holds more than twenty five percent (25%) interest in Tenant, if Tenant is a partnership, joint venture, association or co-tenancy, shall be deemed a Transfer and shall be subject to the provisions of this **Article 19**. Notwithstanding the foregoing, Landlord hereby acknowledges and consents to Tenant's right, without further approval from Landlord but only after written notice to Landlord, to sublease the Premises or assign its interest in this Lease (i) to a corporation that directly, or indirectly through one or more intermediaries, controls, is

controlled by or is under common control with Tenant; (ii) in the event of the merger or consolidation of Tenant with another corporation; provided that immediately following the events enumerated in clauses (i) to (ii) above, the tangible net worth of Tenant, calculated in accordance with generally accepted accounting principles, consistently applied, and the credit standing of Tenant is not less than the tangible net worth, calculated in accordance with generally accepted accounting principles, consistently applied, and credit standing of Tenant immediately prior to the events described in clauses (i) through (ii) above (collectively, the **"Permitted Transfers"**). No Permitted Transfer shall relieve Tenant of its liability under this Lease and Tenant shall remain liable to Landlord for the payment of all Minimum Monthly Rent, Operating Expenses and Additional Rent and the performance of all covenants and conditions of this Lease applicable to Tenant.

19.6 Transfer Pursuant to Bankruptcy Code. Anything to the contrary notwithstanding, if this Lease is assigned (or all or a portion of the Premises is sublet) to any person or entity pursuant to the provisions of the Bankruptcy Code, 11 U.S.C. 101 *et. seq.* (the **"Bankruptcy Code"**), any and all monies or other consideration payable or otherwise to be delivered in connection with such assignment or subletting shall be paid or delivered to Landlord, shall be and remain the exclusive property of Landlord and shall not constitute property of Tenant or of its estate within the meaning of the Bankruptcy Code. Any and all monies or other consideration constituting Landlord's property under the preceding sentence not paid or delivered to Landlord shall be held in trust for the benefit of Landlord and be promptly paid or delivered to Landlord. Any assignee pursuant to the Bankruptcy Code shall be deemed to have assumed all of Tenant's obligations under this Lease. Any such assignee shall on demand by Landlord execute and deliver to Landlord a written instrument confirming such assumption.

ARTICLE 20

NOTICES

All notices, requests and demands to be made hereunder shall be in writing at the address set forth in the Basic Lease Provisions, as applicable, by any of the following means: (a) personal service (including service by recognized overnight delivery/courier service, such as DHL or FEDEX); or (b) registered or certified, first class mail, return receipt requested. Such addresses may be changed by notice to the other party given in the same manner provided above. Any notice, request, or demand sent pursuant to clause (a) of this **Article 20** shall be deemed received upon such personal delivery or service (or the date of refusal, if personal service or delivery is refused), and if sent pursuant to clause (b), shall be deemed received three (3) days following deposit in the mails.

ARTICLE 21

SURRENDER OF POSSESSION.

21.1 Surrender. At the expiration of the tenancy created hereunder, whether by lapse of time or otherwise, Tenant shall surrender the Premises broom clean and in good condition and repair, and shall remove all of its personal property, furniture, fixtures, and equipment, and all cabling and wiring installed by or for Tenant. Landlord shall have the right to elect to require Tenant to remove any or all of Tenant's Work and/or any of Tenant's Changes or other alterations, by written notice given to Tenant not later than thirty (30) days after the scheduled Expiration Date hereof. Tenant's obligations shall include the repair of any damage occasioned by the installation, maintenance or removal of Tenant's personal property, furniture, fixtures, equipment, cabling and wiring, as well as any Tenant's Work, Tenant's alterations or Tenant's Changes that Tenant is hereby required to remove, and the removal of any generators or storage tanks installed by or for Tenant (whether or not the installation was consented to by Landlord), and the

removal, replacement, or remediation of any soil, material or ground water contaminated by Tenant's Permittees, all as may then be required by applicable Laws.

21.2 Holding Over. If Tenant fails to surrender the Premises at the expiration or earlier termination of this Lease, occupancy of the Premises after the termination or expiration shall be that of a tenancy at sufferance. Tenant's occupancy of the Premises during the holdover shall be subject to all the terms and provisions of this Lease and Tenant shall pay an amount (on a per month basis without reduction for partial months during the holdover) equal to one hundred fifty percent (150%) for the first ninety (90) days of the holdover period and two hundred percent (200%) thereafter, in each case, of the greater of: (1) the sum of the Minimum Annual Rent and Additional Rent due for the period immediately preceding the holdover; or (2) the fair market gross rental for the Premises as determined by Landlord. No holdover by Tenant or payment by Tenant after the expiration or early termination of this Lease shall be construed to extend the Term or prevent Landlord from immediate recovery of possession of the Premises by summary proceedings or otherwise. In addition to the payment of the amounts provided above, if Landlord is unable to deliver possession of the Premises to a new tenant, or to perform improvements for a new tenant, as a result of Tenant's holdover, Tenant shall be liable to Landlord for all damages, including, without limitation, consequential damages, that Landlord suffers from the holdover. Nothing herein shall be construed as consent to such holding over.

ARTICLE 22

QUIET ENJOYMENT

Subject to the provisions of this Lease and conditioned upon performance of all of the provisions to be performed by Tenant hereunder, Landlord shall secure to Tenant during the Lease Term the quiet and peaceful possession of the Premises and all rights and privileges appertaining thereto, free from hindrance or molestation by Landlord and those claiming by, through or under Landlord.

ARTICLE 23

SUBORDINATION

Unless otherwise required by a lender, this Lease shall be subordinate to any mortgage or deed of trust held by any lender, now or hereafter in force against the Premises or the Property or any part thereof, and to all advances make or to be made upon the security thereof. If any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by Landlord, Tenant shall, at the option of the lender or other purchaser at any such foreclosure or sale, attorn to and recognize the purchaser as the Landlord under this Lease. Although the subordination in the immediately preceding sentence shall be self-operating, Tenant agrees, within fifteen days following the request of Landlord, to execute such documents or instruments as may be requested by Landlord or its lender(s) to confirm such subordination, provided that such mortgagees or beneficiaries agree in writing not to disturb Tenant's possession of the Premises in the event of foreclosure if Tenant is not in default. The failure of Tenant to so timely execute any such instrument or other document shall constitute a default hereunder. If Tenant fails to execute and deliver such instrument or other document within said ten (10) day period, Tenant shall pay a fee to Landlord of Fifty Dollars ($50) per day for each day after the expiration of such fifteen (15) day period on which the executed subordination agreement is delivered to Landlord, without limiting Landlord's other rights and remedies in connection with such default by Tenant. Notwithstanding the foregoing, Tenant's obligations under this Section to subordinate in the future are conditioned on the holder of each such future Landlord's Mortgage executing a commercially reasonable nondisturbance agreement.

ARTICLE 24

ESTOPPEL CERTIFICATE; FINANCIAL STATEMENTS

Tenant shall, at any time and from time to time but not to exceed more than three times in any calendar year within fifteen (15) days after written request therefor by Landlord, without charge, deliver a certificate to Landlord or to any person or entity designated by Landlord, certifying the date the Lease Term commenced, the date the rent commenced and is paid through, the amount of rent and other charges due under the Lease, the expiration date of the Lease Term, that this Lease is then in full force and effect, setting forth the amount and nature of modifications, defenses, or offsets, if any, claimed by Tenant, and any other factual matter concerning the Lease, the Tenant, or the Premises requested by Landlord or such person or entity. If Tenant fails to deliver such certificate within said fifteen (15) day period, Tenant shall be deemed to have given such certificate as above provided without modification and shall be deemed to have admitted the accuracy of any information supplied by Landlord to a prospective purchaser or mortgagee.

Tenant acknowledges that it has provided Landlord with certain financial statement(s) as a material inducement to Landlord's agreement to lease the Premises to Tenant, and that Landlord has relied on the accuracy of such financial statement(s) in entering into this Lease. Tenant represents and warrants that the information contained in such financial statement(s) is true, complete and correct in all material respects. Within ten (10) days from request by Landlord, Tenant will make available to Landlord or to any prospective purchaser or lender of the Property, audited financial statements (and, if requested by Landlord, statements of gross sales of products and services made at or from the Premises) for Tenant and any guarantor, provided, if Tenant is not a publicly traded entity, that Landlord or any such prospective purchaser or lender agrees to maintain such statements and information in confidence, and provided further that if audited financial statements of Tenant are not available at the time of such request, Tenant may deliver unaudited statements prepared in accordance with generally accepted accounting principles consistently applied and certified to be true and correct by Tenant's chief financial officer. Notwithstanding the foregoing, so long as the named Tenant herein is a publicly traded corporation and its financial information is readily available to the public, Tenant will not be required to deliver additional financial statements to Landlord.

ARTICLE 25

DEFAULT

25.1 Default. The occurrence of any or more of the following events shall constitute a material breach and default of this Lease (each, an "Event of Default"):

(a) Any failure by Tenant to pay Minimum Monthly Rent, Operating Expenses, Additional Rent or any other charge when due; or

(b) Any failure by Tenant to observe or perform any other provision, covenant or condition of this Lease to be observed or performed by Tenant not provided for in **subparagraph (a)** above and **subparagraphs (c), (d)** and **(h)** below where such failure continues for thirty (30) days after written notice thereof by Landlord to Tenant, provided that if the nature of such breach is such that although curable, the breach cannot reasonably be cured within a thirty (30) day period, an Event of Default shall not exist if Tenant shall commence to cure such breach and thereafter rectifies and cures such breach with due diligence, but in no event later than sixty (60) days after the written notice; or

(d) A general assignment by Tenant for the benefit of creditors, or the filing by or against Tenant of any proceeding under any insolvency or bankruptcy law, or the appointment of a trustee or receiver to take possession of all or substantially all of Tenant's assets located upon the Premises or of Tenant's interest in this Lease; or

(e) Any three (3) or more failures of the type described in **Paragraph 25.1(a)** in any twelve (12) month period; or

(f) Any failure by Tenant to commence construction of Tenant's work within thirty (30) days after substantial completion of Landlord's Work and to thereafter diligently prosecute such construction to completion, where such failure continues for five (5) days after written notice thereof by Landlord to Tenant; or

(g) The conducting by Tenant of a going out of business sale, bankruptcy sale or any similar liquidation sale in violation of the provisions of this Lease where such sale does not permanently cease within twenty-four (24) hours after written notice of such violation by Landlord to Tenant; or

(h) The occurrence of an Event of Default as defined in any other provision of this Lease.

25.2 Remedies.

(a) Reentry and Termination. Upon and during the continuance of an Event of Default, Landlord, in addition to any other remedies available to Landlord at law or in equity, at Landlord's option, may without further notice or demand of any kind to Tenant or any other person:

1. Declare the Lease Term ended and reenter the Premises and take possession thereof and remove all persons therefrom, and Tenant shall have no further claim to the Premises; or

2. Without declaring this Lease ended, reenter the Premises and occupy the whole or any part thereof for and on account of Tenant and collect any unpaid Minimum Monthly Rent, rent, Additional Rent, Operating Expenses and other charges, which have become payable, or which may thereafter become payable; or

3. Even though Landlord may have reentered the Premises, thereafter elect to terminate this Lease and all of the rights of Tenant in or to the Premises.

(b) Express Termination Required. Should Landlord have reentered the Premises under the provisions of **Paragraph 25.2(a)(2)** above, Landlord shall not be deemed to have terminated this Lease, or the liability of Tenant to pay any Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges thereafter accruing, or to have terminated Tenant's liability for damages under any of the provisions of this Lease, by any such reentry or by any action, in unlawful detainer or otherwise, to obtain possession of the Premises, unless Landlord shall have notified Tenant in writing that Landlord had elected to terminate this Lease. Tenant further covenants that the service by Landlord of any notice pursuant to the unlawful detainer statutes of the State where the Property is situated and the surrender of possession pursuant to such notice shall not (unless Landlord elects to the contrary at the time of or at any time subsequent to the serving of such notices and such election is evidenced by a written notice to Tenant) be deemed to be a termination of this Lease.

(c) Damages. Should Landlord elect to terminate this Lease pursuant to the provisions of **Paragraphs 25.2(a)(1)** or **25.2(a)(3)** above, Landlord may recover from Tenant as damages, the following:

1. The worth at the time of award of any unpaid Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges which had been earned at the time of such termination; plus

2. The worth at the time of award of the amount by which the unpaid Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges which would have been earned after termination until the time of award exceeds the amount of such loss Tenant proves could have been reasonably avoided; plus

3. The worth at the time of award of the amount by which the unpaid Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges for the balance of the Lease Term after the time of award exceeds the amount of such loss that Tenant proves could be reasonably avoided; plus

4. any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform Tenant's obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including, but not limited to any costs or expenses incurred by Landlord in (i) retaking possession of the Premises, including reasonable attorneys' fees, (ii) maintaining or preserving the Premises after the occurrence of an Event of Default, (iii) preparing the Premises for reletting to a new tenant, including repairs or alterations to the Premises for such reletting, (iv) leasing commissions, and (v) any other costs necessary or appropriate to relet the Premises; plus

5. At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by the laws of the State where the Property is situated.

(d) Alternative Damages. Should Landlord elect to bring an action against Tenant in unlawful detainer or for damages or both or otherwise (and Landlord may bring as many actions as Landlord may elect to bring throughout the Lease Term), without terminating this Lease, Landlord may recover from Tenant as damages the following:

1. The worth at the time of award of any unpaid Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges which had been earned at the time Landlord recovered possession of the Premises; plus

2. The worth at the time of award of the amount by which the unpaid Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges which would have been earned after the date Landlord recovered possession until the time of award exceeds the amount of such loss Tenant proves could have been reasonably avoided; plus

3. Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform Tenant's obligations under this Lease, including but not limited to, any costs or expenses incurred by Landlord in (i) retaking possession of the Premises, including reasonable attorneys' fees, (ii) maintaining or preserving the Premises after the occurrence of an Event of Default, (iii) preparing the Premises for reletting to a new tenant, including

repairs or alterations to the Premises for such reletting, (iv) leasing commissions, and (v) any other costs necessary or appropriate to relet the Premises; plus

4. At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by the laws of the State where the Property is situated.

(e) Definitions. As used in **Paragraphs 25.2(c)(1), 25.2(c)(2),** and **25.2(d)(1)** above, the "worth at the time of award" is computed by allowing interest at the rate of fifteen percent (15%) per annum. As used in **Paragraphs 25.2(c)(3)** and **25.2(d)(2)** above, the **"worth at the time of award"** is computed by discounting such amount at the discount rate of the Federal Reserve Bank situated nearest to the location of the Property at the time of award plus one (1) percentage point.

(f) Computation of Certain Sums. For all purposes of this **Article 25**, Operating Expenses, Additional Rent and other charges shall be computed on the basis of the average monthly amount thereof accruing during the immediately preceding sixty (60) month period, except that if it becomes necessary to compute such amounts before such a sixty (60) month period has occurred then such amounts shall be computed on the basis of the average monthly amounts accruing during such shorter period.

(g) Use of Fixtures. Upon the occurrence of and during the continuation of any Event of Default, Landlord may, at Landlord's option, permit all of Tenant's fixtures, furniture, equipment, improvements, additions, alterations, and other personal property to remain on the Premises and Landlord shall have the right to take the exclusive possession of same and to use same, rent or charge free, until the Event of Default is cured or, at Landlord's option, at any time during the Lease Term, require Tenant to forthwith remove same. In the event of any entry or taking possession of the Premises, Landlord shall have the right, but not the obligation to remove all or any part of the fixtures, furniture, equipment and other personal property located in the Premises and may place the same in storage at a public warehouse at the expense and risk of the owner or owners thereof.

(h) Cumulative Remedies. The remedies given to Landlord in this **Paragraph 25** shall be in addition and supplemental to all other rights or remedies which Landlord may have at law, in equity or by statute and the exercise of any one remedy shall not preclude the subsequent or concurrent exercise of further or additional remedies.

(i) No Waiver. The waiver by Landlord of any breach of any term, covenant or condition herein contained in this Lease shall not be deemed to be a waiver of such term, covenant or condition of any subsequent breach of the same or any other term, covenant or condition of this Lease. The subsequent acceptance of Minimum Monthly Rent, Operating Expenses, Additional Rent or other charges due hereunder shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease, other than the failure of Tenant to pay the particular amount so accepted regardless of Landlord's knowledge of such preceding breach at the time of acceptance of such amount. No covenant, term, or condition of this Lease shall be deemed to have been waived by Landlord unless such waiver shall be in writing and signed by Landlord.

25.3 Interest. Any sum accruing to Landlord under the terms and provisions of this Lease which shall not be paid when due shall bear interest at the interest rate provided herein from the date the same becomes due and payable by the terms and provisions of this Lease until paid, unless otherwise specifically provided in this Lease. The interest rate which shall apply shall be the lesser of (i) fifteen percent (15%) per annum or (ii) the highest rate allowed by applicable law

ARTICLE 26

INSOLVENCY

26.1 Breach of Lease. Subject to the applicable United States Bankruptcy Code and other laws, the filing of any petition by or against Tenant under any chapter of the Bankruptcy Act, or any successor statute thereto, or the adjudication of Tenant as a bankrupt or insolvent, or the appointment of a receiver or trustee to take possession of all or substantially all of the assets of Tenant, or a general assignment by Tenant for the benefit of creditors, or any other action taken or suffered by Tenant under any state or federal insolvency or bankruptcy act, shall constitute a default under and breach of this Lease by Tenant, regardless of Tenant's compliance with the other provisions of this Lease; and Landlord at its option by written notice to Tenant may exercise all rights and remedies provided for in **Article 25**, including the termination of this Lease, effective of such notice, without the necessity of further notice under **Article 25**.

26.2 Operation of Law. Neither this Lease, nor any interest herein, nor any estate created hereby, shall pass by operation of law under any state or federal insolvency or bankruptcy act to any trustee, receiver, assignee for the benefit of creditors or any other person whatsoever without the prior written consent of Landlord, which shall not be unreasonably withheld. Any purported transfer in violation of the provisions of this **Paragraph 26.2** shall constitute a default under and breach of this Lease, regardless of Tenant's compliance with the other provisions of this Lease; and Landlord at its option by written notice to Tenant may exercise all rights and remedies provided for in **Article 25**, including the termination of this Lease, effective on service of such notice without the necessity of further notice under **Article 25**.

26.3 Non-Waiver. The acceptance of rent at any time and from time to time by Landlord from Tenant as debtor in possession or from a transferee of the type mentioned in **Paragraph 26.2**, shall not preclude Landlord from exercising its rights under this **Article 26** at any time hereafter.

26.4 Events of Bankruptcy

(a) Tenant's becoming insolvent, as that term is defined in Title 11 of the United States Code, entitled Bankruptcy, U.S.C. Sec. 101 *et. seq.* (the **"Bankruptcy Code"**), or under the insolvency laws of the State in which the Premises are situated ("Insolvency Laws");

(b) The appointment of a receiver or custodian for any or all of Tenant's property or assets, or the institution of a foreclosure action upon any of Tenant's real or personal property;

(c) The filing of a voluntary petition under the provisions of the Bankruptcy Code or Insolvency Laws;

(d) The filing of an involuntary petition against Tenant as the subject debtor under the Bankruptcy Code or Insolvency Laws, which is either not dismissed within sixty (60) days of filing, or results in the issuance of an order for relief against the debtor, whichever is later; or

(e) Tenant's making or consenting to an assignment for the benefit of creditors or a common law composition of creditors.

26.5 Landlord's Remedies.

(a) Termination of Lease. Upon occurrence of an Event of Bankruptcy, Landlord shall have the right to terminate this Lease by giving written notice to Tenant; provided, however, that this

Paragraph 26.5(a) shall have no effect while a case in which Tenant is the subject debtor under the Bankruptcy Code is pending, unless Tenant or its Trustee is unable to comply with the provisions of **Paragraph 26.5(d)** and **(e)** below. At all other times this Lease shall automatically cease and terminate, and Tenant shall be immediately obligated to quit the Premises upon the giving of notice pursuant to this **Paragraph 26.5(a)**. Any other notice to quit, or notice of Landlord's intention to re-enter is hereby expressly waived. If Landlord elects to terminate this Lease, everything contained in this Lease on the part of Landlord to be done and performed shall cease without prejudice; subject, however, to the rights of Landlord to recover from Tenant all rent and any other sums accrued up to the time of termination or recovery of possession by Landlord, whichever is later, and any other monetary damages or loss of reserved rent sustained by Landlord.

(b) Suit for Possession. Upon termination of this Lease pursuant to **Paragraph 26.5(a)**, Landlord may proceed to recover possession under and by virtue of the provisions of laws of any applicable jurisdiction, or by such other proceedings, including re-entry and possession, as may be applicable.

(c) Non-Exclusive Remedies. Without regard to any action by Landlord as authorized by **Paragraph 26.5(a)** and **(b)** above, Landlord may at its discretion exercise all the additional provisions set forth in **Article 25**.

(d) Assumption or Assignment by Trustee. In the event Tenant becomes the subject debtor in a case pending under the Bankruptcy Code, Landlord's right to terminate this Lease pursuant to **Paragraph 26.5(a)** shall be subject to the rights of the Trustee in Bankruptcy to assume or assign this Lease. The Trustee shall not have the right to assume or assign this Lease unless the Trustee (i) promptly cures all defaults under this Lease, (ii) promptly compensates Landlord for monetary damages incurred as a result of such default, and (iii) provides adequate assurance of future performance on the part of Tenant as debtor in possession or on the part of the assignee Tenant.

(e) Adequate Assurance of Future Performance. Landlord and Tenant hereby agree in advance that adequate assurance of future performance, as used in **Paragraph 26.5(d)** above, shall mean that all of the following minimum criteria must be met: (i) Tenant must pay its estimated pro rata share of the cost of all services provided by Landlord (whether directly or through agents or contractors and whether or not previously included as part of the Minimum Monthly Rent), in advance of the performance or provision of such services; (ii) the Trustee must agree that Tenant's business shall be conducted in a first class manner, and that no liquidating sales, auctions, or other non-first class business operations shall be conducted on the Premises (iii) the Trustee must agree that the use of the Premises as stated in this Lease will remain unchanged and that no prohibited use shall be permitted; and (iv) the Trustee must agree that the assumption or assignment of this Lease will not violate or affect the rights of other tenants in the Property.

(f) Failure to Provide Adequate Assurance. In the event Tenant is unable to (i) cure its defaults, (ii) reimburse the Landlord for its monetary damages, (iii) pay the rent due under this Lease and all other payments required of Tenant under this Lease on time (or within three (3) days), or (iv) meet the criteria and obligations imposed by **Paragraph 26.5(d)** above, Tenant agrees in advance that it has not met its burden to provide adequate assurance of future performance, and this Lease may be terminated by Landlord in accordance with **Paragraph 26.5(a)** above.

ARTICLE 27

REMEDIES CUMULATIVE

The various rights, elections, and remedies of Landlord contained in this Lease shall be cumulative, and no one of them shall be construed as exclusive of any other, or any right, priority, or remedy allowed or provided for by law.

ARTICLE 28

ATTORNEY'S FEES

If either party hereto shall file any action or bring any proceeding against the other party arising out of this Lease or for the declaration of any rights hereunder, the prevailing party therein shall be entitled to recover from the other party all costs and expenses, including reasonable attorneys' fees, incurred by the prevailing party as determined by the court. If either party ("secondary party") without its fault is made a party to litigation instituted by or against the other party, the primary party shall pay to the secondary party all costs and expenses, including reasonable attorneys' fees, incurred by the secondary party in connection therewith.

ARTICLE 29

LIABILITY OF MANAGER

The Building's Property Manager is Landlord's manager and rental agent in all matters concerning this Lease and the Premises, and Tenant, until notified in writing to the contrary by either the Landlord or Property Manager or the Assignee of Landlord's interest under this Lease, shall recognize such agency and pay all rental, furnish all statements, and give any notice which Tenant may be under the duty of giving hereunder, or may elect to give hereunder, to Property Manager at its offices set forth in the Basic Lease Provisions, instead of to the Landlord. As long as such agency shall exist, the rights and options extended to Landlord shall be deemed extended to Property Manager, and each and every other term and provision of this Lease which is in any way beneficial to the Landlord, including especially every stipulation against liability, or limiting liability, shall inure to the benefit of Property Manager and its agents and shall be applicable to Property Manager and its agents in the same manner and as fully and with the same effect as to Landlord. Whenever Landlord's consent is required, Tenant shall request such consent from Property Manager. The consent of Property Manager shall be deemed the consent of Property Manager and Landlord.

ARTICLE 30

NO PARTNERSHIP

Landlord shall not in any way for any purpose be deemed a partner, joint venturer or member of any joint enterprise with Tenant.

ARTICLE 31

SUBTENANCIES

The voluntary or other surrender of this Lease by Tenant or a mutual cancellation of this Lease shall not effect a merger and shall, at Landlord's option, terminate all existing subtenancies or operate as an assignment to Landlord of any or all of such subtenancies.

ARTICLE 32

SUCCESSORS

This Lease shall be binding upon and shall inure to the benefit of the parties hereto and their successors and permitted assigns. The term **"successors"** is used herein in its broadest possible meaning and includes, but is not limited to, every person succeeding to any interest in this Lease or the premises of Landlord or Tenant herein whether such succession results from the act or omission of such party. Every covenant and condition of this Lease shall be binding upon all assignees, subtenants, licensees, and concessionaires of Tenant.

ARTICLE 33

REMOVAL OF TENANT'S PERSONAL PROPERTY

Upon the expiration of the Term of this Lease or upon any earlier termination thereof, Tenant shall remove at its own expense all trade fixtures, equipment, and personal property (collectively called **"Tenant's Personal Property"**) in this Lease which were installed by Tenant or any subtenant, concessionaire or licensee in or upon the Premises; but if Tenant is in default, Tenant shall not remove Tenant's Personal Property unless notified by Landlord to do so. In case of any injury or damage to the Building or any portion of the Premises resulting from the removal of Tenant's Personal Property, Tenant shall promptly pay to Landlord the cost of repairing such injury or damage. If Tenant fails to so remove Tenant's Personal Property, Landlord may, at Landlord's option, retain any or all thereof, and title thereto shall thereupon vest in Landlord without the execution of documents or sale or conveyance by Tenant; or Landlord may remove any or all items thereof from the Premises and dispose of them in any manner Landlord sees fit, and Tenant shall pay upon demand to Landlord the actual expense of such removal and disposition together with interest from the date of payment by Landlord until repayment by Tenant.

ARTICLE 34

EFFECT OF CONVEYANCE

If, during the Term of this Lease, Landlord conveys its interest in the Property, the Premises or this Lease, then, from and after the effective date of such conveyance, Landlord shall be released and discharged from any and all further obligations and responsibilities under this Lease, and the transferee shall be deemed, without any further agreement between the parties or their successors in interest or between the parties and any such transferee, to have assumed and agreed to carry out any and all of the subsequent covenants and obligations of the Landlord under this Lease. Any security given by Tenant to secure performance of its obligations hereunder may be transferred and assigned by Landlord to such transferee.

ARTICLE 35

LANDLORD'S DEFAULT; NOTICE TO LENDER

35.1 Landlord's Default. In the case of a default by Landlord, Landlord shall commence promptly to cure such default immediately after receipt of written notice from Tenant specifying the nature of such default and shall complete such cure within thirty (30) days thereafter, provided that if the nature of such default is such that it cannot be cured within said thirty (30) day period, Landlord shall have such additional time as may be reasonably necessary to complete its performance, so long as Landlord has proceeded with diligence after receipt of Tenant's notice and is then proceeding with diligence to cure such default.

35.2 Notice to Lender. Whenever Tenant serves notice on Landlord of Landlord's default, written notice shall also be served at the same time upon the mortgagee under any first mortgage or beneficiary under any first deed of trust, so long as Landlord has provided Tenant with written notice of such mortgagee. Such mortgagee or beneficiary shall have the periods of time within which to cure Landlord's defaults as are provided in **Paragraph 35.1**, which periods shall commence to run ten (10) days after the commencement of the periods within which Landlord must cure its defaults under **Paragraph 35.1**. In this connection, any representative of the mortgagee or beneficiary shall have the right to enter upon the Premises for the purpose of curing the Landlord's default. Such mortgagee or beneficiary shall notify Landlord and Tenant in the manner provided by **Article 20** of the address of such mortgagee or beneficiary to which such notice shall be sent, and the agreements of Tenant hereunder are subject to prior receipt of such notice.

35.3 Tenant's Self-Help Remedy. Notwithstanding anything to the contrary elsewhere in the Lease, if Landlord commits a default that materially affects Tenant's use of the Premises, and Tenant has provided simultaneous written notice thereof to Landlord's mortgagee (if any and if Tenant has notice thereof) and Landlord (and/or Landlord's mortgagee if any) has failed to cure or commence to cure such default within the period specified above, Tenant may, without waiving any claim for damages for breach of agreement, thereafter cure the default for the account of the Landlord, which cure shall be preceded by an additional notice given at least three (3) days prior to such cure to Landlord and Landlord's mortgagee that Tenant plans to undertake the cure, and the reasonable cost of such cure shall be deemed paid or incurred for the account of Landlord, and Landlord shall reimburse Tenant for Tenant's out-of-pocket expenditures paid to third parties to effectuate such cure, such reimbursement to be within thirty (30) days after completion of the cure and delivery of an invoice to Landlord showing the costs of cure. If Landlord disputes either the necessity of the cure or the cost thereof, the matter shall be settled by arbitration administered by the American Arbitration Association in accordance with its rules before a single arbitrator of the American Arbitration Association sitting in Seattle, Washington. The arbitrator shall be a person having experience and knowledge about commercial leasing and property management. The arbitration shall be held within sixty (60) days of Landlord notifying Tenant that it disputes the need or the cost of Tenant's cure. The costs of the arbitrator shall be shared equally by the parties. The prevailing party shall be entitled to an award of reasonable attorney's fees. The arbitrator's award shall be final and binding on the parties.

35.4 Independent Covenants; Limitation of Remedies and Landlord's Liability. The obligations of Landlord and Tenant, respectively, under this Lease are expressly agreed by the parties to be independent covenants. If Landlord fails to perform any obligation under this Lease required to be performed by Landlord, Tenant shall have no right to: (i) terminate this Lease; (ii) except as provided in **Paragraph 35.3** above, avail itself of self-help or to perform any obligation of Landlord except as expressly permitted elsewhere in this Lease; (iii) abate or withhold any rent or any other charges or sums payable by Tenant under this Lease; or (iv) any right of setoff. If Landlord is in default hereunder, and as

a consequence Tenant recovers a money judgment against Landlord, such judgment shall be satisfied only out of the proceeds of sale received on execution of the judgment and levy against the right, title and interest of Landlord in the Premises, and out of rent or other income from the Premises receivable by Landlord or out of the consideration received by Landlord from the sale or other disposition of all or any part of Landlord's right, title and interest in the Premises. Neither Landlord, nor any agent, officer, director, partner or employee of Landlord shall be personally liable for any portion of such a judgment. If at any time the holder of Landlord's interest hereunder is a partnership, limited liability company or joint venture, a deficit in the capital account of any partner, member or joint venturer shall not be considered an asset of such partnership, limited liability company or joint venture.

ARTICLE 36

CONSENT

In consideration of each covenant made elsewhere under this Lease wherein one of the parties agrees not to unreasonably withhold its consent or approval, the requesting party hereby releases the other and waives all claims for any damages arising out of or connected with any alleged or claimed unreasonable withholding or consent or approval, and the requesting party's sole remedy shall be to have the consent granted.

ARTICLE 37

INTERPRETATION

The captions by which the articles and paragraphs of this Lease are identified are for convenience only, and shall not affect the interpretation of this Lease. Wherever the context so requires, the singular number shall include the plural, the plural shall refer to the singular and the neuter gender shall include the masculine and feminine genders. If there is more than one signatory hereto as Tenant, the liability of such signatories shall be joint and several. If any provision of this Lease shall be held to be invalid by a court, the remaining provisions shall remain in effect and shall in no way be impaired thereby.

ARTICLE 38

ENTIRE INSTRUMENT

It is understood that there are no oral agreements between the parties hereto affecting this Lease, and this Lease supersedes and cancels any and all previous negotiations, arrangements, brochures, agreements and understandings, if any, between the parties hereto or displayed by Landlord to Tenant with respect to the subject matter thereof, and none thereof shall be used to interpret or construe this Lease. This is the final and complete expression of the parties' agreement, all of the agreements heretofore and contemporaneously made by the parties are contained in this Lease, and this Lease cannot be modified in any respect except by a writing executed by Landlord and Tenant. All terms and conditions hereof shall apply on the date of mutual execution hereof except as otherwise expressly set forth herein. Time is of the essence hereof.

ARTICLE 39

EASEMENTS; RECORDING

This Lease is made expressly subject to:

(a) any conditions, covenants, restrictions, easements, and other matters now or hereafter of record against the Premises or the Property; and

(b) any easements for utilities or ingress and egress which now or hereafter may be placed of record by Landlord for purposes of the common benefit of the occupants of the Property. Tenant agrees, subject to the provisions of **Article 23**, to execute such documents necessary to subordinate its interest hereunder to such easements.

Neither Landlord nor Tenant shall record this Lease or any "short-form" or other memorandum thereof.

ARTICLE 40

SALE BY LANDLORD

The Premises and/or Landlord's interest under this Lease may be freely sold or assigned by Landlord, and in the event of any such sale or assignment, the covenants and obligations of Landlord herein shall be binding on each successive "landlord," and its successors and assigns, only during their respective periods of ownership.

ARTICLE 41

SECURITY MEASURES

Tenant acknowledges (1) that the Minimum Monthly Rent does not include the cost of any security measures for any portion of the Property (2) that neither Landlord nor Property Manager shall have any obligation to provide any such security measures, (3) that neither Landlord nor Property Manager has made any representation to Tenant regarding the safety or security of the Property, and (4) that Tenant will be solely responsible for providing any security it deems necessary to protect itself, its property, and Tenant's invitees in, on, or about the Building and the Property. If Landlord or Property Manager provides any security measures at any time, then neither Landlord nor Property Manager shall be obligated to continue providing such security measures and Landlord and Property Manager shall not be obligated to provide such security measures with any particular standard of care. Tenant assumes all responsibility for the security and safety of Tenant and Tenant's property. Except as otherwise provided to the contrary in this Lease, Tenant releases Landlord and Property Manager from all claims for damage, loss, or injury to Tenant, Tenant's Invitees, and/or to the personal property of Tenant and/or of Tenant's Invitees, even if such damage, loss, or injury is caused by or results from the criminal or negligent acts of third parties. Landlord and Property Manager shall have no duty to warn Tenant of any criminal acts or dangerous conduct that has occurred in or near the Property, regardless of their knowledge of such crimes or conduct, and Tenant is hereby instructed to conduct its own investigation through local police agencies regarding any criminal acts or dangerous conduct that has occurred in or near the Property.

ARTICLE 42

RELOCATION

Landlord shall have the right at all times, which Landlord may exercise upon not less than ninety (90) days' prior written notice (the "**Relocation Notice**") to Tenant, to relocate Tenant from the Premises to Substitute Premises within the Building. As used in this Lease, the term "**Substitute Premises**" means premises within the Building containing square footage that is at least equal to the approximate square footage of the Premises. If Landlord exercises its right to relocate Tenant, then Landlord shall pay all of

the reasonable costs incurred by Tenant in connection with such relocation, including (1) the cost of installing in the Substitute Premises leasehold improvements comparable to those in the Premises; and (2) the cost of relocating Tenant's furniture, fixtures, equipment and inventory to the Substitute Premises. Tenant shall not be responsible for the cost of any repairs to the Premises made necessary by the removal of such fixtures and equipment. In the event Tenant is relocated pursuant to this paragraph, then not later than the date specified in the Relocation Notice, Tenant shall surrender the Premises to Landlord, in the manner of surrender that complies with all of the terms and conditions of this Lease, and Landlord and Tenant shall sign an amendment to this Lease, which amendment shall substitute the Substitute Premises in place of the Premises for all purposes under this Lease. Notwithstanding any provision of this Lease to the contrary, if Landlord issues a Relocation Notice to Tenant and Tenant refuses to relocate by the date specified therein, Landlord may terminate this Lease thereafter at any time upon giving six (6) months' prior written notice to Tenant, and Landlord shall not be liable to Tenant for damages, losses, costs or expenses of any kind (including, without limitation, consequential damages) on account of such termination.

ARTICLE 43

CHOICE OF LAW; WAIVER OF TRIAL BY JURY

The laws of the state in which the Premises are situated shall govern this Lease. Tenant hereby waives trial by jury in any action, proceeding or counterclaim brought by either of the parties hereto on any matters whatsoever arising out of or in any way connected with this Lease, including without limitation, the relationship of Landlord and Tenant, Tenant's use or occupancy of the Premises, or any claim of injury or damage, or the enforcement of any remedy under any law, statute, or regulation.

