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May 16, 2016

Via Federal Express

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RECEIVED

MAY 17 2016

**HEALTH FACILITIES &
SERVICES REVIEW BOARD**

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

**Re: Southern Illinois Gastrointestinal Endoscopy Center (Proj. No. 15-061)
Response to Request for Additional Information**

Dear Mr. Constantino:

On behalf of Zahoor Makhdoom, M.D.; Southern Illinois Gastrointestinal Endoscopy Center, LLC; and Southern Illinois GI Specialists, LLC (collectively, the "Applicants"), this letter is in response to the Illinois Health Facilities and Services Review Board (the "State Board") request for additional information regarding the certificate of need ("CON") application for the above referenced project dated April 28, 2016.

1. Medicare and Medicaid Certification

The State Board inquired about enrollment in the Medicare and Medicaid programs. The Applicants intend to promptly apply for Medicare and Medicaid certification after the endoscopy center is licensed by the Illinois Department of Public Health ("IDPH"). Medicare and Medicaid enrollment is a multi-step process that when done correctly may take 6 to 9 months to complete. To be eligible to enroll in Medicare (which is a prerequisite to Medicaid enrollment), a facility must be licensed by IDPH. Once the endoscopy center is so licensed, it must then submit its Medicare enrollment application (855B) to its Medicare Administrative Contractor ("MAC") for initial approval. By law, the MAC has 60 days to review the Medicare application. When its Medicare enrollment application is accepted by the MAC, the endoscopy center will receive a recommendation for approval. At this point, the endoscopy center will submit its application for accreditation by a private accreditation organization such as The Joint Commission or AAAHC. Once the application is received, the accreditor will review the endoscopy center's application for accreditation and conduct a physical survey of the center, which can take up to 90 days. Once the endoscopy center is found in compliance with the Medicare Conditions for Coverage,

Mr. Michael Constantino
May 16, 2016
Page 2

the accreditor will submit a copy of the accreditation letter to IDPH, which will forward the application materials to the CMS Regional Office for final approval. Final CMS approval can take an additional 45 days. Obtaining such accreditation deems the provider eligible for Medicare enrollment through what is called "deemed status."

To qualify to participate in the Illinois Medicaid program, a provider must have a valid license issued by IDPH and must be certified to participate in the Medicare program. See 89 Ill. Admin. Code § 140.11. Therefore, only when the endoscopy center is Medicare certified can the Applicants apply for Medicaid certification. While a separate survey is not required, it can take several months for Medicaid enrollment subsequent to Medicare certification.

As noted in the Southern Illinois Gastrointestinal Endoscopy Center CON application, one of the goals of the project is to improve access to colonoscopy to low income patients. Critical to achieving that goal is enrolling in the Medicare and Medicaid programs. The Applicants will promptly apply for Medicare and Medicaid certification when they are eligible to do so. Given the lengthy application process and the need to complete construction and become licensed first, it is not possible to provide with any level of certainty when the endoscopy center will be Medicare and Medicaid certified. It will however, use its best efforts to complete this process anticipating a minimum of 9 months following licensure if there are no delays based on extension of surveys or paperwork processing. Medicare and Medicaid patients are a material part of the anticipated payor mix. Also, most private payors will not contract with an endoscopy clinic until the clinic is enrolled in Medicare. This applicant has every incentive to move forward with the enrollment processes in an expeditious manner.

2. Endoscopy Procedure Volumes

In addition to the inquiry regarding payor enrollment, the April 28th letter indicated that based upon the historical volume of endoscopy procedures performed over the past two years, State Board staff is concerned that Dr. Makhdoom may have exceeded the 50 percent threshold for in-office surgical procedures permitted under the ASTC licensure regulations. While increasing endoscopy procedures coupled with new payor requirements and direct access programs make it imperative for the licensure process to proceed, Dr. Makhdoom has been careful not to exceed the threshold.

There are many professional services relating to patient care provided in the office, some are undertaken by the physician and others by physician extenders. Physician extenders primarily manage patient consultations and follow-up exams while Dr. Makhdoom performs endoscopies. With this model, where physician extenders practice at the same location as Dr. Makhdoom, the practice is able to enhance access to scarce physician resources in Southern

Mr. Michael Constantino
May 16, 2016
Page 3

Illinois. The three physician extenders in the office manage less complex cases but Dr. Makhdoom is available on site. Between endoscopy procedures, he can consult with his colleagues and collaborate on more complex cases. Endoscopy procedures take 10 to 20 minutes of the physician's time per procedure. While there certainly is patient prep and room clean-up, Dr. Makhdoom does not track the precise times of those activities. Endoscopy procedures are scheduled based on blocks of Dr. Makhdoom's time and patients are flipped between rooms for efficiency. For purposes of the licensure analysis, we do not believe that activities are measured by how much time they take and, based on our firm's recent prior experience, we believe it is the number of encounters in each category that is relevant not the time committed to the procedures.

Even if the licensure threshold were to be weighed by time associated with surgical procedures, there is a material volume of other activities which balance the professional time dedicated to endoscopy. In 2015, Dr. Makhdoom performed a total of 1,970 colonoscopies and 845 EGD procedures. Conservatively, Dr. Makhdoom may have dedicated 798 total hours to endoscopy in 2015 which is approximately 43 percent of his time, assuming 7 ½ hours a day 250 days a year (1,875 hours annually).

Again, Dr. Makhdoom is not the only professional rendering patient care and these other activities must be considered. Between the Dr. Makhdoom and the physician extenders, they perform patient consults, capsule endoscopy virtual colonoscopy and hemorrhoid treatment. There are also activities performed by technicians (e.g., imaging and blood draws). Based upon surgical time associated with endoscopic procedures as well as the encounter data, endoscopy procedures do not currently constitute more than 50 percent of the practice's activities.

Dr. Makhdoom is very much aware of the ASTC regulation permitting a physician practice to perform in-office surgical procedures without an ASTC license, provided surgical procedures do not constitute more than 50 percent of the activities of the practice. He regularly monitors his endoscopy volumes and, from time to time, must postpone non-emergent endoscopy procedures to ensure