ARTICLE 44

HAZARDOUS SUBSTANCES

44.1 Indemnity. Tenant shall be solely responsible and liable for, and shall indemnify, defend and hold harmless Landlord for, from and against any and all Hazardous Substances existing on the Premises or the Property or any other property, or present in or on the air, ground water, soil, buildings or other improvements or otherwise in, on, under or about the Premises or the Property or any other property, resulting from the Handling by Tenant's Permittees of any Hazardous Substance during the period of Tenant's occupancy or use of the Premises. Without limiting the generality of the foregoing, Tenant shall, at any time during the Term of the Lease and at the end of the Term of the Lease, perform all work necessary to render the Premises or any other property "clean" and free of all Hazardous Substances, in accordance with all present and then-applicable Laws.

44.2 Covenant. Tenant shall not knowingly cause or permit any Hazardous Substance to be Handled in, upon, under or about the Premises (or any part thereof) or any part of the Property by Tenant's Permittees without the prior written consent of Landlord. Notwithstanding the foregoing, Tenant shall promptly deliver to Landlord true copies of all governmental permits and approvals relating to the Handling of Hazardous Substances and all correspondence sent or received by Tenant's Permittees regarding any Handling of Hazardous Substances in or about the Premises, including, without limitation, inspection reports and citations.

44.3 Definitions. As used in this **Article 44**, the following terms shall have the following definitions:

(a) **"Hazardous Substance"** means any chemical, compound, material, substance or other matter that: (i) is a flammable explosive, asbestos, radioactive material, nuclear medicine material, drug, vaccine, bacteria, virus, hazardous waste, toxic substance, petroleum product, or related injurious or potentially injurious material, whether injurious or potentially injurious by itself or in combination with other Substance; (ii) is controlled, designated in or governed by any Hazardous Substance Law; (iii) gives rise to any reporting, notice or publication requirements under any Hazardous Substance Law; or (iv) gives rise to any liability, responsibility or duty on the part of Tenant or Landlord with respect to any third person under any Hazardous Substance Law. The term Hazardous Substance shall not refer to any medical waste, as that term is herein defined.

(b) **"Handle"** or **"Handled"** or **"Handling"** means generated, produced, brought upon, used, handled, stored, treated or disposed of.

(c) **"Tenant's Permittees"** means and includes Tenant, Tenant's employees, licensees, contractors, subcontractors, representatives, agents, officers, partners, directors, subtenants, sub-subtenants and invitees.

(d) **"Laws"** means all applicable present and future laws, ordinances, rules, regulations, statutes, requirements, actions, policies, and common law of any local, state, Federal or quasi-governmental agency, body, board or commission.

44.4 Breach of Obligations. If Tenant breaches the obligations set forth in Paragraphs 44.1 and 44.2 of this Lease, or if the presence of Hazardous Substances in, upon, under or about the Premises caused or permitted by Tenant's Permittees results in contamination of the Premises or any other property, or if contamination of the Premises or any other property by Hazardous Substances otherwise occurs or exists at any time during or after the Term of this Lease, resulting from Tenant's Permittee's use of the Premises, then Tenant shall indemnify, defend and hold Landlord harmless from and against any and all liabilities, costs, expenses, claims, judgments, damages, penalties, fines or losses (including without limitation, damages for the loss or restriction on use of rentable or usable space or of any amenity of the Premises or the Property, claims by any government agency or other third parties, and sums paid in settlement of claims, attorneys' fees, consultants' fees, experts' fees and the like) which arise at any time during the Term of this Lease or after the Term of this Lease as a direct result therefrom. This obligation of Tenant to indemnify, defend and hold Landlord harmless shall survive and extend beyond the expiration or earlier termination of this Lease and includes, without limitation, indemnification against all costs incurred in connection with any investigation of site conditions or any studies, testing, reports, monitoring, clean-up, detoxification, decontamination, repairs, replacements, restoration and remedial work required by any federal, state or local governmental agency, authority or political subdivision because of any Hazardous Substance present in soil, ground water, air, buildings or other improvements or otherwise in, upon, under or about the Premises or the adjacent Property or any other property, air or water. Without limiting the foregoing, if the presence of any Hazardous Substance in, on, under or about the Premises or the Property due to the Handling of Hazardous Substances by Tenant's Permittees results in contamination of the Premises or the Property or any other property, air or water, Tenant shall immediately take all actions at its sole cost and expense as are necessary or appropriate to return the Premises and the Property to the condition existing prior to the Handling, provided that Tenant obtains Landlord's prior written approval of such actions and of the contractors and other persons performing such actions, which approval shall not be unreasonably withheld, so long as such actions would not potentially have any materially adverse long-term or short-term effect on the Premises or the Property. In any event, any and all actions by Tenant to return the Premises and the Property to the condition existing prior to the Handling of any such Hazardous Substance shall be done in compliance with all Laws, and in such a manner and at such times as to avoid interference with and/or inconvenience to any or all other tenants, occupants, contractors and invitees of any adjacent property to the maximum extent possible. It

is the intent of Landlord and Tenant (and Landlord and Tenant hereby agree) that Landlord shall have no liability whatsoever for the existence or presence of Hazardous Substances in, upon, under or about the Premises resulting from the Handling of any Hazardous Substances in connection with Tenant's occupancy or use of the Premises, and that Tenant shall have sole and absolute responsibility for the existence or presence of Hazardous Substances in, upon, under or about the Premises and shall fully indemnify and hold Landlord harmless from and against any liabilities, costs, expenses (including attorneys' fees), claims, judgments, damages, demand, penalties, fines and losses arising from or in connection with the existence or presence of Hazardous Substances in, upon, under or about the Premises or the migration thereof from or to the Premises resulting from the Handling of any Hazardous Substances in connection with Tenant's occupancy or use of the Premises. Tenant's obligations under this Article shall survive the termination of this Lease.

44.5 Handling; Notices. Without in any way diminishing or waiving the limitations on and obligations of Tenant set forth in this **Article 44**, if Tenant's Permittees Handle Hazardous Substances in, upon, under or about the Premises, such Handling shall be done in full compliance with all Laws. In that connection, Landlord and its agents and representatives shall have the right, but not the obligation, at Tenant's cost, to enter onto and to inspect the Premises and conduct investigations, studies, tests, reports, monitoring and analysis of the Premises and any and all Hazardous Substances at any and all reasonable times to determine whether Tenant is complying with its obligations under this Lease; provided, however, that before Landlord enters the Premises to conduct any such tests or investigations, Landlord shall provide Tenant with at least five (5) working days' prior notice. Furthermore, Tenant shall immediately upon receipt thereof, provide to Landlord written notice of the following:

(a) Any enforcement, clean-up or other regulatory action taken or threatened by any governmental authority with respect to the presence of any Hazardous Substances in, upon under or about the Premises or the migration thereof from or to other property;

(b) All demands or claims made or threatened by any third party against Tenant or the Premises relating to any loss or injury resulting from any Hazardous Substances;

(c) Any spill, release, discharge or disposal of Hazardous Substances in, upon, under or about the Premises;

(d) All matters with respect to which Tenant is required to give notice pursuant to any applicable health and safety regulations.

Landlord shall have the right to join and participate in, as a party if it so elects, any legal proceedings or actions affecting the Premises initiated in connection with any Hazardous Substances or related laws.

ARTICLE 45

AUTHORITY

If Tenant is other than a natural person, each person executing this Lease on behalf of Tenant hereby covenants and warrants to Landlord that: such person is duly authorized to execute this Lease on behalf of Tenant; Tenant is duly qualified in all respects; all steps have been taken prior to the date hereof to qualify Tenant to do business in the state in which the Premises are situated; all franchise and other taxes have been paid to date; and all forms, reports, fees and other documents necessary to comply with applicable laws will be filed when due. Tenant will furnish to Landlord promptly upon demand, a

corporate resolution, proof of due authorization of partners, or other appropriate documentation reasonably requested by Landlord evidencing the due authorization of Tenant to enter into this Lease.

ARTICLE 46

BROKERS

Tenant hereby represents and warrants that, other than Landlord's Broker and Tenant's Broker, Tenant has not employed any broker with regard to this Lease and that Tenant has no knowledge of any other broker being instrumental in bringing about this Lease transaction. Tenant shall indemnify Landlord against any expense incurred by Landlord as a result of any claim for brokerage or other commissions made by any other broker, finder, or agent, whether or not meritorious, employed by Tenant or claiming by, through or under Tenant. Tenant acknowledges that Landlord shall not be liable for any representations of Landlord's leasing agent or other agents of Landlord regarding this Lease transaction except for the representations and covenants of Landlord expressly set forth in this Lease.

ARTICLE 47

TENANT REPRESENTATION

Neither Tenant nor any of its constituent partners, members or shareholders, nor any beneficial owner of Tenant or of any such partner, member or shareholder (i) is listed on the Specially Designated Nationals and Blocked Persons List maintained by the Office of Foreign Asset Control, Department of the Treasury (**"OFAC"**) pursuant to the Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) (**"Order"**); (ii) is listed on any other list of terrorists or terrorist organizations maintained pursuant to the Order, the rules and regulations of OFAC or any other applicable requirements contained in any enabling legislation or other Executive Orders in respect of the Order (the Order and such other rules, regulations, legislation or orders are collectively called the "Orders"); (iii) is engaged in activities prohibited in the Orders; or (iv) has been convicted, pleaded nolo contendere, indicted, arraigned or custodially detained on charges involving money laundering or predicate crimes to money laundering.

ARTICLE 48

MEDICAL OFFICE PROVISIONS

48.1 Medical, Biological, and Infectious Waste. Tenant may use medical and/or dental supplies and materials, and may generate Medical Wastes (defined below) which are commonly found in medical and/or dental offices, laboratories and clinics. Tenant's generation, use, storage and disposal of such supplies, materials and Medical Wastes shall strictly comply with all applicable local, state and federal laws, codes, rules, regulations and guidelines. Tenant represents and warrants to Landlord that, except as set forth in the preceding sentences, Tenant's intended use of the Premises does not involve the use, production, disposal or bringing on to the Premises of any other hazardous waste or materials.

48.2 Definition. As used herein, **"Medical Wastes"** shall be defined to include the following:

(a) medical devices or paraphernalia such as syringes, sutures, cotton swabs or pads, sponges, bandages, or wraps of any sort, or any other item which is utilized to treat any patient or other person for any medicinal, medical, diagnostic, dental, or therapeutic reason or purpose;

(b) any material of any type or nature whatsoever that are radioactive to any degree, whether as the result of their manufacture, use or application;

(c) any device or thing which is intended to come into contact with any part of the body, whether or not such item or device is so utilized prior to its disposal, including without limitation sharps,

(d) any instrument or thing which is designed for use or application in the office of Tenant, whether or not such device, instrument or thing is intended for any medical, dental, diagnostic, or therapeutic use; and

(e) any device, instrument or thing which has become infected, contaminated, diseased, or otherwise exposed to harmful, contagious, or communicable organisms, bacteria, or other life forms.

48.3 Use Limitations: Liability. Tenant agrees not to maintain in or around the Premises any activity or instrumentality dangerous to life or limb or to permit any objectionable noise or odor to escape or be emitted from the Premises or to permit anything to be done upon the Premises that would tend to create a nuisance or to disturb any other Tenants of the Building. Tenant shall not permit use of the Premises by doctors and/or dentists not affiliated with Tenant without Landlord's prior written approval. Tenant agrees to not operate an urgent care facility, ambulatory surgery center, or any other facility or enterprise within the Premises that requires a health care facility license under applicable law. Tenant agrees that Medical Waste generated within the Premises shall be disposed of separately from waste materials such as paper refuse and other abandoned items commonly thought of as trash. Tenant also agrees that Tenant will not mix or place Medical Waste in regular trash containers. Tenant will keep Medical Waste containers segregated and make them available for regular removal from the Building by Tenant or Tenant's contractors. Landlord shall have no obligation or liability for the removal or disposal of any Medical Wastes. Tenant also agrees to separate particular items of Medical Waste for separate disposal as required by law. The parties further agree that, in the event any harm or injury of any type or nature whatsoever, should be caused to, incurred by, inflicted upon, or suffered by any individual, including Tenant or Tenant's agents, employees, patients, visitors, invitees or licensees, or Landlord or any of its agents, employees, guests, visitors, invitees or licensees, as the result of the failure of Tenant to timely, thoroughly and completely dispose of Medical Waste, or as the result of coming into contact, whether by touching, breathing, inhaling, or in any other manner ingesting or consuming such item, or by being exposed in any manner thereto, Tenant shall be liable to such individual, and shall save and hold Landlord and its principals and other tenants, agents, employees, patients, visitors, invitees or licensees harmless against any damages, liability, claims, causes of action or judgments arising therefrom. Tenant shall be liable to and shall pay any injured party for all damages, costs or expenses, including attorney fees, arising out of any exposure, harm, injury, disease, contamination, or affliction suffered as the result of any Medical Waste stored, generated, or disposed of by Tenant or in or around the Premises.

48.4 Insurance. Tenant agrees to maintain customary professional liability insurance coverage which shall insure against any action, error, or omission of Tenant, its employees and agents, in connection with the provision of any health care and/or dental services provided by Tenant, its employees and agents, in the Premises, in an amount customary for physicians and/or dentists in the area practicing in the same medical or dental specialty as that practiced by Tenant which liability insurance shall provide coverage for any occurrence during the Term that may subsequently give rise to a claim being made against Tenant for professional malpractice. If the professional liability insurance obtained by Tenant is written on a claims-made basis, and if at any time after the expiration or termination of this Lease, Tenant ceases to maintain professional liability insurance in an amount of One Million Dollars ($1,000,000) covering the acts or omissions of Tenant during the Term of this Lease, Tenant shall purchase the optional extension period coverage under its professional liability insurance policy. Tenant's obligation to maintain professional liability insurance shall remain in force after the termination of this Lease.

48.5 Death or Disability of Principal. In case of the death or total and permanent physical disability of Tenant during the Term of this Lease, Tenant, or Tenant's personal representative, may terminate this Lease upon ninety (90) days prior written notice for death, and ninety (90) days prior written notice for disability, delivered to Landlord and upon furnishing to Landlord proof reasonably satisfactory to Landlord of such death or disability. Disability shall be deemed to be total when of such an extent that Tenant is prevented thereby from practicing or engaging in the profession which was engaged in by Tenant at the Premises at the time such disability occurred, and such total disability shall be deemed to be permanent when it is present and shall have existed continuously for at least three (3) months.

48.6 Removal/Restoration of Alterations. Notwithstanding anything to the contrary elsewhere in this Lease, Tenant shall, upon termination or earlier expiration of the Term, remove and retain possession of all of its built-in laboratory equipment and medical and/or dental cabinetry and trade cabinets, and repair any damages to the Premises caused by such removal.

48.7 Signage. Tenant understands that the Building is presently equipped and maintained principally for the use and occupancy of physicians, surgeons, dentists, and kindred professions and businesses, and that unprofessional advertising by tenants would cause substantial damage to Landlord.

IN WITNESS WHEREOF, the parties hereto have executed this lease the day and year first above written.

[SIGNATURES ON NEXT PAGE]

LANDLORD:

GRE KRUGER LLC, a Washington limited liability company

By:
Name: Kelli Jo Norris
Its: Authorized Signatory
Date: 4/30/07

TENANT:

PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation

By:
Print Name: JASON SCHNEIGER M
Date: 4/27/07

STATE OF WASHINGTON
ss.
COUNTY OF KING

I certify that I know or have satisfactory evidence that Kari E Nevis is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the Authorized Signatory of GRE KRUGER LLC, a Washington limited liability company, to be the free and voluntary act of such limited liability company for the uses and purposes mentioned in the instrument.

Dated this 30th day of April, 2009.

CRYSTAL MARIE WARD Commission Expires NOTARY PUBLIC 08-11-2010 STATE OF WASHINGTON

Crystal Marie Ward
(Signature of Notary)

Crystal Marie Ward
(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at Kent WA
My appointment expires 8/11/2010

STATE OF WASHINGTON
ss.
COUNTY OF King

I certify that I know or have satisfactory evidence that Jason Schneier is the person who appeared before me, and said person acknowledged that said person signed this instrument, on oath stated that said person was authorized to execute the instrument and acknowledged it as the MD of PUGET SOUND GASTROENTEROLOGY, P.S., a Washington professional service corporation, to be the free and voluntary act of such corporation for the uses and purposes mentioned in the instrument.

Dated this 29 day of April, 2009.

(Signature of Notary)

(Legibly Print or Stamp Name of Notary)
Notary public in and for the state of Washington,
residing at [illegible], WA
My appointment expires 10-11-10

50965211.9

EXHIBIT "A"

LEGAL DESCRIPTION

TRACTS 29 AND 31, SOLNER'S FIVE ACRE TRACTS, ACCORDING TO THE PLAT THEREOF, RECORDED IN VOLUME 7, OF PLATS, PAGE 25, RECORDS OF SNOHOMISH COUNTY, WASHINGTON;

TOGETHER WITH VACATED SPRUCE STREET ADJOINING SAID TRACTS 29 AND 31 AS VACATED ON APRIL 9, 1928 IN VOLUME 30 OF COMMISSIONER'S RECORDS, PAGE 165;

EXCEPT THE WEST 331.60 FEET OF SAID TRACT 29, AS CONDEMNED IN SNOHOMISH COUNTY SUPERIOR COURT CAUSE NUMBER 78-2-01473-7;

AND EXCEPT THAT PORTION OF TRACT 31 LYING EASTERLY OF THE WEST LINE OF PRIMARY STATE HIGHWAY NUMBER 1, AS ESTABLISHED BY DEED TO THE STATE OF WASHINGTON RECORDS OF SNOHOMISH COUNTY RECORDING NUMBER 339775;

AND EXCEPT THAT PORTION OF TRACT 31 THEREOF CONVEYED TO THE CITY OF LYNNWOOD BY DEED RECORDED UNDER AUDITOR'S FILE NUMBER 9801200732.
SITUATE IN THE COUNTY OF SNOHOMISH, STATE OF WASHINGTON.

EXHIBIT "B"

SPACE PLANS

[See attached five (5) sheets.]

EXHIBIT "C"

ALLOWANCES

1. Carpet and Paint Allowance. Tenant shall be entitled to reimbursement of its hard costs actually incurred for labor and materials to install new carpet in and paint the Premises, up to a maximum total of the Carpet and Paint Allowance provided in the Basic Lease Provisions, under the conditions set forth below, but payment or nonpayment thereof shall not relieve Tenant of its responsibility and pay for all costs thereof. If Tenant is not then in uncured default under this Lease, Landlord shall reimburse the Carpet and Paint Allowance within thirty (30) days after final completion of the work and receipt by Landlord of lien releases from all contractors and suppliers whom Tenant has contracted with in connection with such work. If Tenant fails to request the Carpet and Paint Allowance after satisfaction of the preconditions set forth above by the Expiration Date of the Initial Term hereof (or, if Tenant duly exercises the First Extended Term Option, by the first (1st) anniversary of the Commencement Date of the First Extended Term) (such date, the "**Request Deadline**"), Tenant shall be conclusively deemed to have waived any right to receive the Carpet and Paint Allowance. The parties acknowledge that the Carpet and Paint Allowance may be drawn by Tenant at any time after mutual execution hereof and before the Request Deadline. However, if Tenant does not duly exercise the First Extended Term Option and the parties do not agree otherwise, Tenant shall reimburse Landlord the unamortized portion of the Carpet and Paint Allowance actually paid to Tenant (amortized without interest over a five (5)-year period commencing on the date the Carpet and Paint Allowance is paid), such amount to be reimbursed prior to the Expiration Date of the Initial Term of this Lease.

2. Tenant Improvement Allowance.

a. Basic Allowance. If Tenant duly exercises its First Extended Term Option, Tenant shall also be entitled to reimbursement of its hard costs actually incurred for labor and materials to perform tenant improvements and alterations to the Premises as mutually agreed to by the parties, up to a maximum total of the Basic Allowance provided in the Basic Lease Provisions (in addition to and not in lieu of the Carpet and Paint Allowance), under the conditions set forth below, but payment or nonpayment thereof shall not relieve Tenant of its responsibility and pay for all costs thereof.

b. Additional Allowance. At Tenant's election, and in addition to the Basic Allowance, Landlord shall contribute up to an additional amount not to exceed the Additional Allowance provided in the Basic Lease Provisions. To the extent received by Tenant, Tenant shall pay additional Minimum Rent for the remainder of the Term (Initial Term plus First Extended Term) in an amount necessary to fully repay the Additional Allowance, amortized at eight percent (8%) per annum, over the remainder of the Term (Initial Term plus First Extended Term). Tenant shall notify Landlord how much of the Additional Allowance Tenant has elected to receive from Landlord at any time after Tenant exercises its First Extended Term Option and before commencement of any tenant improvements or alterations to the Premises by Tenant. Such election shall be final and binding on Tenant, and may not thereafter be modified without Landlord's consent, which may be granted or withheld in Landlord's sole and absolute subjective discretion. Upon substantial completion of such tenant improvements or alterations, the final amount of the Additional Allowance shall be determined by Landlord and notice of such adjusted final amount, along with a recalculation of the additional Minimum Rent due from Tenant under this Lease, shall be given to Tenant.

c. General. If Tenant is not then in uncured default under this Lease, Landlord shall reimburse the Tenant Improvement Allowance within thirty (30) days after final completion of the work and receipt by Landlord of lien releases from all contractors and suppliers whom Tenant has contracted with in connection with such work. If Tenant fails to request the Tenant Improvement Allowance after

satisfaction of the preconditions set forth above by the first (1st) anniversary of the Commencement Date of the First Extended Term, Tenant shall be conclusively deemed to have waived any right to receive the Tenant Improvement Allowance.

EXHIBIT "D"

RULES AND REGULATIONS

1. The sidewalks, halls, passages, elevators, stairways, exits and entrances of the Building shall not be obstructed by Tenant or used by it for any purpose other than for ingress and egress from the Premises. The halls, passages, exits, entrances, elevators, retail arcade, escalators, balconies and stairways are not for the use of the general public, and Landlord shall in all cases retain the right to control and prevent access to those areas by all persons whose presence in the judgment of Landlord would be prejudicial to the safety, character, reputation and interests of the Building and its tenants, provided that nothing in this Lease shall be construed to prevent access to persons with whom Tenant normally deals in the ordinary course of its business, unless those persons are engaged in illegal activities. Tenant shall not go upon the roof of the Building, except in areas that Landlord may designate as "Common Areas" from time to time.

2. The Premises shall not be used for lodging or sleeping. Unless ancillary to a restaurant or other food service use specifically authorized in Tenant's Lease, no cooking shall be done or permitted by Tenant on the Premises, except that the preparation of hot beverages and use of microwave ovens for Tenant and its employees shall be permitted. No animals of any kind shall be permitted at the Building except as may be required by applicable law.

3. Landlord shall provide at no cost to Tenant up to five (5) keys to the Premises; all additional or lost keys shall be at Tenant's expense. Tenant may not install any additional locks in the Premises without Landlord's prior consent, and all such locks must be keyed to the Building's master system. Tenant shall not alter any lock or install a new or additional lock or any bolt on any door of the Premises, which Landlord requires access to without furnishing Landlord with a key for any lock and obtaining Landlord's prior permission. Tenant, upon the termination of its tenancy, shall deliver to Landlord all keys and/or security cards to doors in the Building and the Premises that shall have been furnished to Tenant and in the event of loss of any keys and/or security cards so furnished, shall pay Landlord for the lost keys and/or security cards and changing of locks as a result of such loss.

4. The persons employed by Tenant to move equipment or other items in or out of the Building must be acceptable to Landlord. Landlord shall have the right to prescribe the weight, size and position of all equipment, materials, supplies, furniture or other property brought into the Building. No safes or other objects larger or heavier than the elevator of the Building is limited to carry shall be brought into or installed on the Premises without Landlord's prior written consent. Heavy objects shall, if considered necessary by Landlord, stand on wood strips of thickness as is necessary to properly distribute the weight of those objects. Landlord will not be responsible for loss of or damage to any property from any cause, and all damage done to the Building by moving or maintaining Tenant's property shall be repaired at the expense of Tenant. The moving of heavy objects shall occur only between those hours as may be designated by and only upon written notice to Landlord and the persons employed to move heavy objects in or out of the Building must be acceptable to Landlord.

5. Tenant shall not use or keep in the Premises or the Building any kerosene, gasoline or flammable or combustible fluid or materials or use any method of heating or air conditioning other than that permitted by Landlord. Tenant shall not sweep or throw or permit to be swept or thrown from the Premises any debris or other substance into any of the corridors, halls or lobbies or out of the doors or windows or into the stairways of the Building and Tenant shall not use, keep or permit to be used or kept any foul or noxious gas or substance in the Premises. Tenant shall not use, keep or permit or suffer the

Premises to be occupied or used in a manner offensive or objectionable to Landlord or other occupants of the Building by reason of noise, odors and/or vibrations, or interfere in any way with other tenants or those having business in the Building.

6. During non-business hours and on holidays as designated by the Landlord, access to the Building, or to the halls, corridors or stairways in the Building, or to the Premises, may be refused unless the person seeking access is known to the Building and has a pass or is properly identified. Landlord shall in no case be liable for damages for the admission to or exclusion from the Building of any person whom Landlord has the right to exclude under Rule 1 above. In case of invasion, mob, riot, public excitement or other circumstances rendering that action advisable in Landlord's opinion, Landlord reserves the right to prevent access to the Building during the continuance of that activity by taking those actions that Landlord may deem appropriate, including closing entrances to the Building. Any person, whose presence in the Building at any time shall in the sole judgment of Landlord, be prejudicial to the safety, character, reputation and interests of the Building or its Tenants may be denied access to the Building or may be ejected there from. Landlord may require any persons leaving the Building with any package or other object to exhibit a pass from Tenant from whose premises the package or object is being removed, but the establishment and enforcement of such requirement shall not impose any responsibility on Landlord for the protection of any Tenant against the removal of property from the Premises of Tenant.

7. Tenant shall see that the doors of the Premises are closed and securely locked when Tenant's employees leave the Premises, after hours.

8. The toilet rooms, toilets, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, no foreign substance of any kind whatsoever shall be deposited in any of them, and any damage resulting to them from Tenant's misuse shall be paid for by Tenant.

9. Except with the prior written consent of Landlord, Tenant shall not sell, or permit the sale from the Premises of newspapers, magazines, periodicals, theatre tickets or any other goods, merchandise or service, nor shall Tenant carry on, or permit or allow any employee or other person to carry on, business in or from the Premises for the service or accommodation of occupants of any other portion of the Building, nor shall the Premises be used for manufacturing of any kind, or for any business or activity other than that specifically provided for in Tenant's Lease. No Tenant shall obtain for use upon the Premises ice, towel and other similar services, or accept barbering or shoe polishing services in the Premises, except from persons authorized by Landlord and at hours and under regulations fixed by Landlord.

10. Tenant shall not install any radio or television antenna, loudspeaker or other device on the roof or exterior walls of the Building.

11. Tenant shall not use in any space, or in the Common Areas of the Building, any handtrucks except those equipped with rubber tires and side guards or other material handling equipment as Landlord may approve. No other vehicles of any kind shall be brought by Tenant into the Building or kept in or about the Premises.

12. No sign, advertisement or notice visible from the exterior of the Premises shall be inscribed, painted or affixed by Tenant on any part of the Building or the Premises without the prior written consent of Landlord. If Landlord shall have consented at anytime, whether before or after the execution of this Lease, that consent shall in no way operate as a waiver or release of any of the provisions of this Rule 12 or of this Lease, and shall be deemed to relate only to the particular sign,

advertisement or notice so consented to by Landlord and shall not be construed as dispensing with the necessity of obtaining the specific written consent of Landlord with respect to each and every such sign, advertisement or notice other than the particular sign, advertisement or notice, as the case may be, so consented to by Landlord. All signs shall comply with the requirements of the Building's Sign Criteria.

13. Except as shown in the design plan approved by Landlord, the sashes, sash doors, windows, glass relites, and any lights or skylights that reflect or admit light into the halls or other places of the Building shall not be covered or obstructed and, there shall be no hanging plants or other similar objects in the immediate vicinity of the windows or placed upon the window sills or hung from the window heads. Tenant shall not use any blinds, shades, awnings, or screens in connection with any window or door of the premises unless approved in writing by Landlord. Tenant shall not use any drape or window covering facing any exterior glass surface other than the standard drape established by Landlord.

14. No tenant shall lay linoleum or other similar floor covering so that it is affixed to the floor of the Premises in any manner except by a paste, or other material which may easily be removed with water, the use of cement or other similar adhesive materials being expressly prohibited. The method of affixing any linoleum or other similar floor covering to the floor, as well as the method of affixing carpets or rugs to the Premises, shall be subject to approval by Landlord. The expense of repairing any damage resulting from a violation of this Rule 14 shall be borne by the Tenant by whom, or by whose agents, clerks, employees or visitors, the damage shall have been caused.

15. Tenant shall not overload the floor of the Premises or mark, drive nails, screw or drill into the partitions, woodwork or plaster or in any way deface the premises or any part thereof.

16. Tenant shall not employ any person or persons other than the janitor of Landlord for the purpose of cleaning the premises unless otherwise agreed to by Landlord. Except with the written consent of Landlord no person or persons other than those approved by Landlord shall be permitted to enter the Building for the purpose of cleaning the same. Tenant shall not cause any unnecessary labor by reason of Tenant's carelessness or indifference in the preservation of good order and cleanliness. Landlord shall in nowise be responsible to any Tenant for any loss of property on the premises, however occurring, or for any damage done to the effects of any Tenant by the janitor or any other employee or any other person.

17. All loading, unloading, and delivery of merchandise, supplies, materials and furniture to the Premises shall be made during reasonable hours and in entryways and elevators as Landlord shall designate. In its use of the loading areas on the first basement floor, Tenant shall not obstruct or permit the obstruction of loading areas, and at no time shall Tenant park vehicles in the loading areas except for loading and unloading.

18. Canvassing, soliciting, peddling or distribution of handbills or any other written material in the Building is prohibited and Tenant shall cooperate to prevent these activities.

19. Tenant shall not permit the use or the operation of any coin operated machines on the Premises, including, without limitation, vending machines, video games, pinball machines, or pay telephones without the prior written consent of Landlord.

20. Landlord may direct the use of all pest extermination and scavenger contractors throughout the Building and/or Premises at intervals as Landlord may require.

21. If Tenant desires telephone or telegraph connections, Landlord will direct service technicians as to where and how the wires are to be introduced. No boring or cutting for wires or otherwise shall be made without directions from Landlord. The location of telephones, call boxes and other office equipment affixed to the Premises shall be subject to the approval of Landlord.

22. Tenant shall immediately, upon request from Landlord (which request need not be in writing), reduce its lighting in the Premises for temporary periods designated by Landlord, when required in Landlord's judgment to prevent overloads of mechanical or electrical systems of the Building. Tenant shall see that the doors of the premises are closed and securely locked before leaving the Building and must observe strict care and caution that all water faucets or water apparatus are entirely shut off before Tenant or Tenant's employees leave the Building, and that all electricity, gas or air shall likewise be carefully shut off, so as to prevent waste or damage, and for any default or carelessness.

23. Landlord reserves the right to select the name of the Building and to change the name as it may deem appropriate from time to time, and Tenant shall not refer to the Building by any name other than: (a) the names as selected by Landlord (as that name may be changed from time to time), or (b) the postal address, approved by the United States Post Office. Tenant shall not use the name of the Building in any respect other than as an address of its operation in the Building without the prior written consent of Landlord.

24. The requirements of Tenant will be attended to only upon application by telephone or in person at the office of the Building manager. Employees of Landlord shall not perform any work or do anything outside of their regular duties unless under special instruction from Landlord.

25. Tenant acknowledges that the Building is a "no smoking" building and Tenant shall cause its employees, contractors, and invitees to observe all local, state, and federal laws, codes, and ordinances in connection with any use of tobacco products in and around the Building.

26. Landlord may waive any one or more of the Rules and Regulations for the benefit of any particular tenant or tenants, but no waiver by Landlord shall be construed as a waiver of the Rules and Regulations in favor of any other tenant or tenants, nor prevent Landlord from thereafter enforcing any Rules and Regulations against any or all of the tenants in the Building.

27. Wherever the word "Tenant" occurs in these Rules and Regulations, it is understood and agreed that it shall mean Tenant's assigns, subtenants, associates, agents, clerks, employees and visitors. Wherever the word "Landlord" occurs in these Rules and Regulations, it is understood and agreed that it shall mean Landlord's assigns, agents, clerks, employees and visitors.

28. These Rules and Regulations are in addition to, and shall not be construed in any way to modify, alter or amend, in whole or part, the terms, covenants, agreements and conditions of any Lease of Premises in the Building. Landlord shall have the right to modify the foregoing Rules and Regulations and add new Rules and Regulations from time to time, which such new or modified Rules and Regulations shall become effective thirty (30) days after delivery thereof to Tenant.

Exhibit G

Southwest Snohomish Planning Area Map

Southwest Snohomish Secondary Health Service Area Zip Code Map

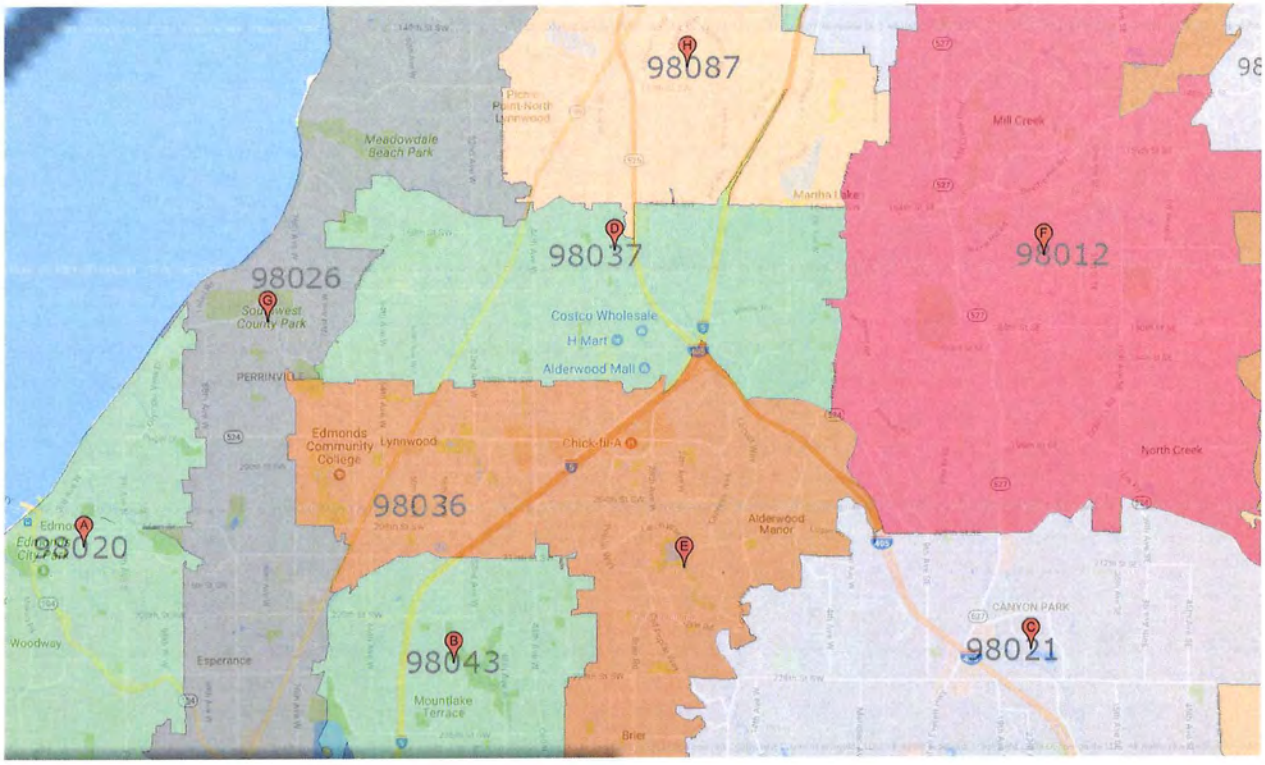

Exhibit H

Population Data

Supplemental Projections of the Total Resident Population for Growth Management
2017 GMA Projections - Medium Series

	Census	Estimate		Projection							
	2010	2015	2017	2018	2019	2020	2021	2022	2023	2024	2025
State	6,724,540	7,061,410	7,310,300	7,426,346	7,535,510	7,638,415	7,736,240	7,827,874	7,916,032	8,001,476	8,085,043
Adams	18,728	19,410	19,870	20,143	20,397	20,633	20,874	21,078	21,276	21,472	21,666
Asotin	21,623	22,010	22,290	22,432	22,554	22,657	22,830	22,941	23,042	23,137	23,227
Benton	175,177	188,590	193,500	196,364	199,045	201,563	204,954	207,695	210,391	213,065	215,740
Chelan	72,453	75,030	76,830	77,579	78,256	78,868	79,742	80,424	81,078	81,712	82,335
Clallam	71,404	72,650	74,240	74,463	74,616	74,707	75,344	75,744	76,122	76,486	76,847
Clark	425,363	451,820	471,000	480,899	490,353	499,400	508,136	516,454	524,563	532,508	540,344
Columbia	4,078	4,090	4,100	4,088	4,072	4,052	4,040	4,022	4,003	3,982	3,962
Cowlitz	102,410	104,280	105,900	106,991	107,982	108,885	109,780	110,470	111,107	111,702	112,267
Douglas	38,431	39,990	41,420	42,279	43,100	43,883	44,500	45,109	45,693	46,258	46,807
Ferry	7,551	7,710	7,740	7,774	7,801	7,821	7,851	7,862	7,869	7,877	7,882
Franklin	78,163	87,150	90,330	93,541	96,667	99,712	102,684	105,422	108,176	110,959	113,781
Garfield	2,266	2,260	2,200	2,208	2,213	2,217	2,214	2,204	2,195	2,184	2,175
Grant	89,120	93,930	95,630	98,052	100,385	102,634	104,498	106,160	107,794	109,408	111,014
Grays Harbor	72,797	73,110	72,970	73,250	73,462	73,613	74,043	74,195	74,337	74,475	74,617
Island	78,506	80,600	82,790	83,283	83,698	84,044	84,910	85,544	86,147	86,728	87,297
Jefferson	29,872	30,880	31,360	31,818	32,246	32,646	33,015	33,318	33,616	33,912	34,211
King	1,931,249	2,052,800	2,153,700	2,181,564	2,207,401	2,231,408	2,257,650	2,283,693	2,308,542	2,332,421	2,355,571
Kitsap	251,133	258,200	264,300	268,411	272,274	275,910	279,250	282,166	284,969	287,685	290,344
Kittitas	40,915	42,670	44,730	45,514	46,255	46,958	47,568	48,198	48,798	49,372	49,927
Klickitat	20,318	21,000	21,660	21,682	21,684	21,667	21,737	21,785	21,824	21,855	21,882
Lewis	75,455	76,660	77,440	78,436	79,360	80,220	81,065	81,702	82,302	82,874	83,425
Lincoln	10,570	10,720	10,700	10,731	10,752	10,765	10,829	10,849	10,867	10,882	10,897
Mason	60,699	62,200	63,190	64,725	66,199	67,621	68,668	69,620	70,544	71,448	72,339
Okanogan	41,120	41,860	42,110	42,473	42,797	43,084	43,409	43,615	43,804	43,981	44,149
Pacific	20,920	21,210	21,250	21,289	21,308	21,311	21,423	21,456	21,483	21,508	21,532
Pend Oreille	13,001	13,240	13,370	13,565	13,746	13,919	14,035	14,133	14,219	14,298	14,369
Pierce	795,225	830,120	859,400	874,137	888,066	901,251	913,426	924,876	935,842	946,412	956,682
San Juan	15,769	16,180	16,510	16,602	16,680	16,743	16,965	17,113	17,257	17,401	17,545
Skagit	116,901	120,620	124,100	126,415	128,612	130,705	132,296	133,823	135,305	136,753	138,184
Skamania	11,066	11,430	11,690	11,815	11,928	12,034	12,169	12,276	12,377	12,476	12,573
Snohomish	713,335	757,600	789,400	807,659	825,176	841,998	853,365	865,573	877,286	888,574	899,527
Spokane	471,221	488,310	499,800	505,924	511,578	516,807	522,275	526,857	531,271	535,569	539,816
Stevens	43,531	44,030	44,510	44,990	45,429	45,830	46,238	46,537	46,816	47,082	47,337
Thurston	252,264	267,410	276,900	282,965	288,768	294,333	299,069	303,611	308,012	312,300	316,508
Wahkiakum	3,978	3,980	4,030	4,025	4,016	4,006	3,987	3,968	3,948	3,926	3,902
Walla Walla	58,781	60,650	61,400	61,673	61,888	62,049	62,567	62,866	63,149	63,422	63,695
Whatcom	201,140	209,790	216,300	221,214	225,925	230,450	233,566	236,702	239,738	242,700	245,610
Whitman	44,776	47,250	48,640	48,846	49,005	49,124	49,394	49,604	49,792	49,964	50,125
Yakima	243,231	249,970	253,000	256,527	259,816	262,887	265,874	268,209	270,478	272,708	274,932

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Exhibit I
American Cancer Society Screening Guidelines

Colorectal Cancer Screening for Average-Risk Adults: 2018 Guideline Update From the American Cancer Society

Andrew M. D. Wolf, MD[1]; Elizabeth T. H. Fontham, MPH, DrPH[2]; Timothy R. Church, PhD[3]; Christopher R. Flowers, MD, MS[4]; Carmen E. Guerra, MD[5]; Samuel J. LaMonte, MD[6]; Ruth Etzioni, PhD[7]; Matthew T. McKenna, MD[8]; Kevin C. Oeffinger, MD[9]; Ya-Chen Tina Shih, PhD[10]; Louise C. Walter, MD[11]; Kimberly S. Andrews, BA[12]; Otis W. Brawley, MD[13]; Durado Brooks, MD, MPH[14]; Stacey A. Fedewa, PhD, MPH[15]; Deana Manassaram-Baptiste, PhD, MPH[16]; Rebecca L. Siegel, MPH[17]; Richard C. Wender, MD[18]; Robert A. Smith, PhD[19]

[1]Associate Professor and Attending Physician, University of Virginia School of Medicine, Charlottesville, VA; [2]Emeritus Professor, Louisiana State University School of Public Health, New Orleans, LA; [3]Professor, University of Minnesota and Masonic Cancer Center, Minneapolis, MN; [4]Professor and Attending Physician, Emory University School of Medicine and Winship Cancer Institute, Atlanta, GA; [5]Associate Professor of Medicine of the Perelman School of Medicine and Attending Physician, University of Pennsylvania Medical Center, Philadelphia, PA; [6]Independent retired physician and patient advocate; [7]Biostatistician, University of Washington and the Fred Hutchinson Cancer Research Center, Seattle, WA; [8]Professor and Director, Division of Preventive Medicine, Department of Family and Preventive Medicine, Emory University School of Medicine, Atlanta, GA; [9]Professor and Director of the Duke Center for Onco-Primary Care, Durham, NC; [10]Professor, Health Services Research, The University of Texas MD Anderson Cancer Center, Houston, TX; [11]Professor and Attending Physician, University of California, San Francisco and San Francisco VA Medical Center, San Francisco, CA; [12]Director, Cancer Control Department, American Cancer Society, Atlanta, GA; [13]Chief Medical and Scientific Officer and Executive Vice President-Research, American Cancer Society, Atlanta, GA; [14]Vice President, Cancer Control Interventions, Cancer Control Department, American Cancer Society, Atlanta, GA; [15]Strategic Director for Risk Factor Screening and Surveillance, American Cancer Society, Atlanta, GA; [16]Director, Cancer Control Department, American Cancer Society, Atlanta, GA; [17]Strategic Director, Surveillance Information Services, American Cancer Society, Atlanta, GA; [18]Chief Cancer Control Officer, American Cancer Society, Atlanta, GA; [19]Vice President, Cancer Screening, Cancer Control Department, American Cancer Society, Atlanta, GA.

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Abstract: In the United States, colorectal cancer (CRC) is the fourth most common cancer diagnosed among adults and the second leading cause of death from cancer. For this guideline update, the American Cancer Society (ACS) used an existing systematic evidence review of the CRC screening literature and microsimulation modeling analyses, including a new evaluation of the age to begin screening by race and sex and additional modeling that incorporates changes in US CRC incidence. Screening with any one of multiple options is associated with a significant reduction in CRC incidence through the detection and removal of adenomatous polyps and other precancerous lesions and with a reduction in mortality through incidence reduction and early detection of CRC. Results from modeling analyses identified efficient and model-recommendable strategies that started screening at age 45 years. The ACS Guideline Development Group applied the Grades of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria in developing and rating the recommendations. The ACS recommends that adults aged 45 years and older with an average risk of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on noncolonoscopy screening tests should be followed up with timely colonoscopy. The recommendation to begin screening at age 45 years is a *qualified recommendation*. The recommendation for regular screening in adults aged 50 years and older is a *strong recommendation*. The ACS recommends (*qualified recommendations*) that: 1) average-risk adults in good health with a life expectancy of more than 10 years continue CRC screening through the age of 75 years; 2) clinicians individualize CRC screening decisions for individuals aged 76 through 85 years based on patient preferences, life expectancy, health status, and prior screening history; and 3) clinicians discourage individuals older than 85 years from continuing CRC screening. The options for CRC screening are: fecal immunochemical test annually; high-sensitivity, guaiac-based fecal occult blood test annually; multitarget stool DNA test every 3 years; colonoscopy every 10 years; computed tomography colonography every 5 years; and flexible sigmoidoscopy every 5 years. **CA Cancer J Clin 2018;000:000-000.**

Keywords: adenoma, colonoscopy, computed tomography colonoscopy, colorectal and rectal neoplasms, mass screening and early detection, mortality, occult blood, radiography, sigmoidoscopy, stool testing

Corresponding author: Robert A. Smith, PhD, Vice President, Cancer Screening, Cancer Control Department, American Cancer Society, 250 Williams Street, Suite 600, Atlanta, GA 30303; robert.smith@cancer.org

Members of the American Cancer Society Guideline Development Group (GDG) serve as volunteers and received no compensation from the ACS. Current members are: Timothy R. Church, PhD; Ruth Etzioni, PhD; Christopher R. Flowers, MD; Elizabeth T. H. Fontham, DrPH (Co-Chair); Carmen Guerra, MD; Samuel J. LaMonte, MD; Matthew T. McKenna, MD; Kevin C. Oeffinger, MD (Chair); Ya-Chen Tina Shih, PhD; Louise C. Walter, MD; and Andrew M. D. Wolf, MD (Chair of the Committee Subgroup for CRC Guideline Update).

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Correction added after online publication 29 May 2018. A statement was corrected in the third paragraph of the Age to Begin CRC Screening section on page 7.

Introduction

Colorectal cancer (CRC) is the fourth most commonly diagnosed cancer among adults in the United States.[1] Over 140,000 Americans are expected to be diagnosed with CRC in 2018. It is the second leading cause of cancer death, leading to over 50,000 deaths annually.[1] CRC disease burden varies across racial groups, with the highest incidence and mortality rates in blacks, American Indians, and Alaska Natives.[2]

Temporal trends in CRC incidence and mortality among adults aged 55 years and older have shown a decline for several decades that accelerated around 2000, particularly among adults aged 65 years and older.[2,3] Although changes in exposure to risk factors account for an estimated one-half of the reduction in incidence and one-third of the reduction in mortality before 2000, subsequent accelerated declines in incidence and mortality since 2000 are largely attributable to increased uptake of screening, with improved treatment also contributing to mortality reductions.[3-6] In contrast, among adults younger than 55 years, there was a 51% increase in the incidence of CRC from 1994 to 2014 and an 11% increase in mortality from 2005 to 2015.[7,8]

Risk factors associated with a Western lifestyle that have been shown to increase CRC risk include: cigarette smoking; excess body weight; diet, including high consumption of alcohol and red and processed meat and low consumption of fruits/vegetables, dietary fiber, and dietary calcium; and physical inactivity.[9,10] Islami et al estimated that a significant proportion of CRC incidence among women and men in 2014 (50.8% and 58.2%, respectively) was attributable to these lifestyle factors.[10] Thus, there is an important opportunity to reduce risk across the population through lifestyle modification. The use of aspirin in selected individuals has also been demonstrated to reduce the likelihood of developing CRC.[11-14] Risk for developing CRC is associated with several identified hereditary CRC conditions; a family history of CRC[15]; medical conditions, including chronic inflammatory bowel disease[16] and type 2 diabetes[17]; and a history of abdominal or pelvic radiation for a previous cancer.[18-21]

The detection and subsequent removal of precursor lesions detected during screening and the detection of CRC at an earlier, more favorable stage have been shown to significantly reduce incidence and mortality. The increased understanding of the natural history of CRC and precursor lesions and the development and accumulation of evidence on screening technologies have supported the evolution of screening recommendations and implementation of CRC screening in clinical practice and public health programs.[22]

This guideline is intended to provide guidance to adults at average risk of CRC, to clinicians who counsel and refer patients to CRC screening, and to health care systems to support best practices in the early detection and prevention of CRC. The American Cancer Society (ACS) first published evidence-based recommendations for early detection of cancer of the colon and rectum in 1980.[23] The most recent update of recommendations for individuals at average risk occurred in 2008 and was based on an evidence-based consensus process that included the ACS, the US Multi-Society Task Force (USMSTF) on Colorectal Cancer (representing the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), and the American College of Radiology.[24] Since 2008, evidence has accumulated on the different screening modalities, test performance in population-based screening programs, and the changing risk of CRC.[3,25,26] This guideline update is based on an assessment of the underlying burden of disease; the strength of evidence and the balance of benefits and harms for available screening tests; and consideration of patient values and preferences, including the importance of choice in the selection of screening test options.

Materials and Methods

The ACS follows a protocol for developing and disseminating guidelines that is designed to maintain transparency, consistency, and rigor.[27,28] This process includes the use of systematic evidence reviews on the topic, consideration of the overall balance of benefits and harms of interventions and patient preferences, a guidelines panel of scientific

Disclosures: Timothy R. Church reports grants from Epigenomics and personal fees from GRAIL Bio outside the submitted work; he is a member of the Physician's Data Query (PDQ) for Screening and Prevention Editorial Board (National Cancer Institute [NCI], National Institutes of Health [NIH], Chair of the CONFIRM trial Data and Safety Monitoring Board (Veterans Affairs), site principal investigator for the Prostate, Lung, Colon, and Ovarian Cancer Screening Trial (funded by the NIH), and site principal investigator for the National Colonoscopy Study (funded by the NIH through Memorial Sloan Kettering Cancer Center). Christopher R. Flowers reports multiple relationships with industry but none directly related to colorectal cancer screening; personal fees from Spectrum, Celgene, Optum Rx, Seattle Genetics, Gilead, Bayer, Karyopharm, Astra Zeneca, and Beigene; unpaid consultant work for Genentech/Biogen-Idec/Roche and Millennium/Takeda; research funding to the Emory University School of Medicine and Winship Cancer Institute from AbbVie, Acerta, Celgene, Gilead Sciences, Infinity Pharmaceuticals, Janssen Pharmaceutical, Millennium/Takeda, Spectrum, Onyx Pharmaceuticals, Phamacyclics, and the NIH (grants R21CA158686, U01CA195568, and K24CA208132), the Burroughs Wellcome Fund, and the V Foundation; and personal fees for developing educational presentations from Clinical Care Options, Educational Concepts, PRIME Oncology, and Research to Practice. Otis W. Brawley and Stacey A. Fedewa are employed by the ACS, which received a grant from Merck Inc for intramural research outside the submitted work; however, their salary is solely funded through ACS. The ACS receives partial funding from the Centers for Disease Control and Prevention (CDC) to support the National Colorectal Cancer Roundtable, of which Richard C. Wender is the Chair, Robert C. Smith is the Co-Chair, and Durado Brooks is a Steering Committee member, to support initiatives related to colorectal cancer screening. The ACS also received contributions from Bracco Diagnostics Inc, Polymedco Inc, Exact Sciences, Medtronic GI Solutions Inc, Quest Diagnostics, Epigenomics Inc, Clinical Genomics, Medial Early Sign, the American Society for Gastrointestinal Endoscopy, the American College of Gastroenterology, the American College of Radiology, and the American Gastroenterological Association to support the annual meeting of the National Colorectal Cancer Roundtable. ACS cancer screening guideline development is supported by ACS operational funds; neither the Roundtables nor the sources of funding described in this disclosure have had any role, involvement, or have made any financial contribution to ACS screening guideline development or approval. All remaining authors report no conflicts of interest.

experts without any direct professional specialization in the issue under review, a transparent disclosure and management process that minimize biases and conflicts of interest, explicit explanation of the logical relationships between screening interventions and health outcomes, and ratings of both the quality of evidence and the strength of the recommendations.

The ACS Guideline Development Group (GDG), a multidisciplinary panel of volunteers comprising generalist clinicians, biostatisticians, epidemiologists, economists, and a patient representative, is charged with the development and update of the ACS cancer screening guidelines. The GDG has full responsibility for interpretation of the evidence, formulating the recommendations, deliberation and voting on the recommendations and strength, and writing the guideline. A record of voting on the recommendations is kept without attribution. While the GDG attempts to achieve complete agreement, a three-quarters majority is considered acceptable for adopting a recommendation and assigning strength. For the update of the CRC screening guideline, a subcommittee consisting of 6 GDG members had primary responsibility for reviewing the evidence, drafting recommendations, and preparing the manuscript for publication, although the entire GDG reviewed and voted on the updated guideline. ACS staff members served as guideline methodologists and in an administrative capacity to support the GDG. ACS staff members also contributed cancer screening and CRC expertise to the GDG evaluation of the evidence and participated in preparation of the manuscript but did not formulate recommendations or vote to approve the final guideline. Guideline development is supported by ACS general operating funds.

Individuals with recognized clinical and research expertise in the areas of CRC natural history, detection, diagnosis, and decision making were invited to advise the GDG and to provide broader knowledge and understanding of the complexity of CRC screening (see Supporting Information). The GDG consulted the expert advisors at several stages in the guideline development process: the expert advisors were requested to respond to questions about the key evidence questions and the evidence and logic underlying screening recommendations and to assess the primary evidence reports and suggest additional data for consideration. In addition, they served as external reviewers of the draft recommendation statements and the guideline manuscript before publication.

Participants (GDG members, ACS staff, expert advisors) in all stages of the guideline development process were required to disclose all financial and nonfinancial (personal, intellectual, practice-related) relationships and activities that might be perceived as posing a conflict of interest in the update of the CRC screening guideline. The GDG chairpersons had the responsibility to ensure balanced perspectives were considered in deliberations and decision making.

For the update of the CRC screening guideline, the GDG chose to use 2 reports commissioned by the US Preventive Services Task Force (USPSTF) for its 2016 CRC screening recommendation update as sources of evidence to inform recommendations: a systematic evidence review on CRC screening and a report of simulation modeling findings from the Cancer Intervention and Surveillance Modeling Network (CISNET) CRC group.[26,29-31] The evidence synthesis conducted for the USPSTF addressed 3 issues: the effectiveness of screening in reducing incidence and mortality from CRC, the test performance characteristics of different screening tests for detecting CRC and important precursor lesions, and the adverse effects associated with different screening tests. Three microsimulation models of CRC screening developed as part of the CISNET consortium estimated the impact of a variety of programmatic screening strategies for the screening-eligible US population. The CISNET-CRC group consists of 3 CRC microsimulation models that were independently developed for the evaluation of interventions, and their use to date principally has focused on screening. The 3 models differ somewhat in their underlying assumptions about the natural history of CRC, which allows for estimation of outcomes based on these different assumptions. The CISNET-CRC models include: 1) MISCAN-CRC, with investigators from Erasmus University Medical Center and Memorial Sloan Kettering Cancer Center; 2) SimCRC from the University of Minnesota and Massachusetts General Hospital; and 3) CRC-SPIN from RAND Corporation.[32]

To gain additional understanding of outcomes associated with different screening strategies (particularly starting age) for black and white adults, the ACS commissioned a modeling study by the MISCAN and SimCRC investigators (2 of the CISNET modeling groups) that extended the previous analysis conducted for the USPSTF. The objective was to assess the potential benefit (life-years gained and CRC deaths averted) and the burden of different CRC screening strategies for black and white women and men.[33] Subsequently, the GDG determined that recent evidence demonstrating a significant increase in CRC incidence among individuals younger than 55 years, which was attributable to a strong birth-cohort effect,[3] warranted a reevaluation of the optimal age to start screening in the average-risk population. Additional modeling analyses by the MISCAN investigators incorporated recent Surveillance, Epidemiology, and End Results (SEER) incidence data and evaluated screening outcomes for the general US population.[34] Analyses of outcomes for race-specific and sex-specific groups by MISCAN and SimCRC, which initially were carried out

under the assumption of stable incidence, were repeated to incorporate recent SEER incidence data.[33]

Under the direction of the GDG, the ACS staff performed a supplemental literature review to examine differential risk and screening outcomes in racial and ethnic subgroups. In addition, literature searches were conducted to identify relevant new studies that have addressed screening outcomes since completion of the USPSTF evidence review. The GDG also examined data provided by the ACS Surveillance and Health Services Research Program on disease burden using data from the SEER program.[35] Unless otherwise indicated, all incidence and mortality rates are per 100,000 person-years and age-adjusted to the US standard population.

While the primary source of evidence for this guideline used a different rating system for the appraisal of evidence,[26,29] the GDG applied the principles of the Grades of Recommendations, Assessment, Development, and Evaluation (GRADE) and GRADE Evidence-to-Decision (EtD) frameworks in formulating and assigning the strength of recommendations.[36,37] The principal GRADE decision-making criteria are: 1) balance between desirable and undesirable effects—the greater the difference between desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted, and the narrower the difference, the higher the likelihood that a qualified recommendation is warranted; 2) quality of evidence—the higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted; and 3) values and preferences—the greater the uniformity or certainty in values and preferences, the higher the likelihood that a strong recommendation is warranted. Each recommendation was designated by the GDG as either *strong* or *qualified*, in accordance with GRADE guidance.[38] A strong recommendation conveys the consensus that the benefits of adherence to the intervention outweigh the undesirable effects and that most patients would choose the intervention. A qualified recommendation indicates there is clear evidence of benefit (or harm) but less certainty either about the balance of benefits and harms or about patients' values and preferences, which could lead to different individual decisions. Additional elements included in the GRADE EtD framework and considered in this guideline are the impact on health equity, feasibility, and acceptability.[37] The ACS does not apply cost and resource use as a decision-making criterion for recommendations. Actual costs of CRC screening tests and follow-up examinations vary widely in the United States, and costs, coverage, and reimbursement may be important considerations for individuals when making decisions about screening tests (see Patient considerations of cost and reimbursement, below).

Before final preparation of a manuscript for publication, the guideline was submitted to the ACS Mission Outcomes Committee and Board of Directors for review and approval of the proposed recommendations. The expert advisors and representatives from 30 relevant outside organizations were then invited to participate in an external review of the guideline. Responses were documented and reviewed by the GDG to determine whether modifications in the recommendations or narrative were warranted, and adopted changes were incorporated in the final manuscript.

Considerations in Developing Recommendations

Outcomes of Screening

The GDG identified reduction in CRC mortality (measured as life-years gained [LYGs] in the modeling reports) and incidence as the principal benefits of screening. Although the previous ACS guideline gave priority to CRC incidence reduction, in this update, the GDG did not prioritize incidence reduction over mortality reduction. There is variability in prevention potential among the available screening tests, but all noncolonoscopy screening tests contribute to prevention through colonoscopy follow-up and adenoma removal after a positive initial screening test, as demonstrated by the reduction in incidence in the US guaiac fecal occult blood test (gFOBT) randomized trial.[39] Although prevention is highly valued by patients, test preparation, invasiveness, potential costs, and other considerations will lead some patients to prefer a noncolonoscopy test for screening. Greater value was placed on the role of patient preferences and on the potential to increase CRC screening utilization through offering choice in screening test options. The GDG recognized the potential relevance of other beneficial outcomes, including reduction of disease and treatment morbidity and improved quality of life, but identified no studies that demonstrated direct associations with screening.

The principal recognized harms of CRC screening, which are rare, are those associated with colonoscopy (bleeding, perforation, cardiorespiratory complications of sedation) as a primary screening test or as a follow-up of other positive noncolonoscopy tests.[26,40,41] The harm conventionally associated with workup of false-positive test results is partly mitigated when a normal follow-up examination removes the patient from the screening pool for 10 years. In addition to estimating the number of colonoscopy-related complications, the CISNET modeling group used the number of colonoscopies required as a proxy for harms and a measure of the burden of CRC screening.[30] The GDG regarded the number of colonoscopies (and related risk of complications) as a proxy for harms. Individual patient burden was considered primarily in the context of patient decision making on the basis of test attributes. For computed tomography colonography (CTC), attention was given to additional

potential harms associated with radiation exposure and workup of incidental findings not leading to residual benefit. Screening test performance measures (sensitivity, specificity, etc) were included as important outcomes in evaluating the evidence on screening tests. Relatively low importance was ascribed to the beneficial effect of reassurance from a negative screening test as well as to the burden of anxiety precipitated by a false-positive test result.

Evidence-Based Inferential Reasoning

Results from randomized controlled trials (RCTs) of CRC screening with either a stool-based test (gFOBT) or a structural examination (flexible sigmoidoscopy [FS]) have demonstrated mortality reductions associated with the detection of advanced neoplasia in asymptomatic adults.[26] The evidence of benefit for all other screening tests is limited to test performance data demonstrating the ability to detect early stage CRC and/or advanced adenomas and observational studies. In addition to this body of evidence for the individual modalities, the GDG adopted evidence-based inferential reasoning to extrapolate from the evidence establishing a rationale for using the detection of occult blood as an effective screening tool to support fecal immunochemical testing (FIT) and multitarget stool DNA (mt-sDNA) testing, which includes multiple molecular assays combined with a hemoglobin immunoassay. Similarly, findings from RCTs of FS provide a compelling "proof of concept" for structural evaluation of the colon to detect both CRC and adenomas as an effective approach to reducing CRC incidence and mortality. In addition to examining the test performance and observational data on the other 2 currently available structural examinations (colonoscopy and CTC), the GDG made the judgment to extrapolate the RCT evidence on FS.

Use of Modeling Studies

Given the limited evidence on long-term outcomes for the different screening options as well as direct comparisons, modeling studies have been used to compare the potential effectiveness of different screening strategies, and the results of these studies have influenced the USPSTF CRC screening recommendations.[30,42-44] The CISNET investigators have devised a methodology to identify model-recommended screening strategies for consideration among the numerous unique strategies that are generated by combinations of tests with different starting and stopping ages and screening intervals.

Model-recommended screening strategies for individual tests are based on the balance of benefits, expressed as LYGs (corrected for life-years lost because of screening complications) versus burden and harms, expressed as the number of colonoscopies required for a given strategy (screening, follow-up, surveillance, and diagnosis of symptomatic cancer). The burden of noncolonoscopy tests is addressed by grouping and comparing screening options that have similar test characteristics, resulting in 4 separate classes of screening tests (ie, colonoscopy, all stool tests, FS, and CTC). Strategies within each class that achieve the highest LYGs for a given number of colonoscopies are deemed efficient, whereas strategies that achieve at least 98% of the highest LYGs are deemed "near-efficient." For all efficient and near-efficient strategies, an efficiency ratio (ER) is estimated, which is a measure of burden to benefit based on the ratio of the incremental number of colonoscopies divided by the incremental number of LYGs compared with the nearest less effective efficient strategy. From the efficient or near-efficient strategies in each class, model-recommendable strategies are those that have an acceptable overall benefit and ER (balance of burden to benefit).[33,34]

The limitations of modeling arise from the uncertainty inherent in the parameters and assumptions that underpin the model inputs. One such assumption in the CISNET models[30,31] is 100% adherence to all screening strategies, including 100% adherence to follow-up colonoscopy for positive initial noncolonoscopic screening examinations. The assumption of full adherence allows for comparison of the screening options under a uniform scenario. However, actual screening and follow-up adherence rates vary by test, setting, and population group, meaning that actual outcomes could diverge from predicted outcomes based on differential uptake and follow-up. These limitations are acknowledged by the CISNET investigators and were acknowledged by the GDG in integrating modeling results with empirical evidence.

Patient Preferences, Choice, and Adherence

CRC screening presents a unique challenge and opportunity, as there are multiple screening tests with variability in supporting evidence of effectiveness, risk of harm, prevention potential, and patient burden. There is no consistent, direct evidence that adults prefer any one CRC screening tool or strategy over others. Individual preferences can be influenced by patient education about screening, test characteristics (ie, accuracy, degree of invasiveness, test preparation, required screening interval, and cost), and clinician recommendation.[45-50] The ACS is committed to increasing utilization to achieve the benefits of CRC screening by recommending that patients be given an opportunity to choose a testing strategy, thus increasing the likelihood of adherence. Patient preference is an important consideration, although the choice of test must be predicated on high-quality screening test options that are accessible to the patient, and there must be access to follow-up colonoscopy if needed.

TABLE 1. American Cancer Society Guideline for CRC Screening, 2018

Recommendations[a]
The ACS recommends that adults aged 45 y and older with an average risk[b] of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on noncolonoscopy screening tests should be followed up with timely colonoscopy.
The recommendation to begin screening at age 45 y is a *qualified recommendation.*
The recommendation for regular screening in adults aged 50 y and older is a *strong recommendation.*
The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 y continue CRC screening through the age of 75 y *(qualified recommendation).*
The ACS recommends that clinicians individualize CRC screening decisions for individuals aged 76 through 85 y based on patient preferences, life expectancy, health status, and prior screening history *(qualified recommendation).*
The ACS recommends that clinicians discourage individuals over age 85 y from continuing CRC screening *(qualified recommendation).*
Options for CRC screening
Stool-based tests
• Fecal immunochemical test every y
• High-sensitivity, guaiac-based fecal occult blood test every y
• Multitarget stool DNA test every 3 y
Structural examinations
• Colonoscopy every 10 y
• CT colonography every 5 y
• Flexible sigmoidoscopy every 5 y

ACS, American Cancer Society; CRC, colorectal cancer; CT, computed tomography. [a]A strong recommendation conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening. Qualified recommendations indicate there is clear evidence of benefit (or harm) of screening but less certainty about the balance of benefits and harms or about patients' values and preferences, which could lead to different decisions about screening. [b]These recommendations represent guidance from the ACS for persons without a history of adenomatous polyps or CRC and not at increased risk for CRC due to a family history of CRC, a confirmed or suspected hereditary CRC syndrome (such as familial adenomatous polyposis or Lynch syndrome), a personal history of abdominal or pelvic radiation for a previous cancer, or a personal history of inflammatory bowel disease.

Recommendations

The ACS recommends that adults aged 45 years and older with an average risk of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on noncolonoscopy screening tests should be followed up with timely colonoscopy. The recommendation to begin screening at age 45 years is a *qualified recommendation*. The recommendation for regular screening in adults aged 50 years and older is a *strong recommendation* (Table 1).

This recommendation for CRC screening in average-risk adults is based on the GDG's judgment of the preponderance of benefits of CRC screening over harms, the overall quality of the evidence on screening outcomes, recent evidence related to the incidence of disease, evidence demonstrating the influence of test preference on adherence to recommendations, and the high value individuals place on preventing and avoiding death from CRC.[51,52] The GDG chose to issue a general overall recommendation for CRC screening rather than recommendations for the use of specific individual tests. Although there is significant variability among the available screening tests in the volume and quality of supporting evidence, the overall quality of the evidence was judged to be good and sufficient to support a recommendation for screening with any of the 6 included strategies (Table 1). On the basis of the strength of the evidence and on the judgment of an overall preponderance of benefit, the recommendation for regular screening in adults aged 50 years and older has been designated as a "strong" recommendation. The recommendation to begin screening at age 45 years is based on disease burden, results from microsimulation modeling, and the reasonable expectation that screening will perform similarly in adults aged 45 to 49 years as in persons for whom screening is currently recommended. However, the long-standing recommendation to initiate CRC screening at age 50 years means that there are limited data on screening outcomes in adults aged 45 to 49 years. Because of differences in the type and quality of evidence for screening in adults younger than 50 years, as described below, the recommendation to start screening at age 45 years has been designated as "qualified."

Age to Begin CRC Screening

Burden of disease

When initiating this guideline update and examining the burden of disease, the GDG initially focused on higher than average incidence before age 50 years in some racial subgroups.[35,53] Beginning screening earlier in these groups would be consistent with a disease burden approach and could contribute to reducing disparities.[2,54,55] Some organizations already have recommended that blacks and Alaska Natives begin screening before age 50 years based on their higher incidence at younger ages.[56-58] However, prior reports showing the persistence of a trend of increasing CRC incidence in adults younger than 50 years[59-62] and the recent work by Siegel et al[3] demonstrating that this rising incidence was the result of a strong birth-cohort effect that would carry forward with age led the GDG to reevaluate the age to initiate screening in all US adults.

CRC incidence rates in the United States have historically varied by sex as well as by race and ethnicity. Among all races combined, CRC incidence is similar in women and men until age 35 years but, thereafter, is higher for men, and the disparity widens with age. CRC incidence among blacks, including those younger than 50 years, has historically been higher than that among whites, Hispanics, and Asian Americans.[2] However, while incidence rates in whites younger than 50 years have risen, incidence rates for blacks younger than 50 years have remained generally stable, resulting in comparable contemporary incidence between the 2 groups (Fig. 1). The CRC incidence rate for individuals younger than 50 years is higher among Alaska Natives than for any other racial/ethnic group in the United States.[2,63] High rates have been reported for some American Indian groups, although this varies by tribe and geographic region.[64]

CRC incidence has declined steadily over the past 2 decades in the population aged 50 years and older because of the combined influence of screening and changes in exposure to risk factors,[4] but there has been about a 51% *increase* in CRC among those younger than 50 years since 1994 (Fig. 2). Increased incidence rates have been particularly notable for rectal cancer, which doubled between 1991 (2.6 of 100,000) and 2014 (5.2 of 100,000) in individuals aged 20 to 49 years.[7] A recent analysis found that adults born around 1990 have twice the risk of colon cancer and 4 times the risk of rectal cancer compared with adults born around 1950, who have the lowest risk.[3]

The factors contributing to this increase in incidence are not understood.[2,3] The increase in incidence observed in the youngest birth cohorts is not likely due to detection bias arising from increased use of colonoscopy, because negligible screening and case finding occur in the youngest cohorts, and the increased incidence in whites is accompanied by an increase in mortality, which is contrary to what would be expected if increased incidence in this group was because of

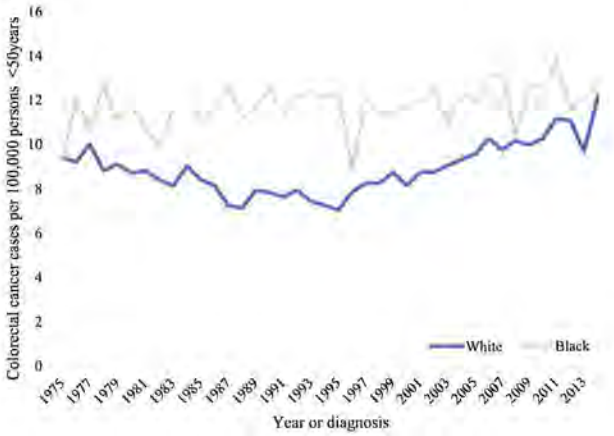

FIGURE 1. Trends in Colorectal Cancer Incidence Rates in Adults Younger Than Age 50 Years by Race, 1975 to 2014.

increased screening.[3] The observation that CRC incidence is increasing in successively younger birth cohorts suggests that the greater burden of CRC in the population younger than 50 years is not just a transient epidemiological phenomenon. Rather, these birth cohorts are carrying the elevated risk with them as they age; increases in colon cancer incidence began in the mid-1980s and have continued through 2013 for the groups aged 20 to 29 years (2.4% per year) and aged 30 to 39 years (1% per year) and in the mid-1990s for the groups aged 40 to 49 years (1.3% per year) and 50 to 54 years (0.5% per year). Rectal cancer incidence rates increased 3.2% per year from 1974 to 2013 in adults aged 20 to 29 years, 3.2% per year from 1980 to 2013 in adults aged 30 to 39 years, and 2.3% per year from the early to mid-1990s to 2013 in adults aged 40 to 54 years.[3] Siegel et al also noted a recent convergence of CRC incidence rates in the groups aged 50 to 54 years and 55 to 59 years (Fig. 3); in the early 1990s CRC incidence rates in adults aged 50 to 54 years were one-half of those in the group aged 55 to 59 years, whereas in 2012-2013 there was just a 12.4% difference in colon cancer rates, and rectal cancer rates were the same for the 2 age groups.[3] This rising incidence in younger age groups coinciding with rapid declines in older age groups has led to a large shift in the age-adjusted proportion of CRC in adults younger than 55 years, from 11.6% during 1989 to 1990 to 16.6% during 2012 to 2013 for colon tumors and from 14.6% to 29.2%, respectively, for rectal tumors.[3]

Although the current age-specific incidence rate among adults aged 45 to 49 years (31.4 per 100,000) is lower compared with that among adults aged 50 to 54 years (58.4 per 100,000),[35] the higher rate in the group aged 50 to 54 years is influenced by lead time associated with the uptake of screening as well as rising incidence because of increasing age. Data from the National Health Interview Survey revealed that approximately 45.3% of adults aged 50 to 54 years reported recent screening with either colonoscopy or

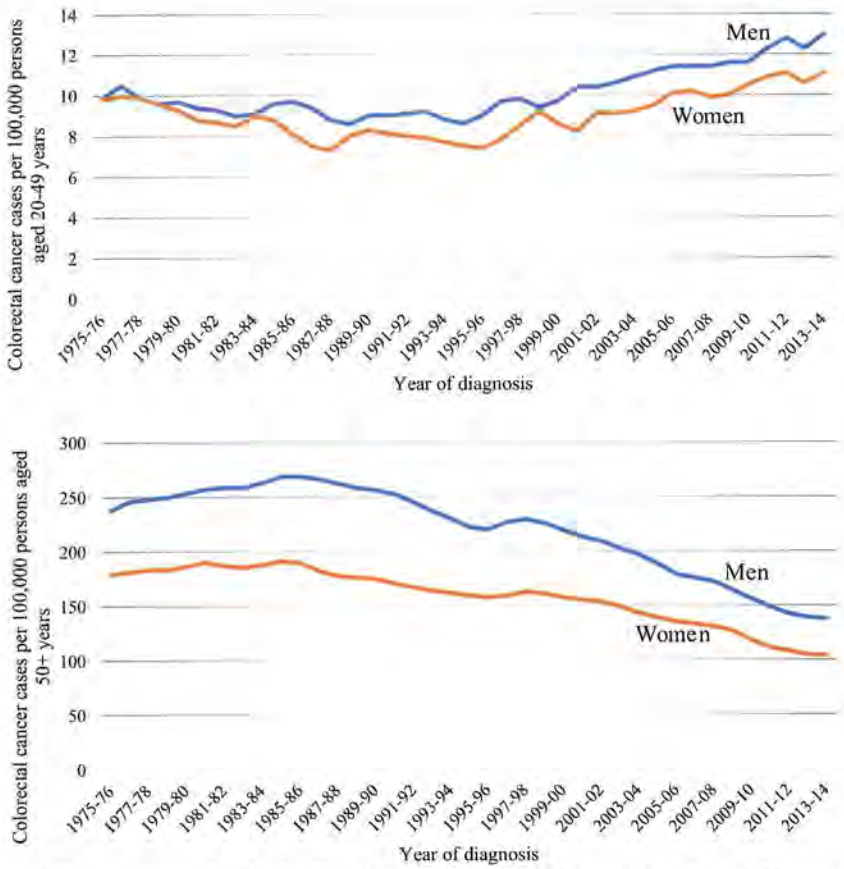

FIGURE 2. Trends in Colorectal Cancer Incidence Rates by Age (Ages 20-49 and Ages 50+) and Sex, 1975 to 2014. Rates are adjusted for delays in reporting and are plotted as a 2-year moving average. Data source: Surveillance, Epidemiology, and End Results program, National Cancer Institute, 2017.

FS in 2015 compared with approximately 17.8% of adults aged 40 to 49 years.[65] Thus, the true underlying risk in adults aged 45 to 49 years is likely closer to the risk in adults aged 50 to 54 years than the most recent age-specific rates would suggest. More noteworthy, however, is that the increase in the annual percentage change in the incidence rate for adults aged 40 to 49 years (1.3%) is more than twice that of adults aged 50 to 54 years (0.5%), suggesting that the risk for the younger cohort will continue to carry forward into the group aged 50 to 54 years.[3]

Although the data described above pertain to trends in the risk of invasive disease, Lieberman et al reported that the prevalence of polyps measuring 9 mm or greater among adults younger than 50 years was 4.2% in whites and 6.2% in blacks, similar to the prevalence of 5.3% in whites and 6.1% in blacks aged 50 to 59 years.[66] Insofar as prevention also is a goal of CRC screening, these data indicating a similar prevalence of large polyps in adults aged 45 to 49 years and 50 to 54 years point to the disease prevention potential of beginning screening at age 45 years.

Further confirmation of a change in underlying disease risk is the increase in CRC mortality among white adults aged 50 to 54 years since 2005, after decades of decline in an age group in which screening is recommended.[3] CRC mortality rates have been increasing since 1995 in whites aged 30 to 39 years and since 2005 in whites aged 40 to 54 years. In contrast, mortality rates have been decreasing since 1970 among blacks aged 20 to 54 years but still were about 50% higher compared with the rates among whites in this age group in 2014 (6.1 vs 4.1 per 100,000).

It is further noteworthy that, of all CRC deaths during 2010 through 2014, a similar proportion of decedents were diagnosed at ages 45 to 49 years (5.1%) compared with ages 50 to 54 years (7.6%) (Fig. 4A). Likewise, of all estimated premature mortality from the disease measured by years of potential lives lost, 10% was because of diagnoses in persons aged 45 to 49 years compared with 13% attributable to diagnoses in those aged 50 to 54 years (Fig. 4B).

Evidence of the effectiveness of screening in adults aged 45 to 49 years

There is limited direct evidence of screening effectiveness in adults younger than 50 years, in large part because of early

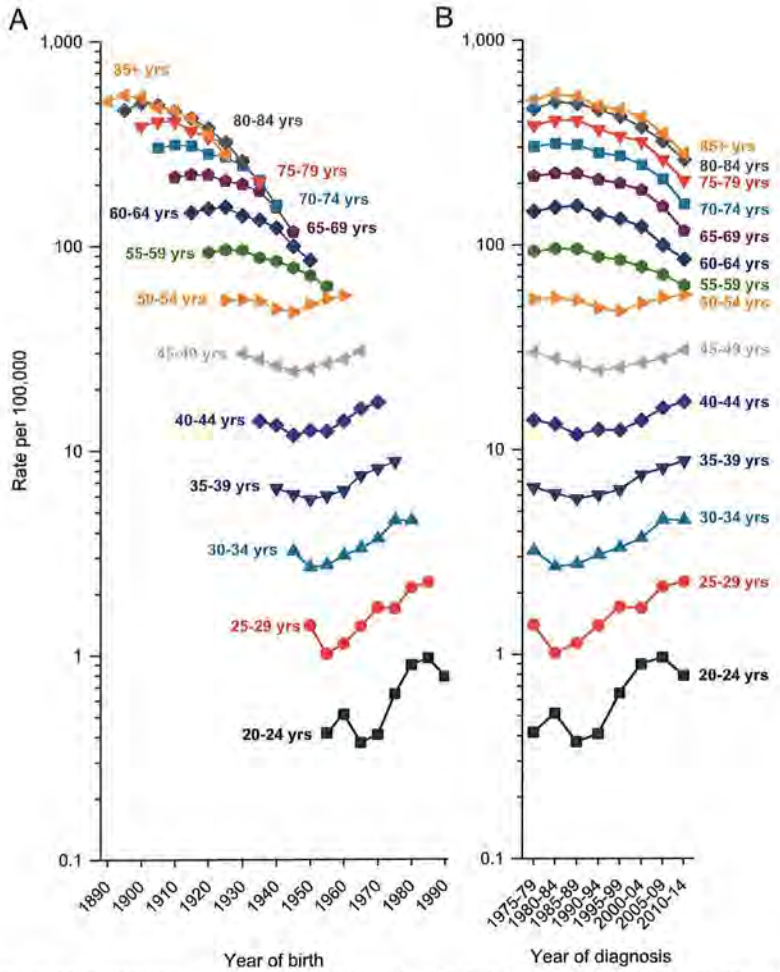

FIGURE 3. Trends in Colorectal Cancer Incidence Rates by Age and Year of Birth, and by Age and Year of Diagnosis, United States, 1975 to 2014. Data source: Surveillance, Epidemiology, and End Results (SEER) program, SEER 9 registries, delayed adjusted rates, 1975-2014, National Cancer Institute.

expert judgments, based on disease burden, that screening should begin at age 50 years.[23,67,68] Most of the RCTs of CRC screening demonstrating benefit had a starting age of 50 years, as do the RCTs of colonoscopy/FIT[25,69] and CTC/colonoscopy/FIT/FS[70-72] that are currently in progress. Three of the European gFOBT trials conducted in the 1980s and 1990s that demonstrated a CRC mortality benefit enrolled persons starting at age 45 years (45-74 years or 75 years).[26] However, all were underpowered for age subgroup analyses, and age-specific outcomes were not reported. Much of the observational evidence demonstrating effectiveness of CRC screening is similarly limited to a starting age of 50 years.

Modeling Analyses

Given the limited empirical data on long-term screening outcomes across screening modalities and strategies and the paucity of comparative data, recommendations for CRC screening over the past decade increasingly have relied on modeling analyses of screening outcomes.[30,42] It should be noted that the modeling report prepared for the USPSTF 2016 CRC screening recommendations determined that, "for all modalities, strategies with screening beginning at age 45 years predominated on the efficient frontier; that is, these strategies generally provided additional LYGs at a lower number of additional colonoscopies than strategies with screening beginning at later ages."[30] However, beginning screening at age 45 years while maintaining the 10-year screening interval, resulted in an increase in the estimated lifetime number of colonoscopies. In 2 models (SimCRC and CRC-SPIN), starting screening at age 45 years but extending the screening interval to 15 years resulted in slightly more LYGs and a similar lifetime number of colonoscopies compared with screening with colonoscopy every 10 years from aged 50 to 75 years.[30] Ultimately, the USPSTF elected not to recommend the younger starting age, judging that the estimated additional LYGs would be "modest," also noting that 1 of the 3 models in the 2016 report (the MISCAN model) did not corroborate the modest increase in LYGs associated with the younger starting

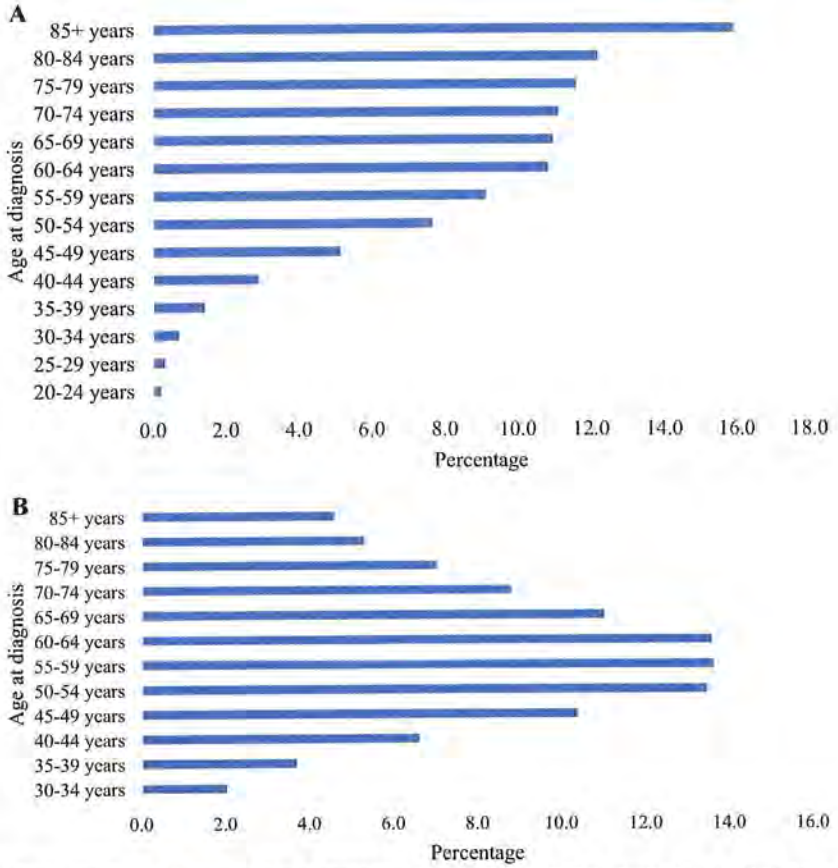

FIGURE 4. Distribution of Colorectal Cancer Burden by Age at Diagnosis, 2010 to 2014. (A) The distribution of colorectal cancer (CRC) deaths by age at diagnosis (n = 20,198) is illustrated among patients who were followed for 20 years after diagnosis. (B) The distribution of person-years of life lost (YLL) because of CRC by age at diagnosis is illustrated among patients who were followed for 20 years after diagnosis. Source: SEER 9 registries.

age and a 15-year screening interval, and citing the lack of empirical evidence for screening younger populations and a 15-year screening interval.[44]

The CISNET modeling analyses used for the 2016 USPSTF update were based on historical CRC incidence data from the prescreening era (1975-1979) to reflect risk without the influence of screening on incidence (prevention and early detection). Although this was a reasonable methodological decision, the model outputs did not reflect changes in incidence because of underlying changes in risk that may have occurred over time. On the basis of the recent trends in CRC incidence before age 55 years described previously[3] and the higher burden of disease in blacks compared with whites, the ACS worked with 2 of the CISNET groups (MISCAN and SimCRC) to reexamine optimal screening strategies, with emphasis on the influence of observed trends in incidence on the age to begin screening. Outcomes of different screening strategies were predicted for the general population under the increased-risk scenario (MISCAN only)[34] and for population subgroups defined by race and sex under both the stable-risk scenario and the increased-risk scenario (MISCAN and SimCRC models).[33]

With respect to the reevaluation of screening strategies for the general population with emphasis on observed trends in incidence, the analyses were similar to those carried out for the USPSTF, with the principal exception of the application of incidence multipliers to adjust risk proportional to the observed increase in incidence in adults younger than 40 years (to rule out any potential contamination from screening). The models also accounted for the higher proportion of tumors in the rectum and distal colon observed in the incidence trends among younger adults.[3] This adjustment in risk was based on the observation that increased incidence in adults younger than 55 years is attributable to a strong birth-cohort effect that began in the 1950s and is carrying over as these cohorts age. Six screening modalities (colonoscopy, CTC, FS, mt-sDNA, FIT, and high-sensitivity gFOBT [HSgFOBT]) were evaluated with variation in the starting age (40, 45, and 50 years), ending age (70, 75, and 80 years), and screening intervals, which varied by screening test, for a total of 132 unique CRC screening strategies.

Among 9 efficient and 5 near-efficient colonoscopy strategies, the strategy recommended by the model under the increased-risk scenario was screening every 10 years from

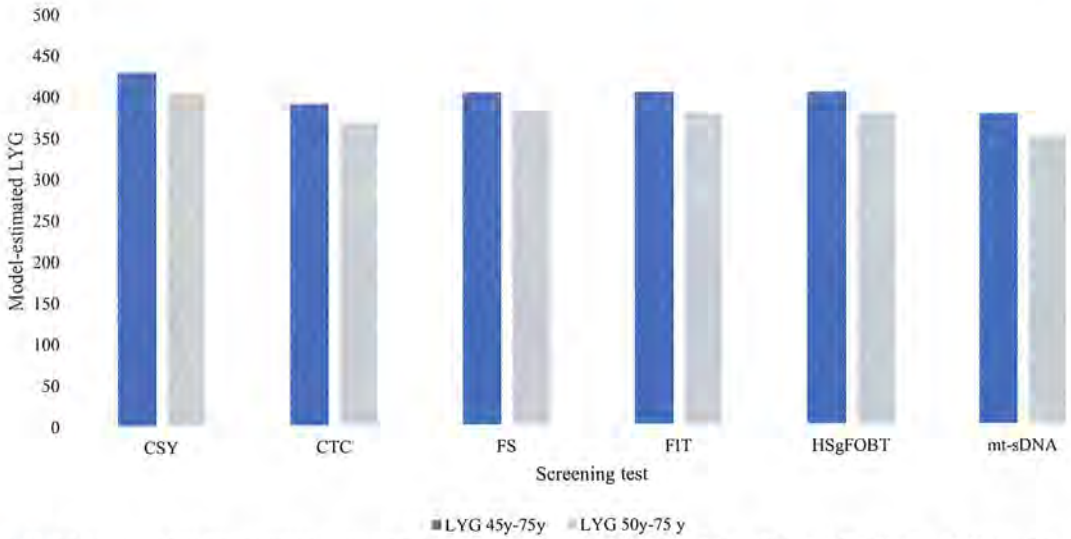

FIGURE 5. Model-Estimated Life-Years Gained (LYG) from Colorectal Cancer Screening Starting at Age 45 Years Versus 50 Years, per 1000 Screened Over a Lifetime. CSY indicates colonoscopy; CTC, computed tomography colonography; FSIG, flexible sigmoidoscopy; FIT, fecal immunochemical test; gFOBT, guaiac-based fecal occult blood test; LYG, life-years gained; mt-sDNA, multitarget stool DNA. Adapted from: Peterse EFP, Meester RGS, Siegal RL, et al. The impact of the rising colorectal cancer incidence in young adults on the optimal age to start screening: microsimulation analysis I to inform the American Cancer Society colorectal cancer screening guideline. *Cancer*. 10.1002/cncr.31543 [epub ahead of print].[34]

ages 45 to 75 years, which, compared with screening every 10 years from ages 50 to 75 years, had 6.2% more LYGs and 17% more colonoscopies per 1000 adults over a lifetime of screening (Fig. 5).[34] This strategy was chosen as the benchmark strategy because it had the highest LYGs among strategies with ERs less than a predetermined benchmark. Other model-recommended strategies for adults aged 45 to 75 years under the increased-risk scenario included annual FIT, CTC every 5 years, and FS every 5 years (Table 2).[34]

In the analysis of race-specific and sex-specific strategies, using 2 CISNET models, CRC screening was evaluated under both stable-risk and increased-risk scenarios. For the analyses in which prescreening era incidence data were used to reflect risk (stable-risk scenario), both models concluded that colonoscopy screening from ages 45 to 75 years was recommendable for black women and men, although the MISCAN model recommended a 10-year interval, and the SimCRC model recommended a 15-year interval.[33] For whites, the SimCRC model recommended the same strategy that was recommended for blacks, while the MISCAN model recommended colonoscopy from ages 50 to 75 years every 10 years. When the models were adjusted for increased incidence, both models recommended screening strategies from ages 45 to 75 years (colonoscopy every 10 years, FIT annually, FS every 5 years, and CTC every 5 years) for both black women and men and white women. For white men aged 45 to 75 years, the SimCRC recommended these same strategies, while the MISCAN model only recommended screening with colonoscopy every 5 years.[33] Thus, under the increased-risk scenario, both overall and race-specific and sex-specific analyses[33,34] by the 2 independent microsimulation models support the conclusion that starting screening at age 45 years is an efficient and recommendable strategy for the general population.

TABLE 2. Model-Estimated Benefits and Burdens of CRC Screening Starting at Age 45 Versus 50 Years, per 1000 Screened Over a Lifetime

SCREENING TEST	LYG	NO. OF CSY	MODEL RECOMMENDABLE
CSY every 10 y, 45-75	429	5646	Yes
CSY every 10 y, 50-75	404	4836	No
CTC every 5 y, 45-75	390	2666	Yes
CTC every 5 y, 50-75	368	2430	No
FSIG every 5 y, 45-75	403	3761	Yes
FSIG every 5 y, 50-75	380	3426	No
FIT yearly, 45-75	403	2698	Yes
FIT yearly, 50-75	377	2402	No
HSgFOBT yearly, 45-75	403	3364	No
HSgFOBT yearly, 50-75	377	2956	No
mt-sDNA every 3 y, 45-75	376	2640	No
mt-sDNA every 3 y, 50-75	350	2331	No

CRC, colorectal cancer; CSY, colonoscopy; CTC, computed tomography colonography; FIT, fecal immunochemical test; FSIG, flexible sigmoidoscopy; HSgFOBT, high-sensitivity, guaiac-based fecal occult blood test; LYG, life-years gained; mt-sDNA, multitarget stool DNA. Adapted from: Peterse EFP, Meester RGS, Siegel RL, et al. The impact of the rising colorectal cancer incidence in young adults on the optimal age to start screening: microsimulation analysis I to inform the American Cancer Society colorectal cancer screening guideline. *Cancer*. 10.1002/cncr.31543 [epub ahead of print].[34]

The MISCAN analyses for the general population also evaluated strategies starting screening at age 40 years. Results indicated a small increase in the number of LYGs (438 vs 429), with the same number of deaths averted (37) per 1000 adults, for colonoscopy every 10 years with a starting age of 40 years compared with 45 years.[34] The incremental burden of additional colonoscopies resulted in an ER for this strategy above 45, which is higher than the model-recommended strategy for starting screening at age 45 years. The incidence of CRC in adults aged 40 to 44 years is 17.6 per 100,000 versus 31.4 per 100,000 for adults aged 45 to 49 years (58.4 per 100,000 for adults aged 50-54 years).[35] Because of lower incidence, the years of life lost because of CRC among persons diagnosed at ages 40 to 44 years are measurably less than in the group ages 45 to 49 years (6% vs 10% of total years of potential lives lost) and well below those in the older age groups for whom screening is currently recommended (Fig. 4B). Trends in incidence and mortality in adults younger than 50 years and accumulating evidence on screening performance in younger populations will continue to be monitored and will be examined in future guideline updates.

As noted above, microsimulation modeling conducted to inform the 2016 update of the USPSTF CRC screening recommendations found that screening strategies beginning at age 45 years provided additional LYGs at a lower number of additional colonoscopies than strategies that began screening at a later age.[30] The analyses conducted for the 2018 ACS update address the principal concerns raised by the USPSTF in choosing not to recommend a younger starting age. First, the modeling analyses conducted for this update incorporating an increased-risk scenario provide stronger support for beginning screening at age 45 years.[33,34] When the MISCAN model, which was the nonconcordant model in the 2016 analysis, was adjusted to reflect increased incidence, screening beginning at age 45 years had a favorable balance of benefit to colonoscopy burden for all adults, and there was an improvement in LYGs compared with starting screening at age 50 years.[33,34] Second, although SimCRC still indicates that colonoscopy screening every 15 years is recommended under the stable-risk scenario, which was not corroborated by MISCAN, there was concordance between the 2 models on a 10-year interval under the increased-risk scenario.[33]

Summary: Age to begin screening

Although there is little evidence on screening outcomes in adults aged 45 to 49 years, observational studies suggest that both structural and stool-based CRC screening tests perform similarly in cancer and adenoma detection among individuals younger than 50 years and among older individuals.[73-75] The GDG acknowledged that the absolute benefit expected from screening in adults aged 45 to 49 years was lower than that in other age groups for which screening is currently recommended but judged that the tradeoff between reduced CRC mortality and incidence and increased number of colonoscopies was favorable.

The GDG considered other factors in formulating its recommendation for the age to start screening. First, the potential harms of colonoscopy (as either a primary screening or follow-up examination) are lower in younger versus older adults.[40] Second, recent estimates indicate that the current colonoscopy capacity in the United States should be able to accommodate the anticipated increase in colonoscopies, performed both as primary screens and as follow-up to positive noncolonoscopy tests.[76] Finally, starting CRC screening earlier also may contribute to reducing disparities in population groups with a higher disease burden (including blacks, Alaska Natives, and some American Indian groups). Although the modeling analyses were unable to include other racial groups or to distinguish Hispanic ethnicity, incidence rates for Asians and Hispanics are similar to those for whites. Therefore, the general recommendation to begin screening at age 45 years should be applicable to all groups.

In summary, based on the recent increase in CRC incidence in younger persons, the analyses demonstrating a favorable benefit-to-burden balance for initiating screening earlier, and the expected reduction in CRC mortality and incidence, the ACS recommends that all adults start CRC screening at age 45 years using any of the screening options presented in Table 1.

Choice of Screening Tests

The recommendation for CRC screening includes offering patients the opportunity to select either a structural (visual) examination or a high-sensitivity stool-based test, depending on patient preference and test availability. As detailed in Table 3, the screening options differ in the extent of patient burden and in ways that can affect a patient's choice of test and subsequent adherence, including screening frequency, screening location (home vs medical facility), need for dietary and/or bowel preparation, need for sedation, time and transportation required, relative ability to prevent versus detect CRC, out-of-pocket cost, risk of complications, and test accuracy. There is evidence that patients will have a preference for one type of screening test over others if provided sufficient information regarding these test attributes, although no single test appears to consistently dominate patient preferences, supporting a strategy of offering choice.[45,47,52,77,78] Intention to screen is also higher if the screening test ordered is consonant with the patient's preference.[47,77] Decision aids that help patients choose among options have been shown to improve knowledge and interest

TABLE 3. Considerations in Choosing a Colorectal Cancer Screening Test[a]

SCREENING TEST	RECOMMENDED SCREENING INTERVAL	EVIDENCE OF EFFECTIVENESS AND TEST PERFORMANCE	LIMITATIONS	PATIENT BURDEN	COST AND REIMBURSEMENT
Stool-based screening tests					
FIT with high sensitivity for cancer	Annual	• Indirect evidence of mortality reduction from RCTs of guaiac-based stool tests • Equivalent or superior performance compared with high-sensitivity gFOBT • Variability in test performance by version and brand	• High nonadherence to annual testing (especially in absence of reminder systems) • Less effective for advanced adenoma detection • Few available tests have published peer-reviewed performance data	• Is done at home • Many brands require only a single sample • No diet or medication restrictions	• Inexpensive compared with structural examinations and mt-sDNA • Follow-up colonoscopy for positive test may be subject to out-of-pocket costs
gFOBT with high sensitivity for cancer (HSgFOBT)	Annual	• Good RCT evidence for incidence and mortality reduction • Performance characteristics vary by version of the test (low-sensitivity gFOBT versions are not recommended for CRC screening)	• High nonadherence to annual testing (especially in absence of reminder system) • Less effective for advanced adenoma detection • Difficulty in ascertaining test performance among the many FDA-cleared tests	• Is done at home • Requires multiple samples • Requires dietary and medication restriction • Higher false-positive rate than FIT leads to more colonoscopies	• Inexpensive compared with structural examinations and mt-sDNA • Follow-up colonoscopy for positive test may be subject to out-of-pocket costs
mt-sDNA	Every 3 y (as per manufacturer)	• Indirect evidence of mortality reduction from RCTs of guaiac-based stool tests • Results from one large, manufacturer-funded trial showed improved sensitivity for cancer and advanced adenomas and poorer specificity compared with FIT	• This is a new test, with limited data on screening outcomes, and its performance needs to be monitored over time • There may be uncertainty in management of positive results followed by a negative colonoscopy	• Can be done at home • Higher false-positive rate than FIT	• More expensive than other stool-based tests • Follow-up colonoscopy for positive test may be subject to out-of-pocket costs

TABLE 3. *Continued*

SCREENING TEST	RECOMMENDED SCREENING INTERVAL	EVIDENCE OF EFFECTIVENESS AND TEST PERFORMANCE	LIMITATIONS	PATIENT BURDEN	COST AND REIMBURSEMENT
Structural (visual) examinations for screening					
Colonoscopy	Every 10 y	• Non-RCT evidence of incidence and mortality reduction • Extrapolation from RCTs of sigmoidoscopy demonstrating mortality reduction • Offers both early detection and prevention of CRC through polypectomy	• Risk of bowel perforation/bleeding and cardiopulmonary complications of anesthesia • Performance is dependent upon adequacy of bowel preparation, the cecal intubation rate, withdrawal time, and adenoma detection rate • Limited collection of quality data in many settings • Level of adherence to 10-y interval is unknown • Lower sensitivity for neoplasia in the proximal than the distal colon	• Requires full bowel cleansing • Requires time off work and a chaperone (if sedation is used)	• Most expensive test, but currently reimbursable for those with insurance coverage • Polypectomy and anesthesia may be subject to out-of-pocket costs
CTC	Every 5 y	• Extrapolation from RCTs of sigmoidoscopy demonstrating mortality reduction • Sensitivity and specificity for cancer and advanced adenomas comparable to colonoscopy	• Incidental extracolonic findings may require workup, with unclear benefit-burden balance • Exposure to low-dose radiation	• Requires full bowel cleansing • Colonoscopy required if test positive. If same day colonoscopy is not possible, a second bowel cleansing will be required before the follow-up colonoscopy.	• Relatively expensive and may not be covered by insurance (not covered by Medicare at this time) • Follow-up colonoscopy for positive test may be subject to out-of-pocket costs
FS	Every 5 y	• Best evidence among structural examinations for reducing mortality and incidence	• Does not examine the proximal colon • Concerns about lack of quality standards, limited availability, failure to achieve a complete examination	• Pain and discomfort • Requires enema prior to procedure • Abnormal findings require second endoscopic procedure (colonoscopy)	• Follow-up colonoscopy for positive test may be subject to out-of-pocket costs

CRC, colorectal cancer; CTC, computed tomographic colonography; FDA, US Food and Drug Administration; FIT, fecal immunochemical test; FS, flexible sigmoidoscopy; gFOBT, guaiac-based fecal occult blood test; mt-sDNA, multitarget stool DNA; RCT, randomized controlled trial. [a]The American Cancer Society considers these options as acceptable choices for CRC screening in average-risk adults. Individuals should be given information on the characteristics related to prevention potential, effectiveness, accuracy, costs, and potential harms of available and accessible tests to make an informed decision on which test to choose for CRC screening. All positive noncolonoscopy screening tests should be followed up with timely colonoscopy as a part of the screening process. Repeating positive noncolonoscopy tests is not acceptable.

in screening and lead to increased screening compared with not providing information.[79]

Trials offering a choice between a stool test and a structural examination compared with either test alone have generally demonstrated greater uptake when a choice is offered. The best evidence in the United States derives from a randomized trial in a safety-net population comparing annual gFOBT versus colonoscopy versus choice between the 2 in which it was demonstrated that choice was more effective than offering colonoscopy alone. In the first year of the study, which included patient navigation (year 1 only), the screening completion rate was 38% for patients offered colonoscopy, 66% for those offered gFOBT, and 68% for those offered a choice.[80] While uptake overall was similar in the gFOBT group versus the choice group, it is clear that a "colonoscopy-only" referral resulted in substantially lower adherence. Adherence to screening declined significantly in subsequent years, reinforcing the importance of patient navigation, reminder systems, and other support strategies in achieving sustained adherence.[80,81] A non-US prospective trial corroborated the finding that offering a choice of FIT or colonoscopy led to significantly greater adherence than offering either test alone.[82] Although providing an array of screening options may enhance uptake and allows patients to exert their autonomy, in one study, offering multiple test options was shown to create confusion and decisional conflict, potentially leading to poor adherence.[83] There clearly is a need to provide clinicians with guidance and tools to facilitate decision making that best meet patients' needs and enhance uptake of screening.

The GDG recognized that the complexity and time requirements for implementing a choice among multiple tests in the clinician-patient encounter may be burdensome. The importance of offering a choice between structural or stool-based testing is included in this guideline in recognition of the role of patient values and preferences and as a practical implementation strategy to improve adherence; clinicians who experience time pressures that conflict with this imperative should look to practice enhancements that take advantage of team-based approaches among practice personnel.[84,85] Importantly, the choice of screening test may be limited by the local availability of high-quality test options or by patient access to tests based on cost or other factors. In this instance, there is little purpose in offering tests that are not readily available and accessible. However, clinicians should be prepared to describe/offer options that are available and introduce additional options if the patient does not appear to be accepting of the tests initially presented.

The information provided on characteristics of the tests in this guideline is designed to facilitate clinician-patient encounters and patient choices consistent with preferences and thus, it is hoped, to increase utilization of CRC screening. In addition, materials to facilitate decision making in selecting a test at the point of care have been developed by the ACS to facilitate implementation of this guideline and are available online (cancer.org/colonmd).[86,87]

Follow-up of positive noncolonoscopy screening tests

Implementation of the screening options included in this guideline is premised on the requirement that the appropriate follow-up to a positive (noncolonoscopic) test is a timely colonoscopy. The follow-up colonoscopy should not be considered a "diagnostic" colonoscopy but, rather, an integral part of the screening process, which is not complete until the colonoscopy is performed. The information provided to patients to facilitate a choice among tests must include the importance of follow-up of a positive (noncolonoscopic) test with colonoscopy. *Repeating a positive stool-based test to determine whether to proceed to colonoscopy is not an appropriate screening strategy.* A retrospective cohort study involving 70,124 patients with a positive FIT result examined the relationship between time to colonoscopy after a positive FIT result and risks of any CRC and of advanced-stage disease.[88] There were no significant differences in the risk of CRC with follow-up colonoscopy performed as late as 7 to 9 months after a positive FIT. After a delay of 10 months or more, however, there was a 48% greater risk of CRC, and the risk of stage III or IV disease was double that of those who received colonoscopy in the first few months after a positive FIT. The risks were even higher when colonoscopy was delayed for 12 months or more (odds ratio, 2.25 for any cancer and 3.22 for advanced-stage disease).[88]

The proportion of patients receiving timely colonoscopy follow-up of positive stool blood test results is fair to poor in many settings. Research has documented failure to complete follow-up colonoscopy within 12 months of a positive stool occult blood test in more than one-half of patients in some settings.[89,90] One study comparing completion rates among 4 health systems in the United States reported that rates of colonoscopy follow-up at 12 months varied from 58% to 83%. In contrast, higher rates of timely colonoscopy follow-up have been documented in organized screening programs. Programmatic elements associated with higher completion rates included explicit organizational targets for time to colonoscopy after a positive stool blood test and performance monitoring with monthly reporting.[91] A recent systematic review endorses the impact of giving providers performance data and reminders and also suggests that patient navigation may increase the rate of colonoscopy completion in this circumstance.[92]

When to Stop CRC Screening

- **The ACS recommends that average-risk adults in good health who have a life expectancy of greater than 10 years continue colorectal cancer screening through the age of 75 years (*qualified recommendation*).**

- **The ACS recommends that clinicians individualize screening decisions for individuals aged 76 through 85 years, based on patient preferences, life expectancy, health status, and prior screening history (*qualified recommendation*).**
- **The ACS recommends that clinicians discourage individuals over age 85 years from continuing screening (*qualified recommendation*).**

There is evidence from RCTs to support CRC screening up to age 75 years in average-risk populations. The US-based Prostate, Lung, Colon, and Ovarian Cancer Screening (PLCO) trial of FS enrolled patients aged 50 to 74 years, and all but one of the gFOBT trials that met acceptable quality standards enrolled patients to at least age 75 years. The US-based gFOBT trial enrolled patients through age 80 years.[26,29] Each of these trials demonstrated reductions in CRC mortality, thus providing an empiric basis for recommending screening average-risk individuals in good health up to age 75 years.

Beyond age 75 years, there is greater uncertainty about the benefit-harm tradeoff for CRC screening. On the basis of data from gFOBT randomized trials, the lag time to CRC screening benefit has been estimated to be 10 years,[93] although this benefit represents a combination of early detection (the benefit is realized sooner than 10 years) and prevention (the benefit is realized after 10 years). Thus, a screening benefit is generally believed to require a minimum 10-year life expectancy. Modeling results indicate that there is little incremental benefit in terms of LYGs for continuing screening after age 75 years in individuals who have been screened regularly from the earliest recommended starting age.[30] However, this often will not be the case, and the absence of a history of normal examinations will be of greater concern for those adults who have not been adherent to recommended screening in the years just before age 75 years. Although the current modeling analyses did not stratify by comorbidity status, previous studies have demonstrated that screening outcomes will be heavily influenced by comorbidity and functional status.[94-96] Moreover, CRC incidence and mortality continue to rise after age 75 years, thus indicating an ongoing opportunity to decrease CRC morbidity and mortality by screening individuals in this age group who are in good health (ie, are expected to live long enough to benefit and are at low risk for treatment complications). The impact of colonoscopy on preventing CRC in the elderly was recently examined in a prospective observational cohort study of Medicare beneficiaries aged 70 to 79 years who had no diagnostic or surveillance colonoscopies in the past 5 years.[97] Among adults aged 70 to 74 years, the absolute risk of CRC over 8 years was reduced by 16% in the group undergoing colonoscopy versus the no-colonoscopy group (2.19% vs 2.62%, respectively), while risk reduction was notably less in individuals aged 75 to 79 years who underwent colonoscopy versus the no-colonoscopy group (2.84% vs 2.97%, respectively).

The harms of screening and diagnostic colonoscopy, including bleeding, perforation, complications of anesthesia, and hospitalization, are greater in the elderly, particularly those older than 80 years, and the risk increases with increasing comorbidity burden.[97,98] In the Medicare cohort study mentioned above, the risk of adverse events from colonoscopy was nearly twice as high among individuals aged 75 to 79 years (10.3 per 1000) compared with individuals aged 70 to 74 years (5.6 per 1000).[97]

Given increased competing mortality risks and the increased risk of colonoscopy-associated complications with greater age, the focus of screening among individuals aged 76 to 85 years should be on healthy individuals with no or few comorbidities who are expected to live at least 10 years. The yield would be expected to be higher in those not up to date with screening.[95] If there is concern regarding colonoscopy risks, then noncolonoscopy options may be preferable. Given the paucity of evidence to inform screening decisions in this age group, patient preference should weigh heavily in the decision. A recent examination of older individuals' views suggested that patients may be receptive to a discussion with a clinician of screening cessation based on age and health status, but not emphasizing limited life expectancy.[99] There are tools that are useful for estimating life expectancy considering an individual's comorbidity and functional status.[100,101]

After age 85 years, the competing mortality risks and risks of CRC screening complications are sufficiently high that it is reasonable to conclude that the potential harms of screening outweigh the potential benefits in this age group. Consequently, health care professionals should not offer screening to individuals in this age group. There may be exceptional circumstances when screening might be considered, such as the individual in excellent health who has not been engaged in routine screening and strongly desires testing; but, in general, screening should be discouraged in individuals older than 85 years.

Options for CRC Screening

Stool-Based CRC Screening Tests

There is consistent RCT evidence to support the use of stool testing for CRC screening. The first tests shown to be effective in screening for CRC were guaiac-based tests (gFOBT), which detect peroxidase activity involving the heme portion of the hemoglobin molecule. Consequently, both low-sensitivity and high-sensitivity gFOBT are vulnerable to false-positive results from nonsteroidal anti-inflammatory drugs that can cause upper gastrointestinal (GI) bleeding, red meat, and dietary peroxidases (found in some vegetables and fruits) as well as false-negative results

from antioxidants, such as vitamin C.[102] In contrast, immunochemical tests (FITs) use antibodies that selectively detect the globin component of human hemoglobin, which provides advantages over gFOBT. Because globin is degraded by digestive enzymes found in the upper GI tract, the positivity of FIT is generally not influenced by upper GI bleeding.[102] Furthermore, because the antibody is specific to human hemoglobin, FITs are not vulnerable to interference from medications, animal hemoglobin (red meat), or peroxidases from foods, thus eliminating the need for the dietary restrictions that are recommended with gFOBT. A third stool test is the mt-sDNA test, which combines an immunochemical assay for hemoglobin, and assays for aberrantly methylated *BMP3*, *NDRG*, and *NDRG4*, mutated *K-ras*, and *β-Actin* in cells exfoliated from colonic neoplasms.[103] Currently, there is only one mt-sDNA test marketed in the United States.[104] (See the online Supporting Information for a more detailed discussion of each test.)

All manufacturers of stool tests recommend that stool collected for CRC screening should be collected at home. However, because gFOBT and FIT require the collection of only small samples of stool, some clinicians bypass the recommendation for home testing by using a single sample of stool collected during digital rectal examination. It has been demonstrated that this practice fails to detect up to 90% of cancers.[105,106] Because of this very low sensitivity for CRC and lack of validation studies, CRC screening guidelines recommend against in-office testing with stool collected during digital rectal examination. Some practices have implemented screening programs that give patients the option of testing a spontaneously passed bowel movement in a dedicated clinic bathroom.

Performance characteristics of individual gFOBT and FIT versions vary. The US Food and Drug Administration (FDA) clearance process does not require manufacturers to provide information on the sensitivity or specificity of their test for the detection of CRC or adenomatous polyps, and tests specifically are cleared only for the detection of occult blood, not for CRC screening. This approach to clearance poses a challenge to clinicians seeking to choose a stool test with high accuracy. The poor performance of nonrehydrated, low-sensitivity gFOBT means that these gFOBT variants cannot be recommended and should not be used for CRC screening, although they still are available in the marketplace. At the time of publication, the only guaiac test evaluated in a population-based study shown to meet performance standards to qualify as a high-sensitivity test (HSgFOBT) is Hemoccult II Sensa (Beckman Coulter Inc., Brea, CA), although there may be other variants that have high sensitivity. The sensitivity of HSgFOBT ranges from 62% to 79%, with specificity ranging from 87% to 96%.[26,107,108]

FITs consistently demonstrate superior sensitivity for cancer and advanced neoplasia and slightly lower specificity compared with low-sensitivity gFOBT. Compared with HSgFOBT, the sensitivity and specificity of FIT tend to be similar or superior. Sensitivity for single-sample FIT ranges from 73% to 92%, and specificity ranges from 91% to 97%.[102,109-112] However, most brands of FIT have limited evidence demonstrating their accuracy for detection of CRC. Daly et al found published data from colonoscopy-confirmed studies of FIT performance for only 6 of the 26 versions of FIT sold in the United States.[113] Because studies have shown variable performance of different FITs across studies in which individuals undergo multiple tests to compare outcomes,[114-116] it should not be assumed that versions of FIT that lack published data have suitable performance characteristics.[117]

The original, low-sensitivity guaiac tests have largely been superseded by HSgFOBT and FIT in organized screening programs around the world, and a similar shift is underway in the United States.[102,118-120] National surveys of CRC screening test utilization do not distinguish between FIT and gFOBT, but overall use of stool testing in the United States is low. In 2015, 7.2% of US adults aged 50 years and older reported having completed a take-home stool-based test (FIT or gFOBT) within the past year.[65] The effectiveness of annual testing depends upon program sensitivity, which depends on multiple, annual opportunities for detection before a cancer or an advanced lesion becomes symptomatic.[121]

In the 2018 MISCAN modeling analysis for the general population under the increased-risk scenario, in which all stool tests were grouped in the same class, annual FIT from ages 45 to 75 years yielded 94% of the LYGs compared with the benchmark strategy (colonoscopy every 10 years from ages 45 to 75 years) and was found to be a model-recommendable strategy.[34] In contrast, annual HSgFOBT from ages 45 to 75 years was not among the model-recommendable strategies (Table 2).[34] Although annual HSgFOBT and FIT from ages 45 to 75 years achieved the same LYGs (403 LYGs), HSgFOBT was less efficient; for a given number of colonoscopies, more LYGs were achievable with FIT compared with HSgFOBT, because the higher false-positive rate of HSgFOBT led to more colonoscopies.

There are no direct harms of CRC screening associated with HSgFOBT and FIT. Harms are associated with injury to the colon or other complications related to colonoscopy performed after a positive HSgFOBT[29] (see Colonoscopy section, below).

In the guideline update, HSgFOBT (eg, Hemoccult II Sensa) remains an option for CRC screening, because it has high sensitivity approaching that of FIT and because of its

lower costs compared with FIT, making it an attractive option in low-resource settings where FIT may not be affordable.

The best evidence for the performance of mt-sDNA testing comes from a large, manufacturer-funded, multicenter, comparative trial of mt-sDNA and FIT testing in average-risk individuals using colonoscopy as the reference standard.[103] The sensitivity of mt-sDNA for CRC was 92.3%, compared with 73.8% for FIT. When the specificity of FIT was matched to that of mt-sDNA (86.6%), its sensitivity to detect CRC improved to 77% but remained significantly below that of mt-sDNA. The sensitivity for advanced adenomas and sessile serrated polyps also was higher for mt-sDNA compared with FIT (42.4% vs 23.8%). One significant advantage of mt-sDNA compared with FIT was its higher detection rate of serrated sessile polyps >1 cm (sensitivity was 42.4% for mt-sDNA and 5.1% for FIT). The specificity of mt-sDNA was significantly lower than that for FIT: 89.8% versus 96.4%, respectively, for participants with a negative colonoscopy, indicating a higher false-positive rate with mt-sDNA.

Like other stool-based tests, the harms of mt-sDNA are associated with the harms of colonoscopy performed for the follow-up of positive tests (see Colonoscopy section below). However, an issue unique to mt-sDNA compared with FIT and HSgFOBT is the uncertainty about the interpretation of a negative follow-up colonoscopy after a positive finding on mt-sDNA. Reported results from the mt-sDNA test currently available in the United States do not indicate which component of the test (FIT or DNA) yielded the positive result. A positive stool DNA test followed by a negative colonoscopy may be caused by failure to detect a visible lesion, neoplastic changes that are not yet visible, or the presence of noncolonic aerodigestive or supracolonic neoplasms. Patients with positive mt-sDNA results and a negative follow-up colonoscopy may undergo more aggressive short-term surveillance because of heightened concerns related to unresolved false-positive findings. In 2 follow-up studies of patients with false-positive results on mt-sDNA with median follow-up of approximately 4 years, no excess rates of CRC or aero-digestive malignancies were identified.[122,123] In a more recent study by Cooper et al that included follow-up mt-sDNA, colonoscopy and upper endoscopy among 12 patients who had prior positive mt-sDNA results and a negative colonoscopy, 7 patients had negative stool tests and colonoscopies, whereas 3 among the remaining 5 patients had positive findings on their follow-up colonoscopy (2 advanced and 1 nonadvanced adenoma).[124] Longer term follow-up will be required to provide greater reassurance and guide management, but the findings from Cooper et al are a reminder that high-quality colonoscopy is critically important, especially in the proximal colon, when following up positive findings on an mt-sDNA test.

In the general population modeling analysis conducted for this guideline update, mt-sDNA was not shown to be a model-recommendable test. Annual mt-sDNA was found to be inefficient within the class of stool tests because of the higher number of colonoscopies required per LYG (Table 2).[34] Mt-sDNA every 3 years (the screening frequency on which FDA clearance was based) yielded 88% of the LYGs from colonoscopy every 10 years (less than the a priori criterion of 90%) and 93% of the LYGs compared with annual FIT testing (Fig. 5).[34]

The GDG concluded that mt-sDNA warrants inclusion among test options based on its sensitivity for detecting CRC, its improved advanced adenoma and serrated sessile polyp detection compared with FIT, and evidence indicating that some adults would choose screening with mt-sDNA over other CRC screening tests.[125]

Options for CRC Structural (Visual) Examinations

Structural (visual) examinations used for CRC screening are procedures that allow the examiner a visual inspection of the bowel. These include endoscopic examinations (FS and colonoscopy) and a radiologic examination (CTC). One feature that distinguishes structural examinations from stool testing is the longer recommended screening interval (*see Supporting Information for a more detailed discussion of each test*).

Structural examinations place more demands on patients than stool testing. All structural examinations require bowel cleansing before the examination: for FS, bowel cleansing rectal enemas are recommended and, for colonoscopy and CTC, the most common bowel cleansing preparation involves ingestion of polyethylene glycol oral laxatives, and patients are usually advised to replace solid foods with a liquid diet the day before bowel cleansing. In a recent systematic review of the effectiveness of various bowel cleansing protocols, the USMSTF noted that the length of time between the last dose of preparation and the initiation of colonoscopy is correlated with the quality of cleansing in the proximal colon. When bowel cleansing is split between the day before and the day of colonoscopy, the data consistently demonstrate superior bowel cleansing performance.[126] On the basis of these findings, the USMSTF strongly recommends use of a split-dose bowel cleansing regimen for elective colonoscopy (strong recommendation, high-quality evidence) and, alternatively, a same-day regimen for patients undergoing an afternoon examination (strong recommendation, high-quality evidence).[126] Colonoscopy usually is performed with sedation, thus requiring a day away from work and a chaperone to provide transportation. FS and CTC usually are performed without sedation, entailing less time commitment than colonoscopy.

The adequacy of bowel preparation and expertise of clinicians performing structural examinations are critical to the effectiveness of CRC screening with structural examinations. Primary care clinicians should ascertain the degree to which recommended quality-assurance programs[127-131] are in place and, in particular, whether the practice is monitoring performance metrics, including the adenoma detection rate.

Colonoscopy

Colonoscopy is the most frequently used CRC screening modality in the United States.[65] It allows direct visual inspection of the entire colon and same-session detection, biopsy, and removal of polyps. Colonoscopy also is used for further evaluation of patients who have had a positive test result on a noncolonoscopy CRC screening examination. The best direct evidence of effectiveness comes from a large, prospective, observational cohort study[132] in which the authors reported a hazard ratio (HR) for CRC mortality of 0.32 (95% confidence interval [95% CI], 0.24-0.45) comparing 1 or more colonoscopy versus no colonoscopy over 24 years, with better results for distal cancers (HR, 0.18; 95% CI, 0.10-0.31) than for proximal cancers (HR, 0.47; 95% CI, 0.29-0.76). Incidence reduction was demonstrated for individuals who had a negative colonoscopy, with an HR of 0.53 (95% CI, 0.40-0.71).[132] In the systematic evidence review, colonoscopy sensitivity for detecting adenomas ≥6 mm (using CTC as the comparator) ranged from 75% to 93%, with a specificity of 94%, and sensitivity for adenomas ≥1 cm ranged from 89% to 98%, with a specificity of 89%.[29]

The 3 CISNET models that informed the USPSTF's 2016 CRC screening recommendation statement[44] estimated that colonoscopy screening every 10 years from ages 50 through 75 years would reduce CRC incidence by 62% to 88% and mortality by 79% to 90%, averting 22 to 24 deaths from CRC per 1000 individuals screened. The median LYGs (270) was superior to that of other testing options.[30] In the general-population MISCAN modeling conducted for the ACS using updated incidence data, colonoscopy every 10 years from ages 45 through 75 years provides a greater reduction in the lifetime risk of CRC and somewhat more LYGs and CRC deaths averted than other recommendable strategies (Fig. 5),[34] although it requires more than twice the number of lifetime colonoscopies as stool-based testing (Table 2).[34]

There is a risk of overdetection and removal of small polyps that have low likelihood of progressing to cancer, increasing the risks associated with polypectomy and potentially leading to unnecessary recommendations for short-term surveillance. Colonoscopy is significantly more likely to miss sessile serrated polyps than typical adenomas.[133,134]

The primary harms from screening colonoscopy include perforation and bleeding, which occur more commonly if polypectomy is performed. The USPSTF evidence synthesis estimated that the risk of perforation is approximately 4 per 10,000 colonoscopies, and the risk of major bleeding is approximately 8 events per 10,000 colonoscopies.[29] The complication rate of colonoscopies performed to follow up positive noncolonoscopy screening tests is significantly higher than that for primary screening colonoscopies.[26,40] Importantly, the harms of colonoscopy rise significantly and nonlinearly with age and comorbidity burden.[135] In a population-based study of 1.6 million Californians undergoing colonoscopy that was published after the USPSTF evidence review, the rate of lower GI bleeding was 5 per 10,000 among those not undergoing biopsy and 36 per 10,000 among those undergoing biopsy or other intervention. The comparable perforation rates were 3 per 10,000 and 6 per 10,000, respectively. Thirty-day non-GI complications were reassuringly low in that study; the risk of myocardial infarction was 2.5 per 10,000 for colonoscopy without biopsy and 4 of 10,000 with biopsy, which was lower than that for comparator procedures (joint aspiration/injection and lithotripsy).[41]

Computed tomography colonography

CTC, sometimes referred to as "virtual colonoscopy," involves the acquisition of thin-slice computed tomography images that can be evaluated as 2-dimensional images or reconstructed into 3-dimensional images of the colorectal lumen, creating views previously available only through a colonoscope. In the 2 largest and highest quality studies of CTC, CRC detection rates with CTC were essentially identical to those achieved with optical colonoscopy.[136,137] A systematic review and meta-analysis of 49 studies using colonoscopy as the reference standard estimated that the sensitivity of CTC for cancer detection was 96.1%, and the sensitivity for adenomas >6 mm ranged from 73% to 98% with a specificity of 89% to 91%.[138]

Screening every 5 years with CTC from aged 50 through 75 years was considered a model-recommendable strategy in the 2016 analyses conducted for the USPSTF.[30,31] The general-population modeling analysis commissioned for the ACS, using updated incidence data, also found that CTC every 5 years from ages 45 through 75 years was a model-recommendable strategy (Table 2).[34]

Adverse events associated with CTC include those associated with bowel preparation, such as abdominal pain, examination related pain, and vasovagal syncope or presyncope. Potentially more serious harms, although very rare, include perforation and the possibility of an induced cancer associated with radiation exposure from single or multiple examinations. A more common occurrence, which may or may not be beneficial, is the identification of extracolonic findings.

Perforation, mostly due to insufflation, is very rare and is estimated to occur in less than 2 per 10,000 procedures.[29] As with any imaging test, radiation exposure commonly is raised as a potential harm, although new screening protocols have resulted in substantial dose reductions, with average doses ranging from <1 to 2 millisieverts (mSv) in recent reports,[139,140] which is less than the 3-mSv-per-year estimate of average background radiation exposure in the United States.[141] This low level of exposure every 5 years has been judged to be a negligible harm when considered in the context of the potential LYGs from avoiding a premature CRC death.[142]

The detection of incidental extracolonic findings with CTC screening is an area of concern. The USPSTF evidence report concluded that, based on empiric evidence, it remains unclear whether extracolonic findings represent a net benefit or harm.[26] In their review of 21 studies ranging in size from 75 to 10,286 patients, Lin et al observed that E4 findings, which are potentially important findings that are judged to require further follow-up, ranged from 1.7% to 12%.[26]

Patients with polyps of significant size will require follow-up colonoscopy to remove the polyps. While same-day colonoscopy for polyp removal can be offered without the need for additional preparation, this requires coordination between medical specialists (radiologists and endoscopists) and facilities (radiology departments and endoscopy suites).[143] If this coordination is not in place, patients who have abnormalities detected at CTC must be scheduled for follow-up colonoscopy in the future, necessitating a repeat of the cathartic bowel preparation and additional time commitment.

Flexible sigmoidoscopy

FS, the first visual inspection examination demonstrated to be effective for CRC screening,[144,145] is an endoscopic procedure that examines the lower half of the colorectal lumen. It is typically performed without sedation and with a more limited bowel preparation than the other structural examinations, usually 1 or 2 enemas. CRC incidence and mortality reductions have been demonstrated by 4 RCTs of FS with 1 or 2 screening examinations (at intervals of every 3-5 years).[145-148] In the pooled analysis conducted for the USPSTF,[26,29] CRC mortality was reduced by 27% over 11 or 12 years of follow-up (relative risk, 0.73; 95% CI, 0.66-0.82). Mortality reduction was significant for distal CRC, but not proximal CRC. CRC incidence was reduced by 21%. PLCO investigators reported significant reductions in the incidence of both distal and proximal cancers.[29] A recent 17-year follow-up of the UK Flexible Sigmoidoscopy Screening Trial reported a 26% reduction in the incidence of CRC and a 30% reduction in mortality. As in the pooled analysis, the overall effectiveness of screening in the UK trial derived from the detection of distal lesions, as there was no significant reduction in incidence or mortality for proximal cancers.[149] A recent pooled analysis of 3 of the 4 trials (PLCO, SCORE, and Norwegian Colorectal Cancer Prevention [NORCCAP]) with a median of 10 to 12 years of follow-up reported an overall 21% reduction in CRC incidence and a 27% reduction in mortality with screening FS.[150] However, neither incidence nor mortality was lowered by FS in women aged 60 years or older, primarily because of the poorer performance of FS in detecting proximal colon cancers, which disproportionately affected older women.

In the MISCAN modeling analyses adjusted for increased incidence, FS every 5 years from ages 45 through 75 years was a model-recommended strategy. In contrast, assuming stable incidence, in the CISNET analysis conducted for the USPSTF 2016 update, FS alone every 5 years or 10 years in adults aged 50 to 75 years was not a model-recommended strategy.[30] The greater efficiency of FS in the updated model is likely attributable to the observation that most of the increased incidence is confined to the rectum and distal colon (Fig. 5).[34]

The use of FS as a CRC screening test has declined markedly over the past several decades in the United States, having been replaced by colonoscopy as the primary structural examination. As of 2010, only 2.5% of adults aged 50 to 75 years reported having an FS in the recommended interval, compared with 60% for colonoscopy.[151]

Despite evidence for the efficacy of FS as a CRC screening test in expert settings, the low level of utilization of FS in the United States raises questions as to whether community-based clinicians have received adequate training or perform a sufficient number of procedures to maintain proficiency. Standards, including depth of insertion, adenoma detection rate, and adequacy of preparation, have been proposed,[130] but rigorous quality standards are not currently in place in the United States. Despite the robust body of RCT evidence demonstrating the effectiveness of FS, low utilization rates coupled with quality concerns led the GDG to consider removing FS as a recommended test. The decision was made to retain it based primarily on the foundation of evidence it provides of a mortality reduction benefit from screening with structural examinations. In addition, there was an acknowledgment that FS might be the primary structural examination available in some geographic areas.

Emerging Technologies Not Currently Recommended for Routine Screening

The following tests are not among the list of recommended CRC screening options but have been cleared by the FDA for use in special circumstances.

Methylated Sept9 DNA

The FDA recently cleared a blood test to detect circulating methylated Septin 9 DNA (m*SEPT9*), a molecular CRC biomarker shed by the tumor into the circulation, as a test for average-risk individuals who have repeatedly refused other forms of CRC screening.[152] According to the FDA, all tests that are available and recommended in the USPSTF CRC screening guidelines should be offered and declined before offering the mSept9 test. Because patients with a positive mSept9 test should be referred for colonoscopy, they must be prepared to undergo a follow-up test that they previously had rejected for screening.

Most studies of mSept9 have been tandem studies comparing advanced neoplasia detection rates with a conventional CRC screening test. The USPSTF evidence report included one prospective study of mSept9 that showed a sensitivity and specificity of 48% and 91%, respectively, for detecting CRC in an average-risk population scheduled to undergo colonoscopy.[29,153] Since the USPSTF review, a retesting of samples from the same prospective cohort using a newer version of the test yielded an improved sensitivity for cancer and advanced adenomas of 68% but a lower specificity of 80%.[154] A second study using the newer version of the test involving US subjects undergoing screening colonoscopy reported similar sensitivity and specificity for screen-detected CRC (73% and 82%, respectively).[155]

Although these studies demonstrate improving test sensitivity, concerns remain about poor specificity compared with recommended screening options and the limited base of evidence in asymptomatic, screening populations. In addition, there has been no microsimulation modeling of the newer version of the test to estimate its benefit, a benefit-harm ratio, or a screening interval for regular testing, which also has not been established by the manufacturer. In addition, mSept9 is a novel blood test for CRC early detection with no comparable screening tests from which to infer a benefit in terms of critical outcomes (CRC mortality or incidence reduction), as there are for the included screening test options. Importantly, the test has not been cleared by the FDA for unrestricted use in general routine screening. Going forward, the performance of plasma DNA tests should be monitored. An accurate blood test would have obvious value in the repertoire of screening options, and even a test with somewhat poorer performance would likely make a contribution in adults persistently nonadherent to screening recommendations. In both instances, adherence would likely be high. However, based on the limitations noted above, at this time, mSept9 is not included in this guideline as an option for routine CRC screening for average-risk adults.

Capsule endoscopy

Early versions of capsule endoscopy, also known as capsule colonoscopy, principally were used to evaluate the small bowel, but interest has grown in the past decade to apply this technology to CRC screening. The device incorporates a camera on both sides of an ingestible capsule that captures images of the colon and rectum as it passes through the GI tract. The images are recorded and stored in an external device worn by the patient and later analyzed by a clinician. The test is complete when the capsule is passed in the stool.[156]

In a systematic review[157] of the diagnostic accuracy and safety of colon capsule endoscopy for the detection of colorectal polyps in persons with signs or symptoms of CRC or at high risk for the disease, the reported pooled sensitivity and specificity of capsule endoscopy were 87% (95% CI, 77%-93%) and 76% (95% CI, 60%-87%), respectively, for the detection of a colorectal polyps $\geq$6 mm. The results showed improved test performance for larger polyps (at least 10 mm), with pooled sensitivity of 89% (95% CI, 77%-95%) and specificity at 91% (95% CI, 86%-95%).[157] Adverse events associated with capsule endoscopy were reported in <4% of patients, which mostly included nausea, vomiting, abdominal pain, and fatigue from the required bowel preparation.[157] Capsule retention is the most serious reported problem and occurred in 0.8% of patients (95% CI, 0.2%-2.4%). Like other endoscopic procedures, capsule endoscopy requires adequate cleansing of the colon and, if polyps are found, a colonoscopy may be needed to further investigate and remove precancerous polyps.

In 2014, the FDA cleared the capsule endoscopy system "for use only in patients who had an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible"[158] and, in 2016, capsule endoscopy was cleared for identifying the location of colon polyps in patients suffering from lower GI bleeding.[159] Capsule endoscopy does not have FDA clearance for CRC screening.

Decision Making and Clinical Considerations

Clinician roles in decision making

This update of the ACS CRC guideline emphasizes the importance of patient preferences and choice to improve uptake and adherence to CRC screening (see Choice of Screening Test, above). Health care professionals and the systems in which they work have a vital role in implementing the ACS recommendation that adults undergo regular screening with either a structural (visual) examination or a high-sensitivity stool-based test, depending on patient preference and test availability. In most settings, either an FIT or an HSgFOBT will be available through the practice and, depending on the patient's insurance coverage, mt-sDNA may be an option. Colonoscopy is the most commonly available structural examination. In a growing number of settings, CTC will be available and, for non-Medicare

beneficiaries, may be covered by the patient's insurance. In some settings, FS may be the most readily available structural examination. From a practical implementation standpoint, the choice offered will usually be among 1 or 2 stool-based tests and 1 or 2 structural examinations. The offering of a choice applies primarily to the *uptake* of screening by individuals who are initiating screening or have failed to adhere to prior recommendations for screening; for these patients, exploring test preferences may be particularly effective to improve adherence to screening. For individuals who have been adherent to screening, it is reasonable for clinicians to continue ordering the same previously completed test without offering new options, unless the patient raises specific concerns. The ACS recognizes that, in some settings (eg, rural or low-resource settings), there may be only one high-quality screening option available for many patients, in which case, discussing a menu of unavailable options is not useful.

Resources for clinicians and patients

This guideline provides a list of options for CRC screening along with considerations for decision making to assist health professionals and patients in selecting the option most likely to be completed (Table 3). In addition, a clinicians' guide and decision support materials have been developed to accompany this guideline to facilitate the decision-making process.[86] It is anticipated that these materials will help both uptake of and adherence to CRC screening by better aligning the selected screening test with patient preferences. The materials can be found online at cancer.org/colonmd.[87]

Patient considerations of cost and reimbursement

There are several important issues for clinicians and patients to keep in mind with regard to the costs of CRC screening. There is wide variation in the costs of screening, depending on which test is chosen, with guaiac and fecal immunochemical tests at the low end ($20-$30),[160] colonoscopy usually priced between $1000 and several thousand dollars,[161] and other testing methods falling between these 2 extremes. Patient out-of-pocket costs for each of these tests may also vary, depending on a variety of factors, including insurance status (insured vs uninsured), type of insurance (ie, low-deductible vs high-deductible plans), and site of service (eg, hospital vs free-standing endoscopy center and within-network vs out-of-network). Insurance policy and interpretation of coding rules may also impact patient costs for CRC screening.

A stipulation in the Patient Protection and Affordable Care Act (ACA) requires provision of preventive services that receive an "A" or "B" recommendation from the USPSTF, including CRC screening, with no copay or deductible for beneficiaries. This provision applies to Medicare and to most commercial insurance plans, and there is evidence that the ACA's elimination of cost-sharing contributed to increases in CRC screening among low-income Medicare beneficiaries.[162] This waiver of cost-sharing is required only for screening examinations. Many patients choosing colonoscopy as their initial screening test will have the procedure with no out-of-pocket costs, but patients covered by Medicare currently incur costs if a polyp is removed, and patients with commercial insurance may still be charged inappropriately for polyp removal during an examination initiated for screening (see below). Furthermore, ACA provisions have been interpreted differently by some insurers; some insurers have judged a personal history of cancer, polyps, or a family history as defining all subsequent colonoscopies as diagnostic, especially if they are performed at shorter intervals than were recommended by the USPSTF for average-risk adults, thus resulting in charges to the patient. Furthermore, if a patient is first screened with a stool test or any other noncolonoscopy examination, then most insurers interpret a colonoscopy performed to follow up a positive initial screen as a diagnostic procedure, meaning that the patient becomes responsible for cost-sharing.[163] A small number of insurers, recognizing that this policy encourages some patients to choose colonoscopy to avoid possible out-of-pocket costs, have opted to treat the colonoscopy after a positive stool test as a continuation of the screening process; legislation in Oregon requires insurers that sell products in that state to treat the follow-up colonoscopy in this manner.[164] Patients living in states that do not have this provision should be informed that, if they choose a noncolonoscopy option as their initial screening test and have an abnormal result, then they may be responsible for some of the costs of colonoscopy. This ACS guideline update strongly recommends that follow-up colonoscopy should be regarded as a part of the continuum of the screening process rather than a diagnostic procedure.

A second policy issue that may impact patient cost also relates to the operational definition of a screening colonoscopy. During implementation of the ACA, many insurers used a narrow classification of screening colonoscopy to guide application of the "no cost-sharing" provision. If a lesion was biopsied or removed during a procedure that had originally been scheduled as a screening colonoscopy, the procedure would often be recoded as a diagnostic examination and thus belatedly and unexpectedly become subject to patient cost-sharing. In 2013 the US Departments of Labor, Health and Human Services, and the Treasury clarified that this was not the intent of the ACA provision on preventive services, issuing guidance to insurers stating that, "polyp removal is an integral part of a colonoscopy" and indicating that commercial plans "may not impose cost-sharing with

respect to a polyp removal during a colonoscopy performed as a screening procedure."[165] Subsequent communications to insurers clarified that anesthesia and pathology services and bowel preparation medications provided in conjunction with a screening colonoscopy must also be covered without cost-sharing.[166-168] Unfortunately, these rule clarifications do not currently apply to the Medicare program; Medicare beneficiaries frequently experience unexpected out-of-pocket liabilities for "screening" colonoscopy if tissue is sampled during the procedure. A recent modeling analysis showed that waiving copays would have a favorable impact on health improvements and costs.[169] Changing the implementation of this element of the ACA in the Medicare program will require federal legislative action.

Insurance coverage policies related to CRC screening are largely driven by the linkage of the ACA's preventive services provisions to USPSTF recommendations. The current USPSTF recommendation to begin CRC screening at age 50 years sets a minimal threshold for insurers; there is no prohibition against coverage for screening at an earlier age. However, it is likely that, in the near term, many individuals aged 45 to 49 years will experience challenges with insurance coverage for their screening examinations and may experience out-of-pocket costs if they seek to begin screening. The ACS and other organizations are working aggressively to educate insurers and policymakers on the rising rates of CRC among younger individuals, the evidence in support of screening for individuals aged 45 to 49 years, and the importance of expanding screening coverage to this group.

Interventions to increase utilization and adherence

Poor utilization of and adherence to CRC screening is a major contributor to avoidable CRC mortality in the United States and has been a persistent challenge since the earliest prospective studies of CRC screening were conducted. A systematic review of 100 prospective studies of participation after first-time invitation found that overall adherence was 47% for gFOBT, 42% for FIT, 35% for FS, 28% for colonoscopy, and 22% for CTC.[170] Only 62.4% of adults older than 50 years in the United States report recent CRC screening consistent with guideline recommendations, with lower rates among American Indians and Alaska Natives (48.4%), Hispanics (27.4%), and the uninsured (25.1%).[171] As noted above, screening rates vary by age (only 45.3% of adults aged 50-54 years report recent CRC screening vs 57.9% of adults aged 50-64 years and 71.8% for adults aged 65-75 years), by education (only 46.7% of adults with less than a high school education report recent CRC screening vs 70.7% of college graduates), and by insurance status (only 25.1% of uninsured adults report recent CRC screening vs 65.6% of insured adults).[171]

Optimizing adherence to CRC screening will require a multipronged approach that addresses the barriers to screening at the individual, provider, organizational, and policy levels with evidence-based interventions. Multicomponent interventions to reduce structural barriers have been found to have greater effects on utilization of colonoscopy and FOBT than when single interventions were used.[172]

One of the most powerful factors for increasing adherence to CRC screening is clinician recommendation. A systematic review reported overwhelming evidence that provider recommendation significantly improves screening rates.[173] Furthermore, as noted above, it has been demonstrated that offering patients a choice of CRC screening tests rather than recommending a single test improves adherence to screening and likely conveys to patients the importance of the recommendation.

Several visit-based strategies have been shown to be effective in improving screening rates within practices and integrated systems, especially reminder systems to help care teams identify patients who are due for screening.[46,174,175] Other effective visit-based strategies include "opportunistic screening" or "in-reach" methods, including offering screening during nurse-driven influenza vaccination clinics.[176-178]

Evidence examining the impact of decision aids on CRC screening adherence is mixed. Several systematic reviews have found that, whereas decision aids increase screening knowledge and modestly increase screening, there were no significant differences in screening interest or behavior among individuals who were exposed to decision aids compared with those who were given general information about CRC screening.[46,79] A study examining the impact of combining a decision aid with patient navigation in a diverse, vulnerable patient population did demonstrate a strong impact on screening completion but was unable to separate the effects of the decision aid from patient navigation.[179] A recent study incorporating an iPad-based CRC decision aid with test-ordering capability into the office visit demonstrated a doubling of CRC screening completion from 15% to 30% among vulnerable primary care patients who were randomized to the intervention.[180]

Nonoffice-based strategies, including "outreach" strategies whereby patients receive invitations to screening via mail, have shown a 5% to 15% increase in adherence rates. Mailed reminders with or without FIT kits/gFOBT cards timed to a scheduled clinic appointment can increase screening.[174,176,181-187] Open-access endoscopy has not been demonstrated to increase scheduling of screening endoscopy, although it is associated with higher procedure completion rates.[188]

RCTs have shown that patient navigation is an effective intervention for implementing stool-based and colonoscopy-based screening programs. Navigation is particularly helpful

in increasing CRC screening in vulnerable populations.[189-198] Investigators have offered helpful guidance on key considerations when designing a successful navigation program.[199,200] Tailored patient navigation that allows the patient's care team to address specific patient barriers to screening, including language, has been shown to be more effective than standard navigation.[195,196,201] Personal invitation letters, preferably signed by the care provider, and reminders mailed to all nonattendees are also highly effective in enhancing CRC screening acceptance.[202]

Multifaceted interventions that target multiple levels of care and consider factors outside the individual clinician's control represent the most effective strategies to enhance CRC screening uptake and adherence, particularly in populations that have multiple barriers to CRC screening (eg, financial barriers, lack of health insurance, low income, low educational attainment, and language barriers). For example, the ACA's elimination of cost-sharing was associated with an increase in utilization of CRC screening in adults with low socioeconomic status likely because of the removal of financial barriers.[162] In community health center settings, Baker et al found that, compared with usual care (computerized reminders, standing orders for home FIT distribution by medical assistants, and clinician feedback on CRC screening rates), patients in an intervention group that also received a mailed reminder letter, a free FIT with low-literacy instructions, a postage-paid return envelope, and automated follow-up telephone and text messages were much more likely than those in usual care to complete screening with a stool test (82.2% vs 37.3%; $P < .001$).[203] After 2 years of follow-up, 71.6% of the intervention group remained fully up to date with CRC screening.[204] Several organizations have compiled valuable resources to facilitate the implementation of multifaceted interventions to increase uptake of and adherence to CRC screening (see Supporting Information).

Discussion

Changes From the Previous Guideline

The most notable change from the 2008 ACS guideline is the recommendation for all average-risk adults to initiate screening for CRC at age 45 years. In addition, the 2018 update provides more specific guidance regarding when to discontinue CRC screening, which was not specifically addressed in the previous guideline. The 2008 guideline stated that CRC prevention should be the primary goal of screening and that tests that detect both early cancer and adenomatous polyps should be encouraged if resources are available and the patient is willing to undergo an invasive test. Although this update places value on both CRC incidence and mortality reduction, the GDG chose not to prioritize among screening tests, emphasizing instead that screening utilization and adherence could be improved and the benefits of screening more fully achieved by offering a choice of tests. This guideline includes 6 test options for CRC screening: specifically, annual FIT or HSgFOBT, mt-sDNA every 3 years, colonoscopy every 10 years, CTC every 5 years, and FS every 5 years. Recommended screening intervals remain unchanged since 2008. Double-contrast barium enema is no longer included as an acceptable screening option (see Supporting Information Table 1).

Considerations in Lowering the Starting Age to 45 Years

The overall quality of the evidence and the balance of benefits and harms were judged to support a strong recommendation for CRC screening in adults aged 50 years and older with any of the included test options. Because until now the recommended age to start has been 50 years, there is very limited direct evidence to support a younger starting age other than the 3 RCTs of gFOBT that started enrollment at age 45 years, although no age-specific results have been published.[205-207] As soon as screening begins to occur regularly in the group aged 45 to 49 years, observational evidence on the performance and outcomes of screening will accrue. The GDG relied on disease burden data and modeling studies to address the question of optimal starting age. Thus, the starting age of 45 years has been designated as a qualified recommendation given the limitations of the evidence base.[38] An absolute mortality benefit in younger age groups will be lower than for older adults and, as some of our reviewers have noted, there will be some increased patient burden associated with a younger starting age. However, the recommendation places a high value on the potential years of life saved, addresses anticipated rising incidence going forward, and is expected to contribute to the reduction in disparities in incidence before age 50 years in some racial groups.[33,34]

In addition to the potential early detection and prevention benefit for adults aged 45 to 49 years, lowering the starting age to 45 years also is likely to have a favorable impact on CRC incidence and incidence-based mortality in the group ages 50 to 54 years. Incidence in this age group is currently increasing, in contrast to the declining incidence in all age groups after age 54 years.[3]

Implementation

The GDG acknowledged the implementation challenges posed by lowering the starting age. First, changing the age to begin screening—a key component of recommendations that heretofore have achieved broad consensus—may contribute to confusion and uncertainty among clinicians and patients as to the best course of action. The ACS will seek to mitigate the impact of conflicting recommendations

through clear communication of its recommendation and rationale, including provider and patient support materials (cancer.org/colonmd).[86] Second, there will likely be a lag between the publication of this recommendation and insurance coverage by all providers of CRC screening starting at age 45 years. The 2010 ACA requires that nongrandfathered commercial insurance plans fully cover USPSTF-recommended screening tests; these are minimum coverage standards for an ACA-qualified health plan, and plans are not restricted from extending CRC screening coverage to individuals aged 45 to 49 years. Third, some have expressed concerns that the US health care infrastructure will be unduly strained by lowering the starting age to 45 years and that efforts should focus instead on increasing screening rates in adults aged 50 years and older. The ACS remains fully committed to increasing screening rates; both expanding the screening to include adults aged 45 to 49 years and increasing screening rates in the population aged 50 years and older can be achieved within the current health care infrastructure. A study that combined results from the 2012 Survey of Endoscopic Capacity with a modeling analysis indicated that increasing screening rates to 80% (with any combination of screening modalities) can be accommodated with current excess capacity.[76] In addition, this guideline places increased emphasis on choice of screening options (not limited to colonoscopy) for those initiating CRC screening.

Patient Choice and Decision Making

Whereas past CRC screening guidelines have prioritized specific tests or specific outcomes (ie, prevention), in this update, the GDG chose to prioritize the opportunity for patients to select either a structural (visual) examination or a high-sensitivity stool-based test, depending on their preference and test availability. This decision does not discount the argument that clinicians and the target population also desire expert advice. However, too many adults who are advised to undergo CRC screening with colonoscopy do not adhere to the advice from the referring provider, and the opportunity to be adherent with CRC screening is missed because of multiple factors, including the failure to ascertain the patient's willingness to undergo an invasive procedure. Health professionals should be prepared to describe and offer options for a structural examination and a stool test and to discuss additional options if the patient does not appear to be accepting of the tests initially presented. As detailed in Table 3, the screening options differ in several ways that influence patient choice. The information provided is designed to facilitate clinician-patient encounters and patient choices consistent with their preferences and thus increase utilization of CRC screening. In addition, materials to facilitate test selection at the point of care have been developed by the ACS.[86,87]

Comparison With Other Guidelines

The USPSTF updated their CRC screening guideline in 2016.[44] CRC screening from ages 50 through 75 years with any of 7 screening strategies was given an "A" recommendation (comparable to a strong recommendation using GRADE criteria), which largely overlaps with the 2018 ACS recommendations. The primary differences are as follows: ACS recommends beginning screening at age 45 years, while the USPSTF recommends beginning at age 50 years and the USPSTF recommends FS every 10 years combined with annual FIT, which is not included in the ACS list of testing options. The ACS GDG relied upon RCT evidence supporting a 5-year screening interval for FS alone, as well as the results of modeling commissioned for this guideline, and concluded that the FS-only option at a 5-year interval should be maintained. The modeling data suggested that any incremental benefit conferred by the combined strategy would be small compared with model-recommended strategies for either test alone, and there also would be the complexity of integrating 2 test schedules. Finally, the GDG expressed concerns about even continuing to endorse FS, given the low availability and utilization in the United States (see Supporting Information Table 1).

In 2017 the USMSTF preferentially recommended screening with colonoscopy every 10 years, annual FIT for individuals declining colonoscopy, and, as second-tier tests, CTC every 5 years, mt-sDNA every 3 years, and FS every 5 to 10 years.[57] The USMSTF recommended that African Americans initiate screening at age 45 years and that average-risk adults belonging to other racial/ethnic groups begin screening at age 50 years. For individuals with no adenomatous findings or CRC at prior screening, the USMSTF recommended discontinuing screening at age 75 years or when life expectancy is less than 10 years; and they recommended continuing screening to age 85 years for those not previously screened, depending on comorbidities (see Supporting Information Table 1).

Screening in Individuals at Increased or High Risk for CRC

This guideline update focuses on CRC screening in average-risk adults and does not address screening or surveillance in persons at increased or high risk for developing CRC. These include individuals with history of adenomatous polyps, a personal history of CRC, a family history of CRC or adenomatous polyps diagnosed in a relative before age 60 years, a personal history of inflammatory bowel disease, a confirmed or suspected hereditary CRC syndrome, or a history of abdominal or pelvic radiation for a previous cancer.[18-21] Updated screening and surveillance recommendations for these groups have been developed by other organizations.[208-211] Identification of candidates for

differential screening requires adequate collection and updating of family history information and appropriate referral for genetic counseling and testing of individuals at increased risk for hereditary syndromes.

Limitations

The recommendation to initiate screening at age 45 years is based on limited empirical data related to outcomes in average-risk individuals who initiate screening between ages 45 and 49 years. The decision to begin screening in average-risk adults at aged 50 years, in both clinical practice and research, has been largely based on expert opinion about an appropriate threshold for the burden of disease, and this practice understandably has limited the available evidence on screening outcomes in adults aged 45 to 49 years. However, the increasing CRC incidence in successive birth cohorts and subsequent, recent increases in mortality in the group ages 50 to 54 years suggest an opportunity to address a well recognized trend and mitigate future increased incidence and mortality. In the presence of the changing epidemiology of CRC, it is important to acknowledge that the desired empirical evidence (ie, prospective data on screening outcomes in adults aged 45-49 years), conservatively, would be a decade or more away even if a large study were launched this year. In the 5 years before the conventionally accepted age to begin screening, there is little evidence to suggest that screening would be less effective in detecting occult blood or advanced neoplasia, apart from the lower but increasing prevalence of disease.

The modeling analysis that supported the recommendation for an earlier starting age did not examine the use of alternating modalities or of combination or hybrid screening strategies. Hybrid strategies have been proposed as a means of decreasing the burden of screening from either an individual or a societal perspective.[96] For example, switching from colonoscopy to a stool-based test or CTC at older ages could theoretically reduce exposure to the higher complication risk associated with colonoscopy with advancing age. With greater confidence about the influence of prior findings on future risk, CRC screening test choice, interval, and stopping age might be tailored based on prior results. This is an area in need of further research, both to determine which hybrid strategies would be most effective and acceptable to the target population and to address the challenge of implementing different hybrid strategies in the primary care setting.

Conclusions

Since the last update of the ACS CRC screening guideline a decade ago, there have been numerous developments in the field of CRC screening that have informed this update. Although the 6 screening options presented in this guideline have not fundamentally changed, the accrual of experimental, observational, and modeling data has served to validate their role in CRC screening and further reinforce the conclusion that the benefits of regular screening with any of the tests in terms of CRC mortality and incidence reduction significantly outweigh the risks and burdens they confer.

One of the most significant and disturbing developments in CRC is the marked increase in CRC incidence—particularly rectal cancer—among younger individuals. While the causes of this increase are not understood, it has been observed in all adult age groups below the age when screening has historically been offered and is contributing significantly to the burden of suffering imposed by premature CRC mortality. Incorporating this epidemiological shift into contemporary modeling of CRC screening demonstrated that the benefit-burden balance is improved by lowering the age to initiate CRC screening to 45 years. Lowering the starting age is expected to benefit not only the segments of the population who suffer disproportionately from CRC—blacks, Alaska Natives, and American Indians—but also those individuals otherwise considered to be at average risk. Moreover, epidemiological trends in cohorts as young as those born in 1990 suggest that the higher risk of developing CRC will be a persistent concern for decades to come.

As outlined in this guideline, there have been substantive advances in our understanding of strategies to overcome barriers to CRC screening through interventions at the patient, provider, office, and system levels that serve to increase uptake of and adherence to screening. Yet, with almost 40% of eligible adults not up to date with CRC screening, it is clear that these interventions too often are not being implemented. Reaching the full potential of CRC screening in the United States will require multifaceted approaches tailored to the individual patient and practice setting. These approaches vary in intensity and resource utilization, but even an intervention as simple as offering a choice of screening test to improve uptake—as emphasized in this guideline—is expected to further the goal of improving screening rates and reducing the burden of suffering from CRC.

In conclusion, the ACS recommends that all US adults at average risk of CRC undergo regular screening with any of the 6 options outlined in this guideline, beginning at age 45 years. Adults in good health should continue screening until age 75 years, beyond which the decision to continue screening should be individualized based on patient preferences, health status, life expectancy, and screening history. Ascribing to the adage that the best CRC screening test is the one that gets done, and done

well, the ACS recommends that patients initiating screening or previously nonadherent with screening be offered a choice of tests based on availability of high-quality options. It is our hope that widespread adoption of this guideline will have a major impact on the incidence, suffering, and mortality caused by CRC. ■

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References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA Cancer J Clin.* 2018;68:7-30.
2. Siegel RL, Miller KD, Fedewa SA, et al. Colorectal cancer statistics, 2017. *CA Cancer J Clin.* 2017;67:177-193.
3. Siegel RL, Fedewa SA, Anderson WF, et al. Colorectal cancer incidence patterns in the United States, 1974-2013 [serial online]. *J Natl Cancer Inst.* 2017;109:djw322.
4. Edwards BK, Ward E, Kohler BA, et al. Annual report to the nation on the status of cancer, 1975-2006, featuring colorectal cancer trends and impact of interventions (risk factors, screening, and treatment) to reduce future rates. *Cancer.* 2010;116:544-573.
5. Tsai MH, Xirasagar S, Li YJ, de Groen PC. Colonoscopy screening among US adults aged 40 or older with a family history of colorectal cancer [serial online]. *Prev Chronic Dis.* 2015;12:140533.
6. Young PE, Womeldorph CM. Colonoscopy for colorectal cancer screening. *J Cancer.* 2013;4:217-226.
7. Surveillance Epidemiology and End Results (SEER) Program. SEER*Stat Database: Incidence-SEER 9 Regs Research Data with Delay-Adjustment, Malignant Only, Nov 2016 Sub (1975-2014) <Katrina/Rita Population Adjustment>-Linked To County Attributes-Total US, 1969-2015 Counties. Bethesda, MD: National Cancer Institute, Division of Cancer Control and Population Sciences, Surveillance Research Program; 2017.
8. Surveillance Epidemiology and End Results (SEER) Program. SEER*Stat Database: Mortality-All COD, Aggregated With State, Total US (1969-2014) <Katrina/Rita Population Adjustment> (underlying mortality data provided by the National Vital Statistics System, 2016). Bethesda, MD: National Cancer Institute, Division of Cancer Control and Population Sciences, Surveillance Research Program, Cancer Statistics Branch; 2017.
9. Moore HG. Colorectal cancer: what should patients and families be told to lower the risk of colorectal cancer? *Surg Oncol Clin North Am.* 2010;19:693-710.
10. Islami F, Goding Sauer A, Miller KD, et al. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin.* 2018;68:31-54.
11. Bibbins-Domingo K; US Preventive Services Task Force. Aspirin use for the primary prevention of cardiovascular disease and colorectal cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2016;164:836-845.
12. Chan AT, Giovannucci EL, Meyerhardt JA, Schernhammer ES, Curhan GC, Fuchs CS. Long-term use of aspirin and nonsteroidal anti-inflammatory drugs and risk of colorectal cancer. *JAMA.* 2005;294:914-923.
13. Cook NR, Lee IM, Zhang SM, Moorthy MV, Buring JE. Alternate-day, low-dose aspirin and cancer risk: long-term observational follow-up of a randomized trial. *Ann Intern Med.* 2013;159:77-85.
14. Rothwell PM, Wilson M, Elwin CE, et al. Long-term effect of aspirin on colorectal cancer incidence and mortality: 20-year follow-up of five randomised trials. *Lancet.* 2010;376:1741-1750.
15. Giglia MD, Chu DI. Familial colorectal cancer: understanding the alphabet soup. *Clin Colon Rectal Surg.* 2016;29:185-195.
16. Herszenyi L, Barabas L, Miheller P, Tulassay Z. Colorectal cancer in patients with inflammatory bowel disease: the true impact of the risk. *Dig Dis.* 2014;33:52-57.
17. Peeters PJ, Bazelier MT, Leufkens HG, de Vries F, De Bruin ML. The risk of colorectal cancer in patients with type 2 diabetes: associations with treatment stage and obesity. *Diabetes Care.* 2015;38:495-502.
18. Reulen RC, Frobisher C, Winter DL, et al. Long-term risks of subsequent primary neoplasms among survivors of childhood cancer. *JAMA.* 2011;305:2311-2319.
19. Henderson TO, Oeffinger KC, Whitton J, et al. Secondary gastrointestinal cancer in childhood cancer survivors: a cohort study. *Ann Intern Med.* 2012;156:757-766, W-260.
20. Baxter NN, Tepper JE, Durham SB, Rothenberger DA, Virnig BA. Increased risk of rectal cancer after prostate radiation: a population-based study. *Gastroenterology.* 2005;128:819-824.
21. Travis LB, Fossa SD, Schonfeld SJ, et al. Second cancers among 40,576 testicular cancer patients: focus on long-term survivors. *J Natl Cancer Inst.* 2005;97:1354-1365.
22. Winawer SJ. The history of colorectal cancer screening: a personal perspective. *Dig Dis Sci.* 2015;60:596-608.
23. Eddy D. Guidelines for the cancer related checkup: recommendations and rationale. *CA Cancer J Clin.* 1980;30:194-240.
24. Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin.* 2008;58:130-160.
25. Quintero E, Castells A, Bujanda L, et al. Colonoscopy versus fecal immunochemical testing in colorectal-cancer screening. *N Engl J Med.* 2012;366:697-706.
26. Lin JS, Piper MA, Perdue LA, et al. Screening for colorectal cancer: updated evidence report and systematic review for the US Preventive Services Task Force. *JAMA.* 2016;315:2576-2594.
27. Brawley O, Byers T, Chen A, et al. New American Cancer Society process for creating trustworthy cancer screening guidelines. *JAMA.* 2011;306:2495-2499.
28. Oeffinger KC, Fontham ET, Etzioni R, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society. *JAMA.* 2015;314:1599-1614.
29. Lin JS, Piper MA, Perdue LA, et al. US Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews. Screening for Colorectal Cancer: A Systematic Review for the US Preventive Services Task Force. Rockville, MD: Agency for Healthcare Research and Quality; 2016.
30. Knudsen AB, Zauber AG, Rutter CM, et al. Estimation of benefits, burden, and harms of colorectal cancer screening strategies: modeling study for the US Preventive Services Task Force. *JAMA.* 2016;315:2595-2609.
31. Zauber A, Knudsen A, Rutter CM, Lansdorp-Vogelaar I, Kuntz KM. Evaluating the Benefits and Harms of Colorectal Cancer Screening Strategies: A Collaborative Modeling Approach. AHRQ Publication No. 14-05203-EF-2. Rockville, MD: Agency for Healthcare Research and Quality; 2015.
32. Cancer Intervention and Surveillance Modeling Network (CISNET). Rockville, MD: Surveillance Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute; 2018. cisnet.cancer.gov/. Accessed January 20, 2018.
33. Meester RGS, Peterse EFP, Knudsen AB, et al. Optimizing colorectal cancer screening by race and sex: microsimulation analysis II to inform the American Cancer Society colorectal cancer screening guideline. *Cancer.* 10.1002/cncr.31542 [epub ahead of print].
34. Peterse EFP, Meester RGS, Siegal RL, et al. The impact of the rising colorectal cancer incidence in young adults on the optimal age to start screening: microsimulation analysis I to inform the American Cancer Society colorectal cancer

screening guideline. *Cancer*. 10.1002/cncr.31543 [epub ahead of print].

35. Howlader N, Noone AM, Krapcho M, et al, eds. SEER Cancer Statistics Review, 1975-2014. Rockville, MD: National Cancer Institute; 2017.
36. Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64:383-394.
37. Alonso-Coello P, Oxman AD, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines [serial online]. *BMJ*. 2016;353:i2089.
38. Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66:726-735.
39. Mandel JS, Church TR, Bond JH, et al. The effect of fecal occult-blood screening on the incidence of colorectal cancer. *N Engl J Med*. 2000;343:1603-1607.
40. Levin TR, Zhao W, Conell C, et al. Complications of colonoscopy in an integrated health care delivery system. *Ann Intern Med*. 2006;145:880-886.
41. Wang L, Mannalithara A, Singh G, Ladabaum U. Low rates of gastrointestinal and non-gastrointestinal complications for screening or surveillance colonoscopies in a population-based study. *Gastroenterology*. 2018;154:540-555.e8.
42. Zauber AG, Lansdorp-Vogelaar I, Knudsen AB, Wilschut J, van Ballegooijen M, Kuntz KM. Evaluating test strategies for colorectal cancer screening: a decision analysis for the US Preventive Services Task Force. *Ann Intern Med*. 2008;149:659-669.
43. US Preventive Services Task Force. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2008;149:627-637.
44. Bibbins-Domingo K, Grossman DC, Curry SJ, et al. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;315:2564-7255.
45. DeBourcy AC, Lichtenberger S, Felton S, Butterfield KT, Ahnen DJ, Denberg TD. Community-based preferences for stool cards versus colonoscopy in colorectal cancer screening. *J Gen Intern Med*. 2008;23:169-174.
46. Holden DJ, Jonas DE, Porterfield DS, Reuland D, Harris R. Systematic review: enhancing the use and quality of colorectal cancer screening. *Ann Intern Med*. 2010;152:668-676.
47. Wolf RL, Basch CE, Brouse CH, Shmukler C, Shea S. Patient preferences and adherence to colorectal cancer screening in an urban population. *Am J Public Health*. 2006;96:809-811.
48. Ho W, Broughton DE, Donelan K, Gazelle GS, Hur C. Analysis of barriers to and patients' preferences for CT colonography for colorectal cancer screening in a nonadherent urban population. *AJR Am J Roentgenol*. 2010;195:393-397.
49. Pignone M, Bucholtz D, Harris R. Patient preferences for colon cancer screening. *J Gen Intern Med*. 1999;14:432-437.
50. Ruffin MT 4th, Creswell JW, Jimbo M, Fetters MD. Factors influencing choices for colorectal cancer screening among previously unscreened African and Caucasian Americans: findings from a triangulation mixed methods investigation. *J Community Health*. 2009;34:79-89.
51. Ely JW, Levy BT, Daly J, Xu Y. Patient beliefs about colon cancer screening. *J Cancer Educ*. 2016;31:39-46.
52. Dolan JG, Boohaker E, Allison J, Imperiale TF. Patients' preferences and priorities regarding colorectal cancer screening. *Med Decis Making*. 2013;33:59-70.
53. Williams R, White P, Nieto J, Vieira D, Francois F, Hamilton F. Colorectal cancer in African Americans: an update [serial online]. *Clin Transl Gastroenterol*. 2016;7:e185.
54. Agrawal S, Bhupinderjit A, Bhutani MS, et al. Colorectal cancer in African Americans. *Am J Gastroenterol*. 2005;100:515-523.
55. Carethers JM. Screening for colorectal cancer in African Americans: determinants and rationale for an earlier age to commence screening. *Dig Dis Sci*. 2015;60:711-721.
56. Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. *Am J Gastroenterol*. 2009;104:739-750.
57. Rex DK, Boland CR, Dominitz JA, et al. Colorectal cancer screening: recommendations for physicians and patients from the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2017;153:307-323.
58. Alaska Native Medical Center. Alaska Native Medical Center Colorectal Cancer Screening Guidelines. Anchorage, AK: Alaska Native Medical Center; 2013. anmc.org/files/CG_ColorectalCancerScreeningGuidelines.pdf. Accessed February 5, 2018.
59. O'Connell JB, Maggard MA, Liu JH, Etzioni DA, Livingston EH, Ko CY. Rates of colon and rectal cancers are increasing in young adults. *Am Surg*. 2003;69:866-872.
60. Siegel RL, Jemal A, Ward EM. Increase in incidence of colorectal cancer among young men and women in the United States. *Cancer Epidemiol Biomarkers Prev*. 2009;18:1695-1698.
61. Austin H, Henley SJ, King J, Richardson LC, Eheman C. Changes in colorectal cancer incidence rates in young and older adults in the United States: what does it tell us about screening. *Cancer Causes Control*. 2014;25:191-201.
62. Bailey CE, Hu CY, You YN, et al. Increasing disparities in the age-related incidences of colon and rectal cancers in the United States, 1975-2010. *JAMA Surg*. 2015;150:17-22.
63. Kelly JJ, Alberts SR, Sacco F, Lanier AP. Colorectal cancer in Alaska Native people, 2005-2009. *Gastrointest Cancer Res*. 2012;5:149-154.
64. Perdue DG, Haverkamp D, Perkins C, Daley CM, Provost E. Geographic variation in colorectal cancer incidence and mortality, age of onset, and stage at diagnosis among American Indian and Alaska Native people, 1990-2009. *Am J Public Health*. 2014;104(suppl 3):S404-S414.
65. National Center for Health Statistics. 2015 National Health Interview Survey (NHIS) Public Use Data File. Hyattsville, MD: Division of Health Interview Statistics, National Center for Health Statistics, National Institutes of Health; 2016.
66. Lieberman DA, Holub JL, Moravec MD, Eisen GM, Peters D, Morris CD. Prevalence of colon polyps detected by colonoscopy screening in asymptomatic black and white patients. *JAMA*. 2008;300:1417-1422.
67. Levin B, Murphy GP. Revision in American Cancer Society recommendations for the early detection of colorectal cancer. *CA Cancer J Clin*. 1992;42:296-299.
68. Winawer SJ, Fletcher RH, Miller L, et al. Colorectal cancer screening: clinical guidelines and rationale [see comments: published errata appear in *Gastroenterology*.1997;112:1060 and 1998;114:625]. *Gastroenterology*. 1997;112:594-642.
69. Dominitz JA, Robertson DJ, Ahnen DJ, et al. Colonoscopy vs Fecal Immunochemical Test in Reducing Mortality From Colorectal Cancer (CONFIRM): rationale for study design. *Am J Gastroenterol*. 2017;112:1736-1746.
70. de Wijkerslooth TR, de Haan MC, Stoop EM, et al. Study protocol: population screening for colorectal cancer by colonoscopy or CT colonography: a randomized controlled trial [serial online]. *BMC Gastroenterol*. 2010;10:47.
71. Sali L, Mascalchi M, Falchini M, et al. Reduced and full-preparation CT colonography, fecal immunochemical test, and colonoscopy for population screening of colorectal cancer: a randomized trial [serial online]. *J Natl Cancer Inst*. 2016;108:djv319.
72. Regge D, Iussich G, Senore C, et al. Population screening for colorectal cancer by flexible sigmoidoscopy or CT colonography: study protocol for a multicenter randomized trial [serial online]. *Trials*. 2014;15:97.
73. Chen CH, Tsai MK, Wen CP. Extending colorectal cancer screening to persons aged 40 to 49 years with immunochemical fecal occult blood test: a prospective cohort study of 513,283 individuals. *J Clin Gastroenterol*. 2016;50:761-768.
74. Imperiale TF, Wagner DR, Lin CY, Larkin GN, Rogge JD, Ransohoff DF. Results of screening colonoscopy among persons 40 to 49 years of age. *N Engl J Med*. 2002;346:1781-1785.
75. Rundle AG, Lebwohl B, Vogel R, Levine S, Neugut AI. Colonoscopic screening in average-risk individuals ages 40 to 49 vs 50 to 59 years. *Gastroenterology*. 2008;134:1311-1315.
76. Joseph DA, Meester RG, Zauber AG, et al. Colorectal cancer screening: estimated future colonoscopy need and current volume and capacity. *Cancer*. 2016;122:2479-2486.
77. Schroy PC 3rd, Emmons K, Peters E, et al. The impact of a novel computer-based

decision aid on shared decision making for colorectal cancer screening: a randomized trial. *Med Decis Making.* 2011;31:93-107.

78. Xu Y, Levy BT, Daly JM, Bergus GR, Dunkelberg JC. Comparison of patient preferences for fecal immunochemical test or colonoscopy using the analytic hierarchy process [serial online]. *BMC Health Serv Res.* 2015;15:175.

79. Volk RJ, Linder SK, Lopez-Olivo MA, et al. Patient decision aids for colorectal cancer screening: a systematic review and meta-analysis. *Am J Prev Med.* 2016;51:779-791.

80. Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med.* 2012;172:575-582.

81. Liang PS, Wheat CL, Abhat A, et al. Adherence to competing strategies for colorectal cancer screening over 3 years. *Am J Gastroenterol.* 2016;111:105-114.

82. Wong MC, Ching JY, Chan VC, et al. Informed choice vs. no choice in colorectal cancer screening tests: a prospective cohort study in real-life screening practice. *Am J Gastroenterol.* 2014;109:1072-1079.

83. Jones RM, Vernon SW, Woolf SH. Is discussion of colorectal cancer screening options associated with heightened patient confusion? *Cancer Epidemiol Biomarkers Prev.* 2010;19:2821-2825.

84. Bodenheimer T, Ghorob A, Willard-Grace R, Grumbach K. The 10 building blocks of high-performing primary care. *Ann Fam Med.* 2014;12:166-171.

85. American Cancer Society, National Colorectal Cancer Roundtable. Tools and Resources: 80% by 2018. Atlanta, GA: American Cancer Society; 2016. nccrt.org/tools/80-percent-by-2018/. Accessed January 22, 2018.

86. Volk RJ, Leal VB, Epstein L, et al. From guideline to practice: the ACS's shared decision making tools for colorectal cancer screening. *CA Cancer J Clin.* 2018;68:000 000.

87. American Cancer Society. ColonMD: Clinicians' Information Source. Atlanta, GA: American Cancer Society; 2018. cancer.org/health-care-professionals/colon-md.html. Accessed February 5, 2018.

88. Corley DA, Jensen CD, Quinn VP, et al. Association between time to colonoscopy after a positive fecal test result and risk of colorectal cancer and cancer stage at diagnosis. *JAMA.* 2017;317:1631-1641.

89. Carlson CM, Kirby KA, Casadei MA, Partin MR, Kistler CE, Walter LC. Lack of follow-up after fecal occult blood testing in older adults: inappropriate screening or failure to follow up? *Arch Intern Med.* 2011;171:249-256.

90. Fisher DA, Jeffreys A, Coffman CJ, Fasanella K. Barriers to full colon evaluation for a positive fecal occult blood test. *Cancer Epidemiol Biomarkers Prev.* 2006;15:1232-1235.

91. Chubak J, Garcia MP, Burnett-Hartman AN, et al. Time to colonoscopy after positive fecal blood test in four US health care systems. *Cancer Epidemiol Biomarkers Prev.* 2016;25:344-350.

92. Selby K, Baumgartner C, Levin TR, et al. Interventions to improve follow-up of positive results on fecal blood tests: a systematic review. *Ann Intern Med.* 2017;167:565-575.

93. Lee SJ, Boscardin WJ, Stijacic-Cenzer I, Conell-Price J, O'Brien S, Walter LC. Time lag to benefit after screening for breast and colorectal cancer: meta-analysis of survival data from the United States, Sweden, United Kingdom, and Denmark [serial online]. *BMJ.* 2013;346:e8441.

94. Lansdorp-Vogelaar I, Gulati R, Mariotto AB, et al. Personalizing age of cancer screening cessation based on comorbid conditions: model estimates of harms and benefits. *Ann Intern Med.* 2014;161:104-112.

95. van Hees F, Saini SD, Lansdorp-Vogelaar I, et al. Personalizing colonoscopy screening for elderly individuals based on screening history, cancer risk, and comorbidity status could increase cost effectiveness. *Gastroenterology.* 2015;149:1425-1437.

96. Dinh T, Ladabaum U, Alperin P, Caldwell C, Smith R, Levin TR. Health benefits and cost-effectiveness of a hybrid screening strategy for colorectal cancer. *Clin Gastroenterol Hepatol.* 2013;11:1158-1166.

97. Garcia-Albeniz X, Hsu J, Bretthauer M, Hernan MA. Effectiveness of screening colonoscopy to prevent colorectal cancer among Medicare beneficiaries aged 70 to 79 years: a prospective observational study. *Ann Intern Med.* 2017;166:18-26.

98. Tran AH, Man Ngor EW, Wu BU. Surveillance colonoscopy in elderly patients: a retrospective cohort study. *JAMA Intern Med.* 2014;174:1675-1682.

99. Schoenborn NL, Lee K, Pollack CE, et al. Older adults' views and communication preferences about cancer screening cessation. *JAMA Intern Med.* 2017;177:1121-1128.

100. Cruz M, Covinsky K, Widera EW, Stijacic-Cenzer I, Lee SJ. Predicting 10-year mortality for older adults. *JAMA.* 2013;309:874-876.

101. Lee S, Smith A, Widera E, Yourman L, Schonberg M, Ahalt C. ePrognosis. San Francisco, CA: Division of Geriatrics, University of California San Francisco; 2018. eprognosis.ucsf.edu/about.php. Accessed February 5, 2018.

102. Young GP, Symonds EL, Allison JE, et al. Advances in fecal occult blood tests: the FIT revolution. *Dig Dis Sci.* 2015;60:609-622.

103. Imperiale TF, Ransohoff DF, Itzkowitz SH. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;371:187-188.

104. Berger BM, Ahlquist DA. Stool DNA screening for colorectal neoplasia: biological and technical basis for high detection rates. *Pathology.* 2012;44:80-88.

105. Collins JF, Lieberman DA, Durbin TE, Weiss DG; Veterans Affairs Cooperative Study Group. Accuracy of screening for fecal occult blood on a single stool sample obtained by digital rectal examination: a comparison with recommended sampling practice. *Ann Intern Med.* 2005;142:81-85.

106. Nakama H, Zhang B, Abdul Fattah AS, Kamijo N. Does stool collection method affect outcomes in immunochemical fecal occult blood testing? *Dis Colon Rectum.* 2001;44:871-875.

107. Levi Z, Birkenfeld S, Vilkin A, et al. A higher detection rate for colorectal cancer and advanced adenomatous polyp for screening with immunochemical fecal occult blood test than guaiac fecal occult blood test, despite lower compliance rate. A prospective, controlled, feasibility study. *Int J Cancer.* 2011;128:2415-2424.

108. Allison JE, Tekawa IS, Ransom LJ, Adrain AL. A comparison of fecal occult-blood tests for colorectal-cancer screening. *N Engl J Med.* 1996;334:155-159.

109. Brenner H, Tao S. Superior diagnostic performance of faecal immunochemical tests for haemoglobin in a head-to-head comparison with guaiac based faecal occult blood test among 2235 participants of screening colonoscopy. *Eur J Cancer.* 2013;49:3049-3054.

110. Ou CH, Kuo FC, Hsu WH, et al. Comparison of the performance of guaiac-based and two immunochemical fecal occult blood tests for identifying advanced colorectal neoplasia in Taiwan. *J Dig Dis.* 2013;14:474-483.

111. Rabeneck L, Rumble RB, Thompson F, et al. Fecal immunochemical tests compared with guaiac fecal occult blood tests for population-based colorectal cancer screening. *Can J Gastroenterol.* 2012;26:131-147.

112. Robertson DJ, Lee JK, Boland CR, et al. Recommendations on fecal immunochemical testing to screen for colorectal neoplasia: a consensus statement by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology.* 2017;152:1217-1237.e3.

113. Daly JM, Xu Y, Levy BT. Which fecal immunochemical test should I choose? *J Prim Care Community Health.* 2017;8:264-277.

114. Raginel T, Puvinel J, Ferrand O, et al. A population-based comparison of immunochemical fecal occult blood tests for colorectal cancer screening. *Gastroenterology.* 2013;144:918-925.

115. Chiang TH, Chuang SL, Chen SL, et al. Difference in performance of fecal immunochemical tests with the same hemoglobin cutoff concentration in a nationwide colorectal cancer screening program. *Gastroenterology.* 2014;147:1317-1326.

116. Hundt S, Haug U, Brenner H. Comparative evaluation of immunochemical fecal occult blood tests for colorectal adenoma detection. *Ann Intern Med.* 2009;150:162-169.

117. Levy BT, Bay C, Xu Y, et al. Test characteristics of faecal immunochemical tests (FIT) compared with optical colonoscopy. *J Med Screen.* 2014;21:133-143.

118. Arana-Arri E, Idigoras I, Uranga B, et al. Population-based colorectal cancer screening programmes using a faecal immunochemical test: should faecal haemoglobin cut-offs differ by age and sex [serial online]? *BMC Cancer.* 2017;17:577.

119. Chen LS, Yen AM, Chiu SY, Liao CS, Chen HH. Baseline faecal occult blood concentration as a predictor of incident colorectal neoplasia: longitudinal follow-up of a Taiwanese population-based colorectal cancer screening cohort. *Lancet Oncol.* 2011;12:551-558.

120. Levin TR, Jamieson L, Burley DA, Reyes J, Oehrli M, Caldwell C. Organized colorectal

cancer screening in integrated health care systems. *Epidemiol Rev.* 2011;33:101-110.

121. Church TR, Ederer F, Mandel JS. Fecal occult blood screening in the Minnesota study: sensitivity of the screening test. *J the Natl Cancer Inst.* 1997;89:1440-1448.

122. Cotter TG, Burger KN, Devens ME, et al. Long-term follow-up of patients having false-positive multitarget stool DNA tests after negative screening colonoscopy: the LONG-HAUL cohort study. *Cancer Epidemiol Biomarkers Prev.* 2017;26:614-621.

123. Geenen DJ, Imperiale TF, Caskey SL, Anderson KA, Berger B. A 3-year observational study of persons with a negative colonoscopy and positive multi-target stool DNA test. Digestive Disease Week 2017 [abstract]. *Gastroenterology.* 2017; 152(suppl 1):S838.

124. Cooper GS, Markowitz SD, Chen Z, et al. Evaluation of patients with an apparent false positive stool DNA test: the role of repeat stool DNA testing [published online ahead of print March 7, 2018]. *Dig Dis Sci.* doi: 10.1007/s10620-018-5001-z.

125. Schroy PC 3rd, Lal S, Glick JT, Robinson PA, Zamor P, Heeren TC. Patient preferences for colorectal cancer screening: how does stool DNA testing fare? *Am J Manag Care.* 2007;13:393-400.

126. Johnson DA, Barkun AN, Cohen LB, et al. Optimizing adequacy of bowel cleansing for colonoscopy: recommendations from the US Multi-Society Task Force on Colorectal Cancer. *Gastrointest Endosc.* 2014; 80:543-562.

127. Fletcher RH, Nadel MR, Allen JI, et al. The quality of colonoscopy services—responsibilities of referring clinicians: a consensus statement of the Quality Assurance Task Group, National Colorectal Cancer Roundtable. *J Gen Intern Med.* 2010;25:1230-1234.

128. Rex DK, Schoenfeld PS, Cohen J, et al. Quality indicators for colonoscopy. *Gastrointest Endosc.* 2015;81:31-53.

129. Robertson DJ, Kaminski MF, Bretthauer M. Effectiveness, training and quality assurance of colonoscopy screening for colorectal cancer. *Gut.* 2015;64:982-990.

130. Levin TR, Farraye FA, Schoen RE, et al. Quality in the technical performance of screening flexible sigmoidoscopy: recommendations of an international multisociety task group. *Gut.* 2005;54:807-813.

131. Dachman AH, Barish MA. Structured reporting and quality control in CT colonography. *Abdom Radiol (NY).* 2018;43: 566-573.

132. Nishihara R, Wu K, Lochhead P, et al. Long-term colorectal-cancer incidence and mortality after lower endoscopy. *N Engl J Med.* 2013;369:1095-1105.

133. de Wijkerslooth TR, Stoop EM, Bossuyt PM, et al. Differences in proximal serrated polyp detection among endoscopists are associated with variability in withdrawal time. *Gastrointest Endosc.* 2013;77:617-623.

134. Kahi CJ, Hewett DG, Norton DL, Eckert GJ, Rex DK. Prevalence and variable detection of proximal colon serrated polyps during screening colonoscopy. *Clin Gastroenterol Hepatol.* 2011;9:42-46.

135. Warren JL, Klabunde CN, Mariotto AB, et al. Adverse events after outpatient colonoscopy in the Medicare population. *Ann Intern Med.* 2009;150:849-857, w152.

136. Johnson CD, Chen MH, Toledano AY, et al. Accuracy of CT colonography for detection of large adenomas and cancers. *N Engl J Med.* 2008;359:1207-1217.

137. Pickhardt PJ, Choi JR, Hwang I, et al. Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. *N Engl J Med.* 2003; 349:2191-2200.

138. Pickhardt PJ, Hassan C, Halligan S, Marmo R. Colorectal cancer: CT colonography and colonoscopy for detection—systematic review and meta-analysis. *Radiology.* 2011;259:393-405.

139. Millerd PJ, Paden RG, Lund JT, et al. Reducing the radiation dose for computed tomography colonography using model-based iterative reconstruction. *Abdom Imaging.* 2015;40:1183-1189.

140. Nagata K, Fujiwara M, Kanazawa H, et al. Evaluation of dose reduction and image quality in CT colonography: comparison of low-dose CT with iterative reconstruction and routine-dose CT with filtered back projection. *Eur Radiol.* 2015;25:221-229.

141. National Research Council, Committee to Assess Health Risks from Exposure to Low Level of Ionizing Radiation. Health Risks From Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2. Washington, DC: The National Academies Press; 2006.

142. Berrington de Gonzalez A, Kim KP, Knudsen AB, et al. Radiation-related cancer risks from CT colonography screening: a risk-benefit analysis. *AJR Am J Roentgenol.* 2011;196:816-823.

143. Pickhardt PJ. CT colonography for population screening: ready for prime time? *Dig Dis Sci.* 2015;60:647-659.

144. Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. *N Engl J Med.* 1992;326:653-657.

145. Atkin WS, Edwards R, Kralj-Hans I, et al. Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. *Lancet.* 2010;375:1624-1633.

146. Holme O, Loberg M, Kalager M, et al. Effect of flexible sigmoidoscopy screening on colorectal cancer incidence and mortality: a randomized clinical trial. *JAMA.* 2014;312:606-615.

147. Schoen RE, Pinsky PF, Weissfeld JL, et al. Colorectal-cancer incidence and mortality with screening flexible sigmoidoscopy. *N Engl J Med.* 2012;366:2345-2357.

148. Segnan N, Armaroli P, Bonelli L, et al. Once-only sigmoidoscopy in colorectal cancer screening: follow-up findings of the Italian Randomized Controlled Trial—SCORE. *J Natl Cancer Inst.* 2011;103:1310-1322.

149. Atkin W, Wooldrage K, Parkin DM, et al. Long term effects of once-only flexible sigmoidoscopy screening after 17 years of follow-up: the UK flexible sigmoidoscopy screening randomised controlled trial. *Lancet.* 2017;389:1299-1311.

150. Holme O, Schoen RE, Senore C, et al. Effectiveness of flexible sigmoidoscopy screening in men and women and different age groups: pooled analysis of randomised trials [serial online]. *BMJ.* 2017; 356:i6673.

151. National Center for Health Statistics. Health, United States, 2016: With Chartbook on Long-Term Trends in Health. Hyattsville, MD: National Center for Health Statistics; 2017.

152. US Food and Drug Administration (FDA). Epi ProColon. Silver Spring, MD: FDA; 2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p130001. Accessed February 6, 2018.

153. Church TR, Wandell M, Lofton-Day C, et al. Prospective evaluation of methylated SEPT9 in plasma for detection of asymptomatic colorectal cancer. *Gut.* 2014;63: 317-325.

154. Potter NT, Hurban P, White MN, et al. Validation of a real-time PCR-based qualitative assay for the detection of methylated SEPT9 DNA in human plasma. *Clin Chem.* 2014;60:1183-1191.

155. Johnson DA, Barclay RL, Mergener K, et al. Plasma Septin9 versus fecal immunochemical testing for colorectal cancer screening: a prospective multicenter study [serial online]. *PloS One.* 2014;9:e98238.

156. Spada C, Pasha SF, Gross SA, et al. Accuracy of first- and second-generation colon capsules in endoscopic detection of colorectal polyps: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol.* 2016;14:1533-1543.e8.

157. Health Quality Ontario. Colon capsule endoscopy for the detection of colorectal polyps: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2015;15:1-39.

158. US Food and Drug Administration (FDA). PillCam COLON 2 Capsule Endoscopy System. Silver Spring, MD: Center for Devices and Radiological Health, FDA; 2014. accessdata.fda.gov/cdrh_docs/pdf12/K123666.pdf. Accessed February 5, 2018.

159. Jabrill A. Medtronic Gains Expanded Indication for PillCam Colon 2 Capsule. FDANews Device Daily Bulletin. Falls Church, VA: FDANews; 2016.

160. Patel SS, Kilgore ML. Cost effectiveness of colorectal cancer screening strategies. *Cancer Control.* 2015;22:248-258.

161. Fitch K, Pyenson B, Blumen H, Weisman T, Small A. The value of colonoscopic colorectal cancer screening of adults aged 50 to 64. *Am J Manag Care.* 2015;21:e430-e438.

162. Fedewa SA, Goodman M, Flanders WD, et al. Elimination of cost-sharing and receipt of screening for colorectal and breast cancer. *Cancer.* 2015;121:3272-3280.

163. Green BB, Coronado GD, Devoe JE, Allison J. Navigating the murky waters of colorectal cancer screening and health reform. *Am J Public Health.* 2014;104:982-986.

164. Oregon State Legislature. House Bill 2560, Relating to Colorectal Cancer Screening. Salem, OR: Oregon State Legislature; 2015. olis.leg.state.or.us/liz/2015R1/Measures/Overview/HB2560. Accessed January 23, 2018.

165. Centers for Medicare and Medicaid Services. Affordable Care Act Implementation

FAQs—Set 12. Baltimore, MD: Centers for Medicare and Medicaid Services; 2015. cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html. Accessed January 23, 2018.

166. Centers for Medicare and Medicaid Services. FAQS About Affordable Care Act Implementation Part 29. Baltimore, MD: Centers for Medicare and Medicaid Services; 2015. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf. Accessed January 23, 2018.

167. Centers for Medicare and Medicaid Services. FAQs About Affordable Care Act Implementation (Part XXVI). Baltimore, MD: Centers for Medicare and Medicaid Services; 2015. cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. Accessed January 23, 2018.

168. Centers for Medicare and Medicaid Services. FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation. Baltimore, MD: Centers for Medicare and Medicaid Services; 2016. cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf. Accessed January 23, 2018.

169. Peterse EFP, Meester RGS, Gini A, et al. Value of waiving coinsurance for colorectal cancer screening in Medicare beneficiaries. *Health Aff (Millwood).* 2017;36:2151-2159.

170. Khalid-de Bakker C, Jonkers D, Smits K, Mesters I, Masclee A, Stockbrugger R. Participation in colorectal cancer screening trials after first-time invitation: a systematic review. *Endoscopy.* 2011;43:1059-1086.

171. White A, Thompson TD, White MC, et al. Cancer screening test use—United States, 2015. *MMWR Morbid Mortal Weekly Rep.* 2017;66:201-206.

172. Community Preventive Services Task Force, Centers for Disease Control and Prevention. The Community Guide. Atlanta, GA: Centers for Disease Control and Prevention; 2018. thecommunityguide.org/findings/cancer-screening-multicomponent-interventions-colorectal-cancer. Accessed February 2, 2018.

173. Peterson EB, Ostroff JS, DuHamel KN, et al. Impact of provider-patient communication on cancer screening adherence: a systematic review. *Prev Med.* 2016;93:96-105.

174. Sequist TD, Zaslavsky AM, Marshall R, Fletcher RH, Ayanian JZ. Patient and physician reminders to promote colorectal cancer screening: a randomized controlled trial. *Arch Intern Med.* 2009;169:364-371.

175. Sabatino SA, Lawrence B, Elder R, et al. Effectiveness of interventions to increase screening for breast, cervical, and colorectal cancers: nine updated systematic reviews for the guide to community preventive services. *Am J Prev Med.* 2012;43:97-118.

176. Castaneda SF, Bharti G, Espinoza-Giacinto RA, et al. Evaluating two evidence-based intervention strategies to promote CRC screening among Latino adults in a primary care setting [published online ahead of print 2017]. *J Racial Ethn Health Disparities.* doi: 10.1007/s40615-017-0395-4.

177. Potter MB, Walsh JM, Yu TM, Gildengorin G, Green LW, McPhee SJ. The effectiveness of the FLU-FOBT Program in primary care: a randomized trial. *Am J Prev Med.* 2011;41:9-16.

178. Potter MB, Ackerson LM, Gomez V, et al. Effectiveness and reach of the FLU-FIT program in an integrated health care system: a multisite randomized trial. *Am J Public Health.* 2013;103:1128-1133.

179. Reuland DS, Brenner AT, Hoffman R, et al. Effect of combined patient decision aid and patient navigation vs usual care for colorectal cancer screening in a vulnerable patient population: a randomized clinical trial. *JAMA Intern Med.* 2017;177:967-794.

180. Miller DP Jr, Denizard-Thompson N, Weaver KE, et al. Effect of a digital health intervention on receipt of colorectal cancer screening in vulnerable patients: a randomized controlled trial [published online ahead of print 2018]. *Ann Intern Med.* doi: 10.7326/M17-2315.

181. Singal AG, Gupta S, Tiro JA, et al. Outreach invitations for FIT and colonoscopy improve colorectal cancer screening rates: a randomized controlled trial in a safety-net health system. *Cancer.* 2016;122:456-463.

182. Kempe KL, Shetterly SM, France EK, Levin TR. Automated phone and mail population outreach to promote colorectal cancer screening. *Am J Manag Care.* 2012;18:370-378.

183. Gupta S, Halm EA, Rockey DC, et al. Comparative effectiveness of fecal immunochemical test outreach, colonoscopy outreach, and usual care for boosting colorectal cancer screening among the underserved: a randomized clinical trial. *JAMA Intern Med.* 2013;173:1725-1732.

184. Church TR, Yeazel MW, Jones RM, et al. A randomized trial of direct mailing of fecal occult blood tests to increase colorectal cancer screening. *J Natl Cancer Inst.* 2004;96:770-780.

185. Levy BT, Daly JM, Xu Y, Ely JW. Mailed fecal immunochemical tests plus educational materials to improve colon cancer screening rates in Iowa Research Network (IRENE) practices. *J Am Board Fam Med.* 2012;25:73-82.

186. Denberg TD, Coombes JM, Byers TE, et al. Effect of a mailed brochure on appointment-keeping for screening colonoscopy: a randomized trial. *Ann Intern Med.* 2006;145:895-900.

187. Baron RC, Mellilo S, Rimer BK, et al. Task Force on Community Preventive Services. Intervention to increase recommendation and delivery of screening for breast, cervical, and colorectal cancers by healthcare providers: a systematic review of provider reminders. *Am J Prev Med.* 2010;38:110-117.

188. Ghooui R, Ramdass S, Friderici J, Desilets DJ. Open access colonoscopy: critical appraisal of indications, quality metrics and outcomes. *Dig Liver Dis.* 2016;48:940-944.

189. Jandorf L, Braschi C, Ernstoff E, et al. Culturally targeted patient navigation for increasing African Americans' adherence to screening colonoscopy: a randomized clinical trial. *Cancer Epidemiol Biomarkers Prev.* 2013;22:1577-1587.

190. Percac-Lima S, Ashburner JM, Zai AH, et al. Patient navigation for comprehensive cancer screening in high-risk patients using a population-based health information technology system: a randomized clinical trial. *JAMA Intern Med.* 2016;176:930-937.

191. Percac-Lima S, Grant RW, Green AR, et al. A culturally tailored navigator program for colorectal cancer screening in a community health center: a randomized, controlled trial. *J Gen Intern Med.* 2009;24:211-217.

192. Lasser KE, Murillo J, Lisboa S, et al. Colorectal cancer screening among ethnically diverse, low-income patients: a randomized controlled trial. *Arch Intern Med.* 2011;171:906-912.

193. Lasser KE, Murillo J, Medlin E, et al. A multilevel intervention to promote colorectal cancer screening among community health center patients: results of a pilot study [serial online]. *BMC Fam Pract.* 2009;10:37.

194. Braun KL, Thomas WL Jr, Domingo JL, et al. Reducing cancer screening disparities in Medicare beneficiaries through cancer patient navigation. *J Am Geriatr Soc.* 2015;63:365-370.

195. Enard KR, Nevarez L, Hernandez M, et al. Patient navigation to increase colorectal cancer screening among Latino Medicare enrollees: a randomized controlled trial. *Cancer Causes Control.* 2015;26:1351-1359.

196. Myers RE, Sifri R, Daskalakis C, et al. Increasing colon cancer screening in primary care among African Americans [serial online]. *J Natl Cancer Inst.* 2014;106:dju344.

197. DeGroff A, Schroy PC 3rd, Morrissey KG, et al. Patient navigation for colonoscopy completion: results of an RCT. *Am J Prev Med.* 2017;3:363-372.

198. Arsenault PR, John LS, O'Brien LM. The use of the whole primary-care team, including community health workers, to achieve success in increasing colon cancer screening rate. *J Healthc Qual.* 2016;38:76-83.

199. DeGroff A, Coa K, Morrissey KG, Rohan E, Slotman B. Key considerations in designing a patient navigation program for colorectal cancer screening. *Health Promot Pract.* 2014;15:483-495.

200. Centers for Disease Control and Prevention (CDC). New Hampshire Colorectal Cancer Screening Program: Patient Navigation Model for Increasing Colonoscopy Quality and Completion: A Replication Manual. Atlanta, GA: National Center for Chronic Disease and Health Promotion, Division of Cancer Prevention and Control, CDC: 2016. cdc.gov/cancer/crccp/pdf/nhcrcsp_pn_manual.pdf. Accessed February 5, 2018.

201. Myers RE, Bittner-Fagan HY, Daskalakis C, et al. A randomized controlled trial of a tailored navigation and a standard intervention in colorectal cancer screening. *Cancer Epidemiol Biomarkers Prev.* 2012;22:109-117.

202. Senore C, Inadomi J, Segnan N, Bellisario C, Hassan C. Optimising colorectal cancer screening acceptance: a review. *Gut.* 2015;64:1158-1177.

203. Baker DW, Brown T, Buchanan DR, et al. Comparative effectiveness of a multifaceted intervention to improve adherence to annual colorectal cancer screening in community health centers: a randomized

clinical trial. *JAMA Intern Med.* 2014;174: 1235-1241.

204. Baker DW, Brown T, Goldman SN, et al. Two-year follow-up of the effectiveness of a multifaceted intervention to improve adherence to annual colorectal cancer screening in community health centers. *Cancer Causes Control.* 2015;26:1685-1690.

205. Faivre J, Dancourt V, Lejeune C, et al. Reduction in colorectal cancer mortality by fecal occult blood screening in a French controlled study. *Gastroenterology.* 2004; 126:1674-1680.

206. Kronborg O, Jorgensen OD, Fenger C, Rasmussen M. Randomized study of biennial screening with a faecal occult blood test: results after nine screening rounds. *Scand J Gastroenterol.* 2004;39:846-851.

207. Scholefield JH, Moss SM, Mangham CM, Whynes DK, Hardcastle JD. Nottingham trial of faecal occult blood testing for colorectal cancer: a 20-year follow-up. *Gut.* 2012;61:1036-1040.

208. Syngal S, Brand RE, Church JM, et al. ACG clinical guideline: genetic testing and management of hereditary gastrointestinal cancer syndromes. *Am J Gastroenterol.* 2015;110:223-362; quiz 363.

209. Giardiello FM, Allen JI, Axilbund JE, et al. Guidelines on genetic evaluation and management of Lynch syndrome: a consensus statement by the US Multi-society Task Force on Colorectal Cancer. *Am J Gastroenterol.* 2014;109:1159-1179.

210. Kahi CJ, Boland CR, Dominitz JA, et al. Colonoscopy surveillance after colorectal cancer resection: recommendations of the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology.* 2016;150:758-768.e11.

211. Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology.* 2012;143:844-857.

Exhibit J

Charity Care Policy

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TITLE OF POLICY: Community Care Program		# PSG-PFS 007
SECTION: Revenue Cycle Management		Page: 1 of 1
		EFFECTIVE: 1/1/2010
APPROVED BY: CFO	REVIEWED:	
	REVISED: 1/1/2018	

Coverage: Any patient who has received services from Puget Sound Gastroenterology, PS (hereafter referred to as the "Organization"), and meets specific income and/or other financial criteria is eligible for the Community Care Program.

Purpose: The purpose of this policy is to provide financial assistance to low- and no-income patients in the form of discounted care up to 100% of the balance owing.

Policy:

A discount of up to 100% of the balance owing may be awarded to any patient meeting financial criteria as described below. Financial Assistance will only be provided after all third party insurance payments, worker's compensation, public aid, or other payments have been received. Discounted care will only be applied to the balance due after such payments are applied. Applicants with income of below 200% of the federal poverty level ("FPL") income guidelines are eligible for financial assistance. Financial assistance shall be provided without consideration of an individual's race, color, creed, national origin, sex, religion, sexual orientation, age, disability, source of income, or any other class protected under Washington or federal law.

Procedures:

1. Patient must apply through PSG's Patient Financial Services department utilizing the PSG Community Care Application. The application requests that the patient provide:
    a. Proof of application to DSHS for Medicaid
    b. Medicaid determination letter
    c. Tax returns and other proof of income for every household member for the past year
        i. If the patient does not have tax returns, then banking statements for the past 12 months
        ii. Three most recent pay stubs (if employed)
2. The Patient Account Specialist will annualize the patient's income based on the information given.

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   a. The Patient Account Specialist will determine if a patient is eligible for the Community Care Program within 10 business days after receipt of a complete application.
   b. If a determination cannot be made within 10 business days, the Patient Account Specialist will provide written notification for the delay.
3. The Patient Account Specialist will notify the patient of the discount he/she will receive.
4. If an application is approved for the Community Care Program, eligibility is granted on a six month basis. If additional services are rendered after this six month approval period, the applicant must reapply to the Community Care Program.

References:
US Dept of Health and Human Services - Federal Poverty Guideline, 2018

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Patient Name:
Account Number:
Amount Considered:
Due Date:

COMMUNITY CARE PROGRAM

We understand that some patients are not able to pay all of their medical bills. For that reason, Puget Sound Gastroenterology, PS has established the Community Care Program to provide discounted care to those who need it. **Please be advised that if services were rendered from a hospital visit, our charges are billed separately from the hospital charges and will require a separate application in order to be considered for any charity write off.** The following are some general guidelines and supporting documentation requirements needed to be considered for our program:

1. It is Puget Sound Gastroenterology's policy that first it must be determined that a patient is *not* eligible for Medicaid (DSHS) before granting financial assistance. A required piece of supporting documentation for financial assistance consideration is an official letter from the Washington State Department of Social and Health Services denying Medicaid coverage for dates of service medical care was rendered. You may apply for Medicaid online, by phone or in person at your local Community Services Office (CSO).

2. Your eligibility for charity will be based on a review of your family's gross income for the past 12 months. We ask you to provide documentation about your income for each working individual in your household.

3. Discounted care will be approved only after all third party insurance payments, worker's compensation, public aid or other payments have been received. Discounted care will be applied to the balance due after such payments are received.

4. We will determine if you are eligible for Puget Sound Gastroenterology, PS Community Care Program within 10 business days after your application has been received with **ALL** supporting documentation. If for some reason we are not able to make a determination within 10 business days, we will notify you by letter as to the reason for delay.

Please note: If your application is approved for a 100% write off or a partial write off, eligibility is granted on a six month basis. If additional services are rendered after this six month approval period, you must reapply for the Community Care Program.

If your application is denied based on your income, Puget Sound Gastroenterology, PS offers payment plan options to assist our patients. Please contact our billing office at (425) 977-4620 to arrange a payment plan.

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COMMUNITY CARE PROGRAM

An official letter from DSHS denying Medicaid or an eligibility determination letter denying Washington Apple Health is required to be considered for the Community Care Program. In order to obtain the applicable denial letter, you must first formally apply for benefits. Below are three ways in which to apply for benefits:

To Apply For Medicaid Benefits Online:

If you are blind, disabled or over the age of 65 apply for Medicaid by visiting:
https://www.washingtonconnection.org

If you are a parent with dependents, a caretaker, pregnant or between the ages of 18 to 64, apply for Washington Apple Health (Medicaid) by visiting:
http://www.wahealthplanfinder.org

*Please note: It is important that when asked if you would like to apply for Washington Apple Health on the wahealthplanfinder website that you select "yes".

To Apply For Benefits By Phone:

Call the Department of Health and Social Services at (800) 562-3022

To Apply For Benefits In Person:

Go to a local Community Services Office. To locate the nearest Community Services Office (CSO), visit website: http://www.dshs.wa.gov/onlinecso/findservice.shtml. On the right-hand side of the page, enter your zip code and the address of the closest office will be listed below.

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Puget Sound Gastroenterology, PS
Community Care Program Application

Patient Name: _____ Date of Birth:_____

Patient Social Security Number: _____

Responsible Party: _____ Relationship to Patient: _____

Mailing Address: _____City, State: _____ Zip Code: _____

Home Phone Number: _____

Patient Insurance Information: _____

Patient Employer: _____

Work Phone Number:_____

Number of People in Household: _____

I understand this information will be used by my physician's office to determine my eligibility for its voluntary charity care program. I certify the information provided is true and accurate to the best of my knowledge. If it is determined that pertinent information has been falsified or withheld, I understand this office may re-evaluate my financial status and take whatever action deemed appropriate.

_____ _____
Patient's Signature Date
(If patient is a minor, responsible party signature)

This page must be completed and ALL of the following documentation is MANDATORY and must be provided OR your Application will be denied without any further reconsideration.

- Proof of All household income (Spouse) for the past three months or a notarized affidavit of unemployment
  - A copy of your federal income tax return for previous year
- A copy of your three recent Checking & Savings bank statements (complete summary)
  - DSHS (Medicaid) letter accepting or denying medical benefits (**Refer to page 2**)

Due Date: **Account Number:** **Amount Considered:**

Please return application to:

Puget Sound Gastroenterology
19000 33rd Ave W Suite 230
Lynnwood WA 98036

Exhibit K

PSG/Edmonds Endoscopy Center Standard of Care Policy

PUGET SOUND
Gastroenterology

Patient Rights	PSG-3200
SECTION III – STANDARDS OF CARE	Page: 1 of 3
	EFFECTIVE: 3/2012
APPROVED BY: PSG Board	REVIEWED: REVISED: 9/12, 1/14, 10/14, 4/15, 1/17

Policy: It is the policy of Puget Sound Gastroenterology Ambulatory Surgery Centers to inform all patients, patient's representative or surrogate of the patient rights and responsibilities prior to their Endoscopy visit.

Procedure: All patients, patient's representatives or surrogates will be given a written copy of their Rights & Responsibilities in "The Endoscopy Patient Brochure" at least 24 hours prior to their procedure unless emergent/urgent circumstances dictate otherwise. The website will have it available for download. The Rights and Responsibilities will be posted in a conspicuous location.

When the patient is admitted, they will be asked if they have received "The Endoscopy Patient Brochure". If not, the patient, the patient's representative or surrogate will be given a copy of this to read and take home if requested. The patient will be asked if they have any questions about the information in the brochure. This will be documented on the "Pre-Procedure Nursing Note".

Patient Rights Patients have:

1. The right to quality care and treatment without discrimination as to race, color, religion, sex or national origin.
2. The right to quality care and treatment given with respect, consideration, dignity and without harassment, abuse or discrimination.
3. The right to be treated in a clean and safe environment free of unnecessary restraints.
4. The right to protection from abuse and neglect.
5. The right to access protective services.
6. The right to privacy and security of information regarding patient's diagnosis, treatment options, communication, and the potential outcomes of the treatment as well as access to information contained in his/her medical record in compliance with HIPAA.
7. The right to confidentiality, personal privacy and security.
8. The right to access spiritual care.
9. The right to communication with others. If communication restrictions are necessary for patient care and safety, this will be explained to the patient and any person designated by the patient.
10. The right to safe use of equipment by trained personnel.
11. The right to refuse to participate in research, investigation or clinical trials without hindering access to care.
12. The right to complain about their care and treatment without fear of retribution or denial of care.
13. The right to understand the indications for any procedure.
14. The right to receive all the information you need to give informed consent for any procedure including the possible risks and benefits of the procedure.
15. The right to be informed of unanticipated outcomes.
16. The right to be aware of fees for services and the billing process.

This is posted in waiting room, in Endoscopy Patient Brochure. PSG Website and Patient Portal

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Patient Rights	PSG-3200
SECTION III – STANDARDS OF CARE	Page: 2 of 3
	EFFECTIVE: 3/2012
APPROVED BY: PSG Board	REVIEWED: REVISED: 9/12, 1/14, 9/14, 4/15, 1/17

17. The right to approve or refuse the release of your medical records except when required by law.
18. The right to refuse care and treatment, to be told what effect this may have on your health and to be involved in resolving problems with care decisions.
19. The right to participate in all decisions involving your healthcare except when such participation is contraindicated for medical reasons.
20. The right to receive complete information about your diagnosis, planned treatment and prognosis. When it is medically inadvisable to give such information to a patient, the information will be provided to a person designated by the patient or to a legally authorized person.
21. The right to refuse to allow care from a student or trainee.
22. The right to exercise any or all of these rights and be free from any act of discrimination, reprisal or punitive action.
23. The right to family input in care decisions, in compliance with existing legal directives of the patient or existing court-issued legal orders

Patient Responsibility and Conduct

1. The patient is responsible to provide the health care providers with information about any past illness, hospitalizations, medications and other health matters.
2. The patient and/or family are responsible for asking questions when they do not understand instructions or explanations given by the healthcare providers and/or staff.
3. The patient is responsible for keeping appointments as scheduled and to telephone the office in case of a cancellation.
4. The patient is responsible for providing his/her healthcare insurance information, and assuring the financial obligations of his/her care are fulfilled as promptly as possible.
5. The patient is responsible to follow health care provider's instructions and plans of treatment and the patient is responsible for the consequences if he/she refuses treatment or fails to follow the practitioner's instructions.
6. The patient is responsible for being respectful and considerate to other patients and organizational personnel.
7. The patient is responsible to discuss consequences of leaving against medical advice with their physician.
8. The patient is responsible to communicate any questions, concerns or needs.

These rights and responsibilities outline the basic concepts of service here at Puget Sound Gastroenterology's Surgery Centers. If you believe, at any time, our staff has not met one or more of the statements during your care here, please ask to speak to a Manager. We will make every attempt to understand your complaint/concern and resolve it immediately. You will receive a response within 14 days. If the resolution does not meet your satisfaction it will be elevated to the Grievance Officer who will investigate further and attempt to resolve it to your satisfaction. You will be provided a written notice of the decision within 14 days of the grievance, unless there are extenuating circumstances.

This is posted in waiting room, in Endoscopy Patient Brochure, PSG Website and Patient Portal

PSG
PUGET SOUND
Gastroenterology

Patient Rights	PSG-3200
SECTION III – STANDARDS OF CARE	Page: 3 of 3
	EFFECTIVE: 3/2012
APPROVED BY: PSG Board	REVIEWED:
	REVISED: 9/12, 1/14, 9/14, 4/15, 1/17

Grievance Officer 19000 33rd Ave W Ste. 230 Lynnwood, WA 98036 425 977-4645	Washington State Department of Health Complaint Hotline **Phone:** 1-800-633-6828 (toll free) or 360-236-4700 **Fax:** 360-236-2626 **Mail:** Washington State Department of Health Health Systems Quality Assurance Complaint Intake P.O. Box 47857 Olympia, WA 98504-7857 **Email:** HSQAComplaintIntake@doh.wa.gov	Web site for the office of the Medicare Beneficiary Ombudsman: Visit: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html Medicare Help & Support: 1-800-MEDICARE (1-800-633-4227)	To report abuse or neglect of a vulnerable adult or a child call local law enforcement at 911 within 48 hours.

Advance Directive Policy

Advance Directives allows a person to give directions about medical care or to designate another person(s) to make medical decisions if he or she should lose decision-making capacity. Advance directives may include living wills, durable powers of attorney or similar documents portraying the patient's preference.

The existence of an advance directive, or lack thereof, will not determine the patient's access to care, treatment or services.

As specialists providing outpatient services in an ambulatory setting, Puget Sound Gastroenterology, PS Endoscopy Center Providers do not directly address advance directives with patients scheduled for procedures at our centers, it is our policy to honor advance directives presented to us by our patients. In addition, if a patient requests advance directive forms or information regarding the health and safety laws for Washington State, they will be provided.

Should an untoward event happen to a patient while he or she is in our facility, it is our policy to stabilize the patient and transport to the appropriate hospital with a copy of the advance directive. Patients not agreeing to this Statement of Limitation will be redirected to another healthcare provider prior to the procedure.

At all Puget Sound Gastroenterology, PS Endoscopy Centers, staff will perform the usual life sustaining procedures and call 911 to transport the patient to the appropriate hospital Emergency Department with a copy of the advance directive if available on the patient's chart.

Disclosure of Physician Interest

As a patient, you are hereby advised that some of the physicians performing procedures in our centers have an ownership in these Centers.

Exhibit L

PSG/Edmonds Endoscopy Center Pro Forma (2019/2020)

Edmonds Endoscopy Center Pro Forma

	2017	2018	2019	2020	
Total revenue	5,685,998.74	5,742,858.73	5,800,287.31	5,858,290.19	
TOTAL Cases	4,703.00	4,750	4,798	4,846	Case volume at 1.0% growth
Average rate per case	1,209.02	1,209.02	1,208.90	1,208.89	
Less: Patient Refunds	(54,349.36)	(40,232.50)	(40,639.06)	(41,045.62)	
Less: Charity Care at 1.16% of net revenue	(65,957.59)	(66,617.16)	(67,283.33)	(67,956.17)	
Net Revenue	5,565,691.79	5,636,009.07	5,692,364.92	5,749,288.40	
General and Administrative Expenses					
Computer Processing Expenses	5,036.81	5,036.81	5,036.81	5,036.81	
Copying and Printing	597.06	597.06	597.06	597.06	
Due and Subscriptions	734.80	734.80	734.80	734.80	
Education	1,883.31	1,883.31	1,883.31	1,883.31	
Finance Charges	15.03	15.03	15.03	15.03	
Travel, Meals and Entertainment	6.88	6.88	6.88	6.88	
Office Supplies	8,936.24	8,936.24	8,936.24	8,936.24	
Total General and Administrative Expenses	17,210.13	**8,273.89**	**8,273.89**	**8,273.89**	
Depreciation and Amortization Expense					
Depreciation	80,328.37	500,000.00	75,000.00	75,000.00	100% bonus depreciation on TI at edmonds in 2018
Total Depreciation and Amortization Expense	80,328.37	**500,000.00**	**75,000.00**	**75,000.00**	
Payroll and Related Expenses					
Benefits	159,611.99	169,188.71	179,340.03	190,100.43	Benefits annual increase at 6%
Payroll Taxes	69,379.03	71,807.30	74,320.55	76,921.77	
Salary and Wages	870,125.69	900,580.09	932,100.39	964,723.91	Salaries annual increase at 3.5%
Total Payroll and Related Expense	1,099,116.71	**1,141,576.09**	**1,185,760.98**	**1,231,746.11**	
Utilities and Facilities					
Facilities	18,732.28	18,732.28	18,732.28	18,732.28	
Rent	72,208.72	74,374.98	76,606.23	78,904.42	3% escalator
Common Area Maintenance Charges	40,820.64	40,820.64	40,820.64	40,820.64	
Repairs and Maintenance	44,797.39	44,797.39	44,797.39	44,797.39	
Total Utilities and Facilities	176,559.03	**178,725.29**	**180,956.54**	**183,254.73**	
Operating and Maintenance Expenses					
Professional Services	21,629.15	22,000.00	22,000.00	22,000.00	
Shipping	402.37	400.00	400.00	400.00	
Bank Service Charge	3.00	3.00	3.00	3.00	
Drugs & Medicines	10,984.21	11,122.99	11,234.21	11,346.55	1.0% case growth rate
Medical Supplies	431,178.02	436,625.55	440,991.48	445,401.38	1.0% case growth rate
Lab Supplies	3,695.00	3,741.68	3,779.10	3,816.89	1.0% case growth rate
Linen Supplies	62,502.43	63,292.09	63,924.96	64,564.21	1.0% case growth rate
Uniform Allowance	356.26	350.00	350.00	350.00	1.0% case growth rate
Other Operating Expense	11,459.16	11,500.00	11,500.00	11,500.00	1.0% case growth rate
Total Operating and Maintenance Expenses	542,209.60	**549,035.31**	**554,182.74**	**559,382.02**	
Taxes and Insurance					
Taxes	53,956.30	54,637.99	55,184.33	55,736.17	B&O Taxes
Total Taxes and Insurance	53,956.30	**54,637.99**	**55,184.33**	**55,736.17**	
Total Operating Expenses	1,969,380.14	**2,432,248.57**	**2,059,358.47**	**2,113,392.92**	
Net income	3,596,311.65	3,203,760.50	3,633,006.45	3,635,895.48	
Add back Interest	-	-	-	-	
Add back Depreciation	80,328.37	500,000.00	75,000.00	75,000.00	
EBITDA	3,676,640.02	3,703,760.50	3,708,006.45	3,710,895.48	
EBITDA Growth		0.74%	0.11%	0.08%	

Exhibit M
PSG (Compilation) Financial Statements (2015/2016/2017)

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Financial Statements

For the Years Ended December 31, 2015 and 2014

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Independent Accountant's Compilation Report

To the Board of Directors
Puget Sound Gastroenterology Associates, P.S.
Seattle, Washington

Management is responsible for the accompanying financial statements of Puget Sound Gastroenterology Associates, P.S. (the Company) which comprise the balance sheet—income tax basis as of December 31, 2015 and 2014, and the related statements of operations and changes in retained deficit—income tax basis for the years then ended and in accordance with accounting principles generally accepted in the United States of America. We have performed a compilation engagement in accordance with Statements on Standards for Accounting and Review Services promulgated by the Accounting and Review Services Committee of the AICPA. We did not audit or review the financial statements nor were we required to perform any procedures to verify the accuracy or the completeness of the information provided by management. Accordingly, we do not express an opinion, a conclusion, nor provide any form of assurance on these financial statements.

The supplementary information contained on pages 5 to 7 is presented for purposes of additional analysis and is not a required part of the basic financial statements. The information is the representation of management. The information was subject to our compilation engagement; however, we have not audited or reviewed the information and, accordingly, do not express an opinion or provide any assurance on such information.

Management has elected to omit substantially all of the disclosures and statement of cash flows required by accounting principles generally accepted in the United States. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Company's financial position, results of operations, and cash flows. Accordingly, these financial statements are not designed for those who are not informed about such matters.

Clark Nuber PS

Certified Public Accountants
May 12, 2016

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Assets
Income Tax Basis
December 31, 2015 and 2014

	2015	2014
Assets		
Current Assets:		
Construction allowance receivable	$ -	$ 101,000
Employee advances		1,862
Self-insured health plan	32,922	
Total Current Assets	**32,922**	**102,862**
Property and Equipment, at Cost:		
Medical equipment	2,988,788	2,985,210
Office equipment	4,308,216	4,249,992
Leasehold improvements	2,161,259	2,144,298
Laboratory equipment	91,648	91,648
Automobiles	15,956	15,956
	9,565,867	9,487,104
Less accumulated depreciation	8,730,445	8,556,897
Net Property and Equipment, at Cost	**835,422**	**930,207**
Other Assets:		
Loan costs, net of accumulated amortization	1,669	1,735
Goodwill, net of accumulated amortization	4,019,299	
Total Other Assets	**4,020,968**	**1,735**
Total Assets	**$ 4,889,312**	**$ 1,034,804**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Liabilities and Stockholders' Deficit
Income Tax Basis
December 31, 2015 and 2014

	2015	2014
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Cash overdraft	$ 36,226	$ 276,942
Current portion of long-term debt	48,994	47,126
Current portion of shareholder loans	619,237	
Line of credit	600,000	525,000
Retirement plan payable	674,686	589,261
Employee benefit withholding payable	39,604	44,560
Other accrued liabilities	20,654	18,861
Total Current Liabilities	**2,039,401**	**1,501,750**
Long-term debt, net of current portion	100,118	181,879
Loans from Shareholders	3,085,739	
Total Liabilities	**5,225,258**	**1,683,629**
Stockholders' Deficit:		
Common stock, no par value 60,000 shares authorized 2,100 shares issued and outstanding	18,071	18,071
Retained deficit	(354,017)	(666,896)
Total Stockholders' Deficit	**(335,946)**	**(648,825)**
Total Liabilities and Stockholders' Deficit	**$ 4,889,312**	**$ 1,034,804**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Statements of Operations and Changes in Retained Deficit
Income Tax Basis
For the Years Ended December 31, 2015 and 2014

	2015	Percentage	2014	Percentage
Revenue	$ 34,707,594	100.00%	$ 34,808,799	100.00%
Operating expenses	12,317,483	35.49%	12,628,451	36.28%
Gross Profit	**22,390,111**	**64.51%**	**22,180,348**	**63.72%**
General and administrative expenses	9,897,433	28.52%	8,702,167	25.00%
Income Before Physician Expenses	**12,492,678**	**35.99%**	**13,478,181**	**38.72%**
Physician expenses	11,889,772	34.25%	12,720,506	36.54%
Operating Income	**602,906**	**1.74%**	**757,675**	**2.18%**
Other Income (Expense):				
Interest income	103	0.00%		0.00%
Interest expense	(16,360)	-0.05%	(19,142)	-0.05%
Interest expense - shareholder loans	(118,820)	-0.34%		0.00%
Charitable contributions	(4,950)	-0.01%	(700)	0.00%
Total Other Expense	**(140,027)**	-0.40%	**(19,842)**	-0.05%
Income Before Income Taxes	**462,879**	**1.34%**	**737,833**	**2.13%**
Income tax expense	(150,000)	-0.43%		0.00%
Net Income	**312,879**	**0.91%**	**737,833**	**2.13%**
Retained deficit, beginning of year	(666,896)		(1,404,729)	
Retained Deficit, End of Year	**$ (354,017)**		**$ (666,896)**	

See independent accountant's compilation report.

SUPPLEMENTARY INFORMATION

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses
Income Tax Basis
For the Years Ended December 31, 2015 and 2014

	2015	Percentage	2014	Percentage
Revenue:				
Revenue	$ 34,554,327	99.56%	$ 34,479,605	99.05%
Fees collected - other		0.00%	268,563	0.77%
Other income	441,648	1.27%	211,080	0.61%
Patient refunds	(288,381)	-0.83%	(150,449)	-0.43%
Total Revenue	**34,707,594**	**100.00%**	**34,808,799**	**100.00%**
Operating Expenses:				
Ancillary salaries	6,005,569	17.30%	5,905,390	16.97%
Administrative salaries	3,279,969	9.45%	3,915,401	11.25%
Health and dental insurance	1,271,621	3.66%	926,754	2.66%
Payroll taxes	772,150	2.22%	800,799	2.30%
Pension contribution	283,432	0.82%	336,281	0.97%
Pension 401(k) match	222,048	0.64%	240,280	0.69%
Insurance-workers' compensation	187,929	0.54%	183,868	0.53%
Dues and memberships	83,067	0.24%	74,560	0.21%
Parking	67,464	0.19%	94,945	0.27%
Licenses	55,820	0.16%	50,571	0.15%
Professional development	36,997	0.11%	35,514	0.10%
Pension plan administration	31,521	0.09%	35,194	0.10%
Meetings - ancillary	9,566	0.03%	17,951	0.05%
Meals and entertainment	5,183	0.02%	6,820	0.02%
Pagers - ancillary	5,147	0.02%	4,123	0.01%
Total Operating Expenses	**12,317,483**	**35.49%**	**12,628,451**	**36.28%**
Gross Profit	**22,390,111**	**64.51%**	**22,180,348**	**63.72%**
General and Administrative Expenses:				
Drugs and medicine	1,581,043	4.56%	1,295,632	3.73%
Directors' and officers' insurance	1,497,897	4.32%	36,357	0.10%
Medical supplies	1,305,822	3.76%	1,343,441	3.87%
Rent	1,287,548	3.71%	2,086,104	6.00%
Business taxes	591,021	1.70%	582,515	1.68%
Depreciation and amortization	460,707	1.33%	310,626	0.89%
Computer services	363,072	1.05%	199,191	0.57%
Malpractice insurance	262,517	0.76%	321,631	0.93%
Equipment maintenance	240,200	0.69%	230,478	0.66%
Linen supplies	233,808	0.67%	232,533	0.67%
Telephone	229,373	0.66%	236,397	0.68%
Consulting services	192,496	0.55%	133,622	0.38%

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Income Tax Basis
For the Years Ended December 31, 2015 and 2014

	2015	Percentage	2014	Percentage
Equipment rentals	184,040	0.53%	261,502	0.75%
Legal services	166,164	0.48%	164,499	0.47%
Accounting services	135,389	0.39%	70,053	0.20%
Office supplies	125,248	0.36%	129,164	0.37%
Network services	110,858	0.32%	112,592	0.32%
Printing and copying	83,635	0.24%	99,499	0.29%
Interpreter services	82,305	0.24%	66,099	0.19%
Postage	78,343	0.23%	85,044	0.24%
Credit card fees	75,065	0.22%	78,452	0.23%
Electronic data processing	74,776	0.22%	72,281	0.21%
Lab supplies	64,739	0.19%	61,359	0.18%
Repairs	58,947	0.17%	66,645	0.19%
Occupancy insurance	48,724	0.14%	31,438	0.09%
Transcription	46,218	0.13%	12,049	0.03%
Bank service charge	40,387	0.12%	39,500	0.11%
Employee relations	33,272	0.10%	42,809	0.12%
Biohazard waste	32,531	0.09%	32,023	0.09%
Utilities	25,548	0.07%	13,010	0.04%
Computer software	21,978	0.06%	24,336	0.07%
Travel	21,879	0.06%	37,423	0.11%
Computer supplies	19,966	0.06%	24,268	0.07%
Cleaning services	19,151	0.06%	46,083	0.13%
Books and subscriptions	17,849	0.05%	12,099	0.03%
Answering service	17,826	0.05%	17,079	0.05%
Non-physician recruitment	15,067	0.04%	15,134	0.04%
Transportation - moving expense	10,278	0.03%	16,049	0.05%
Advertising	8,510	0.02%	16,714	0.05%
Patient education	7,487	0.02%	4,281	0.01%
Waste disposal	6,760	0.02%	5,162	0.01%
Courier services	6,587	0.02%	15,134	0.04%
Late fees	4,626	0.01%	1,600	0.00%
Uniforms	2,891	0.01%	5,459	0.02%
Purchased services	2,722	0.01%	3,111	0.01%
Public relations and patient education	1,113	0.00%	1,014	0.00%
Security services	1,050	0.00%	2,469	0.01%
Physician recruitment		0.00%	5,994	0.02%
Pathology services		0.00%	4,428	0.01%
Petty cash losses		0.00%	360	0.00%
Miscellaneous		0.00%	(2,575)	-0.01%
Total General and Administrative Expenses	**9,897,433**	**28.52%**	**8,702,167**	**25.00%**
Income Before Physician Expenses	**12,492,678**	**35.99%**	**13,478,181**	**38.72%**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Income Tax Basis
For the Years Ended December 31, 2015 and 2014

	2015	Percentage	2014	Percentage
Physician Expenses:				
Physician salaries	10,400,977	29.97%	11,301,744	32.47%
Pension contribution	509,218	1.47%	473,907	1.36%
Payroll taxes	408,258	1.18%	402,610	1.16%
Pension 401(k) match	219,899	0.63%	205,047	0.59%
Health insurance	213,194	0.61%	183,868	0.53%
Insurance - workers' compensation	130,094	0.37%	143,997	0.41%
Dental insurance	8,132	0.02%	9,333	0.02%
Total Physician Expenses	**11,889,772**	**34.25%**	**12,720,506**	**36.54%**
Operating Income	**602,906**	**1.74%**	**757,675**	**2.18%**
Other Income (Expense):				
Interest income	103	0.00%		0.00%
Interest expense	(16,360)	-0.05%	(19,142)	-0.05%
Interest expense - shareholder loans	(118,820)	-0.34%		0.00%
Charitable contributions	(4,950)	-0.01%	(700)	0.00%
Total Other Expense	**(140,027)**	**-0.40%**	**(19,842)**	**-0.05%**
Income Before Income Taxes	**462,879**	**1.34%**	**737,833**	**2.13%**
Income tax expense	(150,000)	-0.43%		0.00%
Net Income	**$ 312,879**	**0.91%**	**$ 737,833**	**2.13%**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Financial Statements

For the Years Ended December 31, 2016 and 2015

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Clark Nuber PS

Independent Accountant's Compilation Report

To the Board of Directors
Puget Sound Gastroenterology Associates, P.S.
Seattle, Washington

Management is responsible for the accompanying financial statements of Puget Sound Gastroenterology Associates, P.S. (the Company) which comprise the balance sheet - income tax basis as of December 31, 2016 and 2015, and the related statements of operations and changes in retained deficit - income tax basis for the years then ended and in accordance with the tax basis of accounting, and for determining that the tax basis of accounting is an acceptable financial reporting framework in the United States of America. We have performed a compilation engagement in accordance with Statements on Standards for Accounting and Review Services promulgated by the Accounting and Review Services Committee of the AICPA. We did not audit or review the financial statements nor were we required to perform any procedures to verify the accuracy or the completeness of the information provided by management. Accordingly, we do not express an opinion, a conclusion, nor provide any form of assurance on these financial statements.

The supplementary information contained on pages 5 to 7 is presented for purposes of additional analysis and is not a required part of the basic financial statements. The information is the representation of management. The information was subject to our compilation engagement; however, we have not audited or reviewed the information and, accordingly, do not express an opinion or provide any assurance on such information.

The financial statements are prepared in accordance with the tax basis of accounting, which is a basis of accounting other than accounting principles general accepted in the United State of America.

Management has elected to omit substantially all of the disclosures and statement of cash flows ordinarily included in financial statements prepared in accordance with the tax basis of accounting. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Company's financial position, results of operations, and cash flows. Accordingly, these financial statements are not designed for those who are not informed about such matters.

Clark Nuber PS
Certified Public Accountants
September 11, 2017

CN
T: 425-454-4919
T: 800-504-8747
F: 425-454-4620
10900 NE 4th St
Suite 1700
Bellevue WA
98004

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Assets
Income Tax Basis
December 31, 2016 and 2015

	2016	2015
Assets		
Current Assets:		
Prepaids	$ 84	$ -
Self-insured health plan		32,922
Total Current Assets	**84**	**32,922**
Property and Equipment, at Cost:		
Medical equipment	3,913,726	2,988,788
Office equipment	3,933,155	4,308,216
Leasehold improvements	2,285,999	2,161,259
Laboratory equipment	131,648	91,648
Automobiles	15,956	15,956
	10,280,484	9,565,867
Less accumulated depreciation	8,876,918	8,730,445
Net Property and Equipment, at Cost	**1,403,566**	**835,422**
Other Assets:		
Deposits	1,800	
Loan costs, net of accumulated amortization	1,603	1,669
Goodwill, net of accumulated amortization	1,779,024	4,019,299
Total Other Assets	**1,782,427**	**4,020,968**
Total Assets	**$ 3,186,077**	**$ 4,889,312**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Liabilities and Stockholders' Deficit
Income Tax Basis
December 31, 2016 and 2015

	2016	2015
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Cash overdraft	$ 222,815	$ 36,226
Current portion of long-term debt	292,898	48,994
Current portion of shareholder loans	325,332	619,237
Line-of-credit	1,500,000	600,000
Retirement plan payable	931,660	674,686
Employee benefit withholding payable	166,246	39,604
Other accrued liabilities	39	20,654
Total Current Liabilities	**3,438,990**	**2,039,401**
Long-term debt, net of current portion	991,479	100,118
Loans from shareholders	1,104,295	3,085,739
Total Liabilities	**5,534,764**	**5,225,258**
Stockholders' Deficit:		
Common stock, no par value 60,000 shares authorized 2,100 shares issued and outstanding	18,071	18,071
Retained deficit	(2,366,758)	(354,017)
Total Stockholders' Deficit	**(2,348,687)**	**(335,946)**
Total Liabilities and Stockholders' Deficit	**$ 3,186,077**	**$ 4,889,312**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Statements of Operations and Changes in Retained Deficit
Income Tax Basis
For the Years Ended December 31, 2016 and 2015

	2016	Percentage	2015	Percentage
Revenue	$ 35,622,554	100.00%	$ 34,707,594	100.00%
Operating expenses	12,863,791	36.11%	12,317,483	35.49%
Gross Profit	**22,758,763**	**63.89%**	**22,390,111**	**64.51%**
General and administrative expenses	12,018,000	33.74%	9,897,433	28.52%
Income Before Physician Expenses	**10,740,763**	**30.15%**	**12,492,678**	**35.99%**
Physician expenses	12,372,129	34.73%	11,889,772	34.25%
Operating (Loss) Income	**(1,631,366)**	**-4.58%**	**602,906**	**1.74%**
Other (Expense) Income:				
Interest income		0.00%	103	0.00%
Loss on sale of asset	(4,707)	-0.01%		0.00%
Charitable contributions	(5,500)	-0.02%	(4,950)	-0.01%
Interest expense	(31,992)	-0.09%	(16,360)	-0.05%
Interest expense - shareholder loans	(47,033)	-0.13%	(118,820)	-0.34%
Loss on shareholder notes redemptions	(144,143)	-0.40%		0.00%
Total Other Expense	**(233,375)**	-0.66%	**(140,027)**	-0.40%
(Loss) Income Before Income Taxes	**(1,864,741)**	**-5.23%**	**462,879**	**1.34%**
Income tax expense	(148,000)	-0.42%	(150,000)	-0.43%
Net (Loss) Income	**(2,012,741)**	**-5.65%**	**312,879**	**0.91%**
Retained deficit, beginning of year	(354,017)		(666,896)	
Retained Deficit, End of Year	**$ (2,366,758)**		**$ (354,017)**	

See independent accountant's compilation report.

SUPPLEMENTARY INFORMATION

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses
Income Tax Basis
For the Years Ended December 31, 2016 and 2015

	2016	Percentage	2015	Percentage
Revenue:				
Revenue	$ 34,963,922	98.15%	$ 34,554,327	99.56%
Other income	950,461	2.67%	441,648	1.27%
Patient refunds	(291,829)	-0.82%	(288,381)	-0.83%
Total Revenue	**35,622,554**	**100.00%**	**34,707,594**	**100.00%**
Operating Expenses:				
Ancillary salaries	6,166,276	17.31%	6,005,569	17.30%
Administrative salaries	3,313,186	9.30%	3,279,969	9.45%
Health and dental insurance	1,490,788	4.18%	1,271,621	3.66%
Payroll taxes	770,014	2.16%	772,150	2.22%
Pension contribution	328,809	0.92%	283,432	0.82%
Pension 401(k) match	238,711	0.67%	222,048	0.64%
Insurance-workers' compensation	156,250	0.44%	187,929	0.54%
Parking	117,181	0.33%	67,464	0.19%
Dues and memberships	81,736	0.23%	83,067	0.24%
Temporary salaries - ancillary	53,423	0.15%		0.00%
Pension plan administration	51,100	0.14%	31,521	0.09%
Licenses	36,827	0.10%	55,820	0.16%
Professional development	35,351	0.10%	36,997	0.11%
Meetings - ancillary	13,215	0.04%	9,566	0.03%
Meals and entertainment	6,861	0.02%	5,183	0.02%
Pagers - ancillary	4,063	0.01%	5,147	0.02%
Total Operating Expenses	**12,863,791**	**36.11%**	**12,317,483**	**35.49%**
Gross Profit	**22,758,763**	**63.89%**	**22,390,111**	**64.51%**
General and Administrative Expenses:				
Rent	2,109,038	5.92%	1,287,548	3.71%
Directors' and officers' insurance	1,875,229	5.26%	1,497,897	4.32%
Drugs and medicine	1,766,478	4.96%	1,581,043	4.56%
Medical supplies	1,385,050	3.89%	1,305,822	3.76%
Depreciation and amortization	1,208,716	3.39%	460,707	1.33%
Business taxes	618,676	1.74%	591,021	1.70%
Computer services	346,679	0.97%	363,072	1.05%
Malpractice insurance	248,977	0.70%	262,517	0.76%
Linen supplies	244,159	0.69%	233,808	0.67%
Consulting services	196,568	0.55%	192,496	0.55%
Equipment maintenance	187,084	0.53%	240,200	0.69%

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Income Tax Basis
For the Years Ended December 31, 2016 and 2015

	2016	Percentage	2015	Percentage
General and Administrative Expenses-Cont'd:				
Telephone	169,094	0.47%	229,373	0.66%
Equipment rentals	156,329	0.44%	184,040	0.53%
Network services	148,973	0.42%	110,858	0.32%
Transcription	123,814	0.35%	46,218	0.13%
Office supplies	108,910	0.31%	125,248	0.36%
Credit card fees	89,789	0.25%	75,065	0.22%
Postage	87,392	0.25%	78,343	0.23%
Lab supplies	86,379	0.24%	64,739	0.19%
Repairs	80,852	0.23%	58,947	0.17%
Interpreter services	77,580	0.22%	82,305	0.24%
Occupancy insurance	76,530	0.21%	19,151	0.06%
Electronic data processing	72,547	0.20%	74,776	0.22%
Non-physician recruitment	64,319	0.18%	15,067	0.04%
Printing and copying	62,646	0.18%	83,635	0.24%
Cleaning services	56,621	0.16%	48,724	0.14%
Biohazard waste	36,111	0.10%	32,531	0.09%
Employee relations	33,446	0.09%	33,272	0.10%
Bank service charge	30,521	0.09%	40,387	0.12%
Computer software	30,295	0.09%	21,978	0.06%
Professional fees	28,678	0.08%		0.00%
Accounting services	27,470	0.08%	135,389	0.39%
Books and subscriptions	25,795	0.07%	17,849	0.05%
Travel	19,485	0.05%	21,879	0.06%
Answering service	19,088	0.05%	17,826	0.05%
Transportation - moving expense	18,643	0.05%	10,278	0.03%
Physician recruitment	17,213	0.05%		0.00%
Advertising	15,550	0.04%	8,510	0.02%
Courier services	13,660	0.04%	6,587	0.02%
Computer supplies	12,586	0.04%	19,966	0.06%
Uniforms	11,705	0.03%	2,891	0.01%
Utilities	7,586	0.02%	25,548	0.07%
Waste disposal	5,242	0.01%	6,760	0.02%
Purchased services	4,664	0.01%	2,722	0.01%
Patient education	4,496	0.01%	7,487	0.02%
Sales taxes	4,389	0.01%		0.00%
Late fees	1,546	0.00%	4,626	0.01%
Security services	1,062	0.00%	1,050	0.00%
Public relations and patient education	285	0.00%	1,113	0.00%
Petty cash losses	55	0.00%		0.00%
Legal services		0.00%	166,164	0.48%
Total General and Administrative Expenses	**12,018,000**	**33.74%**	**9,897,433**	**28.52%**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Income Tax Basis
For the Years Ended December 31, 2016 and 2015

	2016	Percentage	2015	Percentage
Income Before Physician Expenses	**10,740,763**	**30.15%**	**12,492,678**	**35.99%**
Physician Expenses:				
Physician salaries	10,760,638	30.21%	10,400,977	29.97%
Pension contribution	580,726	1.63%	509,218	1.47%
Payroll taxes	410,272	1.15%	408,258	1.18%
Pension 401(k) match	263,749	0.74%	219,899	0.63%
Health insurance	225,959	0.63%	213,194	0.61%
Insurance - workers' compensation	121,407	0.34%	130,094	0.37%
Dental insurance	9,378	0.03%	8,132	0.02%
Total Physician Expenses	**12,372,129**	**34.73%**	**11,889,772**	**34.25%**
Operating (Loss) Income	**(1,631,366)**	**-4.58%**	**602,906**	**1.74%**
Other (Expense) Income:				
Interest income		0.00%	103	0.00%
Loss on sale of asset	(4,707)	-0.01%		0.00%
Charitable contributions	(5,500)	-0.02%	(4,950)	-0.01%
Interest expense	(31,992)	-0.09%	(16,360)	-0.05%
Interest expense - shareholder loans	(47,033)	-0.13%	(118,820)	-0.34%
loss on shareholder notes redemptions	(144,143)	-0.40%		0.00%
Total Other Expense	**(233,375)**	**-0.66%**	**(140,027)**	**-0.40%**
(Loss) Income Before Income Taxes	**(1,864,741)**	**-5.23%**	**462,879**	**1.34%**
Income tax expense	(148,000)	-0.42%	(150,000)	-0.43%
Net (Loss) Income	**$ (2,012,741)**	**-5.65%**	**$ 312,879**	**0.91%**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Financial Statements

For the Years Ended December 31, 2017 and 2016

Table of Contents

Clark Nuber PS

Independent Accountant's Compilation Report

To the Board of Directors
Puget Sound Gastroenterology Associates, P.S.
Seattle, Washington

Management is responsible for the accompanying financial statements of Puget Sound Gastroenterology Associates, P.S. (the Company) which comprise the balance sheets - tax basis as of December 31, 2017 and 2016, and the related statements of operations and changes in retained deficit - tax basis for the years then ended and in accordance with the tax basis of accounting, and for determining that the tax basis of accounting is an acceptable financial reporting framework in the United States of America. We have performed a compilation engagement in accordance with Statements on Standards for Accounting and Review Services promulgated by the Accounting and Review Services Committee of the AICPA. We did not audit or review the financial statements nor were we required to perform any procedures to verify the accuracy or the completeness of the information provided by management. Accordingly, we do not express an opinion, a conclusion, nor provide any form of assurance on these financial statements.

The supplementary information contained on pages 5 to 7 is presented for purposes of additional analysis and is not a required part of the basic financial statements. The information is the representation of management. The information was subject to our compilation engagement; however, we have not audited or reviewed the information and, accordingly, do not express an opinion or provide any assurance on such information.

The financial statements are prepared in accordance with the tax basis of accounting, which is a basis of accounting other than accounting principles general accepted in the United States of America.

Certain accounts in the 2016 financial statements have been reclassified for comparative purposes to conform to the presentation in the 2017 financial statements. The reclassifications have no effect on previously reported total assets, liabilities, stockholders' deficit, or net loss.

Management has elected to omit substantially all of the disclosures and statement of cash flows ordinarily included in financial statements prepared in accordance with the tax basis of accounting. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Company's financial position, results of operations, and cash flows. Accordingly, these financial statements are not designed for those who are not informed about such matters.

Clark Nuber PS
Certified Public Accountants
June 21, 2018

CN

T: 425-454-4919
T: 800-504-8747
F: 425-454-4620

10900 NE 4th St
Suite 1400
Bellevue WA
98004

clarknuber.com

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Assets
Tax Basis
December 31, 2017 and 2016

	2017	2016
Current Assets:		
Prepaids	$ 11,376	$ 84
Employee advances	22	
Note receivable from related party	11,736	
Total Current Assets	**23,134**	**84**
Property and Equipment, at Cost:		
Medical equipment	3,264,861	3,913,726
Office equipment	3,649,714	3,933,155
Leasehold improvements	2,317,003	2,285,999
Laboratory equipment	131,648	131,648
Automobiles	15,956	15,956
	9,379,182	10,280,484
Less accumulated depreciation	8,227,683	8,876,918
Net Property and Equipment	**1,151,499**	**1,403,566**
Other Assets:		
Deposits	1,800	1,800
Loan costs, net of accumulated amortization	1,537	1,603
Goodwill, net of accumulated amortization	1,642,176	1,779,024
Total Other Assets	**1,645,513**	**1,782,427**
Total Assets	**$ 2,820,146**	**$ 3,186,077**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Balance Sheets - Liabilities and Stockholders' Deficit
Tax Basis
December 31, 2017 and 2016

	2017	2016
Current Liabilities:		
Cash overdraft	$ 128,042	$ 222,815
Current portion of long-term debt	332,024	292,898
Current portion of shareholder loans	334,855	325,332
Line-of-credit	1,250,000	1,500,000
Retirement plan payable	1,013,516	931,660
Employee benefit withholding payable	769,760	166,246
Other accrued liabilities	195	39
Total Current Liabilities	**3,828,392**	**3,438,990**
Long-term debt, net of current portion	798,054	991,479
Loans from shareholders	769,440	1,104,295
Total Liabilities	**5,395,886**	**5,534,764**
Stockholders' Deficit:		
Common stock, no par value 60,000 shares authorized 2,100 shares issued and outstanding	18,071	18,071
Retained deficit	(2,593,811)	(2,366,758)
Total Stockholders' Deficit	**(2,575,740)**	**(2,348,687)**
Total Liabilities and Stockholders' Deficit	**$ 2,820,146**	**$ 3,186,077**

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Statements of Operations and Changes in Retained Deficit
Tax Basis
For the Years Ended December 31, 2017 and 2016

	2017	Percentage	2016	Percentage
Revenue	$ 37,526,519	100.00%	$ 35,622,554	100.00%
Operating expenses	13,528,120	36.06%	12,863,791	36.11%
Gross Profit	**23,998,399**	**63.94%**	**22,758,763**	**63.89%**
General and administrative expenses	12,175,471	32.43%	12,018,000	33.72%
Income Before Physician Expenses	**11,822,928**	**31.51%**	**10,740,763**	**30.17%**
Physician expenses	12,226,701	32.58%	12,372,129	34.73%
Operating Loss	**(403,773)**	**-1.07%**	**(1,631,366)**	**-4.56%**
Other Income (Expense):				
Interest income	632	0.00%		0.00%
Loss on shareholder note redemptions		0.00%	(144,143)	-0.40%
Loss on sale of asset	(1,512)	0.00%	(4,707)	-0.01%
Charitable contributions	(13,500)	-0.04%	(5,500)	-0.02%
Interest expense - shareholder loans	(37,761)	-0.10%	(47,033)	-0.13%
Interest expense	(57,365)	-0.15%	(31,992)	-0.09%
Total Other Expense	**(109,506)**	**-0.29%**	**(233,375)**	**-0.65%**
Loss Before Income Taxes	**(513,279)**	**-1.36%**	**(1,864,741)**	**-5.21%**
Income tax benefit (expense)	286,226	0.76%	(148,000)	-0.42%
Net Loss	**(227,053)**	**-0.60%**	**(2,012,741)**	**-5.63%**
Retained deficit, beginning of year	(2,366,758)		(354,017)	
Retained Deficit, End of Year	**$ (2,593,811)**		**$ (2,366,758)**	

See independent accountant's compilation report.

SUPPLEMENTARY INFORMATION

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses
Tax Basis
For the Years Ended December 31, 2017 and 2016

	2017	Percentage	2016	Percentage
Revenue:				
Revenue	$ 36,907,527	98.35%	$ 34,963,922	98.15%
Other income	1,718,168	4.58%	950,461	2.67%
Bad debt recovery	147,444	0.39%		0.00%
Conveyance	(15,684)	-0.04%		0.00%
Patient refunds	(308,646)	-0.82%	(291,829)	-0.82%
Take backs	(922,290)	-2.46%		0.00%
Total Revenue	**37,526,519**	**100.00%**	**35,622,554**	**100.00%**
Operating Expenses:				
Ancillary salaries	6,454,975	17.20%	6,166,276	17.31%
Administrative salaries	3,837,846	10.23%	3,313,186	9.30%
Health and dental insurance	1,260,246	3.36%	1,490,788	4.18%
Payroll taxes	776,449	2.07%	770,014	2.16%
Pension contribution	378,948	1.01%	328,809	0.92%
Pension 401(k) match	249,723	0.67%	238,711	0.67%
Insurance-workers' compensation	160,488	0.43%	156,250	0.44%
Parking	100,539	0.27%	117,181	0.33%
Pension plan administration	78,435	0.21%	51,100	0.14%
Dues and memberships	74,559	0.20%	81,736	0.23%
Professional development	56,436	0.15%	35,351	0.10%
Licenses	40,785	0.11%	36,827	0.10%
Temporary salaries - ancillary	31,505	0.08%	53,423	0.15%
Meetings - ancillary	15,385	0.04%	13,215	0.04%
Meals and entertainment	7,550	0.02%	6,861	0.03%
Pagers - ancillary	4,251	0.01%	4,063	0.02%
Total Operating Expenses	**13,528,120**	**36.06%**	**12,863,791**	**36.11%**
Gross Profit	**23,998,399**	**63.94%**	**22,758,763**	**63.89%**
General and Administrative Expenses:				
Drugs and medicine	2,477,356	6.60%	1,766,478	4.96%
Directors' and officers' salaries	1,872,116	4.99%	1,849,634	5.19%
Rent	1,643,698	4.38%	2,109,038	5.92%
Medical supplies	1,468,095	3.91%	1,385,050	3.89%
Depreciation and amortization	824,080	2.20%	1,208,716	3.39%
Business taxes	631,468	1.68%	618,676	1.74%
Computer services	318,560	0.85%	346,679	0.97%
Equipment maintenance	259,604	0.69%	187,084	0.53%
Malpractice insurance	256,524	0.68%	248,977	0.70%
Linen supplies	217,124	0.58%	244,159	0.69%

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Tax Basis
For the Years Ended December 31, 2017 and 2016

	2017	Percentage	2016	Percentage
Lab supplies	214,592	0.57%	86,379	0.24%
Network services	203,718	0.54%	148,973	0.42%
Consulting services	178,494	0.48%	196,568	0.55%
Office supplies	127,904	0.34%	108,910	0.31%
Repairs	126,951	0.34%	80,852	0.23%
Equipment rentals	117,733	0.31%	156,329	0.44%
Transcription	108,113	0.29%	123,814	0.35%
Telephone	100,162	0.27%	169,094	0.47%
Interpreter services	93,619	0.25%	77,580	0.22%
Credit card fees	92,311	0.25%	89,789	0.25%
Electronic data processing	90,986	0.24%	72,547	0.20%
Postage	83,888	0.22%	87,392	0.25%
Non-physician recruitment	74,377	0.20%	64,319	0.18%
Printing and copying	53,069	0.14%	62,646	0.18%
Employee relations	49,229	0.13%	33,446	0.09%
Professional fees	48,220	0.13%	28,678	0.08%
Cleaning services	47,959	0.13%	56,621	0.16%
Legal services	40,913	0.11%		0.00%
Occupancy insurance	38,736	0.10%	76,530	0.21%
Books and subscriptions	37,156	0.10%	25,795	0.07%
Biohazard waste	35,009	0.09%	36,111	0.10%
Bank service charge	33,677	0.09%	30,521	0.09%
Physician recruitment	31,908	0.09%	17,213	0.05%
Accounting services	28,535	0.08%	27,470	0.08%
Directors' and officers' insurance	25,800	0.07%	25,595	0.07%
Answering service	21,621	0.06%	19,088	0.05%
Courier services	19,271	0.05%	13,660	0.04%
Computer software	19,228	0.05%	30,295	0.09%
Travel	16,029	0.04%	19,485	0.05%
Computer supplies	8,894	0.02%	12,586	0.04%
Advertising	7,254	0.02%	15,550	0.04%
Sales taxes	6,008	0.02%	4,389	0.01%
Waste disposal	5,970	0.02%	5,242	0.01%
Uniforms	4,644	0.01%	11,705	0.03%
Patient education	4,371	0.01%	4,496	0.01%
Public relations and patient education	2,585	0.01%	285	0.00%
Purchased services	1,567	0.00%	4,664	0.01%
Miscellaneous	1,485	0.00%		0.00%
Patient surveys	1,267	0.00%		0.00%
Billing services	1,230	0.00%		0.00%
Security services	1,098	0.00%	1,062	0.00%
Late fees	930	0.00%	1,546	0.00%

See independent accountant's compilation report.

PUGET SOUND GASTROENTEROLOGY ASSOCIATES, P.S.

Schedule I Revenues and Expenses (Continued)
Tax Basis
For the Years Ended December 31, 2017 and 2016

	2017	Percentage	2016	Percentage
Pathology services	150	0.00%		0.00%
Histology reimbursement	150	0.00%		0.00%
Petty cash losses	35	0.00%	55	0.00%
Utilities		0.00%	7,586	0.02%
Transportation - moving expense		0.00%	18,643	0.05%
Total General and Administrative Expenses	**12,175,471**	**32.43%**	**12,018,000**	**33.72%**
Income Before Physician Expenses	**11,822,928**	**31.51%**	**10,740,763**	**30.17%**
Physician Expenses:				
Physician salaries	10,596,627	28.24%	10,760,638	30.21%
Pension contribution	628,479	1.67%	580,726	1.63%
Payroll taxes	428,483	1.14%	410,272	1.15%
Pension 401(k) match	240,959	0.64%	263,749	0.74%
Health insurance	209,355	0.56%	225,959	0.63%
Insurance - workers' compensation	112,867	0.30%	121,407	0.34%
Dental insurance	9,931	0.03%	9,378	0.03%
Total Physician Expenses	**12,226,701**	**32.58%**	**12,372,129**	**34.73%**
Operating Loss	**(403,773)**	**-1.07%**	**(1,631,366)**	**-4.56%**
Other Income (Expense):				
Interest income	632	0.00%		0.00%
Loss on shareholder note redemptions		0.00%	(144,143)	-0.40%
Loss on sale of asset	(1,512)	0.00%	(4,707)	-0.01%
Charitable contributions	(13,500)	-0.04%	(5,500)	-0.02%
Interest expense - shareholder loans	(37,761)	-0.10%	(47,033)	-0.13%
Interest expense	(57,365)	-0.15%	(31,992)	-0.09%
Total Other Expense	**(109,506)**	**-0.29%**	**(233,375)**	**-0.65%**
Loss Before Income Taxes	**(513,279)**	**-1.36%**	**(1,864,741)**	**-5.21%**
Income tax benefit (expense)	286,226	0.76%	(148,000)	-0.42%
Net Loss	**$ (227,053)**	**-0.60%**	**$ (2,012,741)**	**-5.63%**

See independent accountant's compilation report.

Exhibit N
PSG (Edmonds Endoscopy Center)
Historical FTE Counts

Exhibit N
PSG (Edmonds Endoscopy Center)
FTE (three year look back)

Position	Number of FTEs			
	Dec 2017	**Dec 2016**	**Dec 2015**	**Dec 2014**
Endo Medical Director	1	1	1	1
Physicians	6	6	6	6
RN Nurse Manager	1	1	1	1
RN	7	7	7	7
LPN	1	1	1	1
Lead Endoscopy Tech	1	1	1	1
Endoscopy Tech/CNA/CMA	3	3	3	3
PSR (Patient Service Representative)	1	1	1	1
Histology Tech	1	1	1	1
Total	**22**	**22**	**22**	**22**

Exhibit O
Patient Transfer Agreement
(between PSG/Edmonds Endoscopy Center & Swedish Edmonds)

TRANSFER AGREEMENT

This agreement is between:

Swedish Health Services d/b/a
Swedish Edmonds
21601 76th Avenue West
Edmonds, WA 98026

And

Edmonds Endoscopy Center

Swedish Health Services d/b/a Swedish Edmonds, herein referred to as "Swedish", and Edmonds Endoscopy Center, herein referred to as "Facility", enter into an agreement to facilitate continuity of care and timely transfer of patients who require medical facilities, treatment modalities, and/or expertise not available at Facility.

The terms of the agreement are as follows:

1. When a patient's need for transfer from Facility to another facility has been determined by the patient's physician, Swedish agrees to provide Facility with information about its resources sufficient to determine whether the care needed by the patient is available; to perform any required pre-admission screening; to admit the patient as promptly as possible, provided customary admission requirements are met in accordance with Swedish admission policies; and to promptly make available diagnostic and medical services. Patients shall be admitted without regard to race, color, creed, physical or mental handicap, or national origin unless otherwise prohibited by federal or state law or regulation which includes but is not limited to Swedish's inability to meet the patient's care needs.

2. Facility will have the responsibility for arranging the transfer of the patient and agrees to use qualified personnel and equipment as required, including the use of necessary and medically appropriate life support measures during the transfer.

3. The transfer will conform with all applicable State and Federal laws, regulations and obligations. Once any necessary emergency services and care have been provided, transfer may be considered if the patient is stabilized, or if unstable and the transferring physician has deemed the transfer is for a medical reason which requires transfer. Prior to transfer of the patient, the following conditions will be met by Facility:

A. Risks Minimized:
Facility has provided the medical treatment within its capacity which minimizes the risks to the patient's health. The need for transfer has been discussed and reviewed with the patient and his/her authorized representative and they have been informed of the benefits/risks associated with the transfer.

B. Receiving Physician/Facility
Facility has notified a physician at Swedish and obtained his/her consent for receipt of the transfer and confirms that Swedish has agreed to accept the patient and will assume medical care of the patient upon arrival to Swedish.

C. Appropriate Transportation Arrangements
The transferring and receiving physicians shall discuss and achieve consensus on the appropriate method for transport of the patient, including level of qualified personnel and equipment necessary to accompany the patient during transport. The personnel and equipment should be those which a reasonable and prudent physician in his/her locality would use to effect a transfer, including necessary and appropriate medical life support measures.

D. Notice to Patients
The patient, or authorized representative of the patient, must be notified prior to the transfer and of the reasons therefore indicated. The patient's acknowledgement of such notification should be reflected in an appropriate written form. Notification in advance of the transfer is not required where the patient is unaccompanied, Facility has made a reasonable effort to locate an authorized representative of the patient and notification of the patient is not possible due to the patient's mental or physical condition.

4. Facility agrees to provide appropriate documentation of clinical care in order to ensure continuity of patient care. This information should include the patient's medical record (i.e., summary of physician's findings, nursing notes and flow sheets, laboratory and radiology reports, copy of EKG and X-Rays, pertinent diagnostic documentation, etc.) This information will be provided at the time of transfer, or in the case of emergency, as quickly as possible.

5. Facility will be responsible for the transfer or other appropriate disposition of personal effects, particularly money and valuables, and information related to those items.

6. Charges for services performed by either Facility or Swedish shall be collected by the party rendering such services, directly from the patient, third party payor, or other sources normally billed by the party. Neither facility shall have any liability to the other for such charges.

7. This confirms that Facility and referring physician agree to accept the patient in return transfer upon reasonable notice to do so.

8. Nothing in this agreement shall be construed as limiting the rights of either institution to contract with any other facility on a limited or general basis.

9. This agreement shall be in effect for one year, beginning August 1, 2015 and shall automatically be renewed for successive one-year periods. However, it may be terminated by either party upon 30 days written notice.

10. Nothing in this agreement shall be construed in a manner inconsistent with federal or state laws and regulations.

Signed:

Facility:
Edmonds Endoscopy Center

Name: Sarah Skattum

Title: Operations Manager

Date: 7/17/2015

Swedish Health Services d/b/a
Swedish Edmonds

Name: Jennifer Graves

Title: Chief Executive

Date: Jennifer Graves 7/24/2015

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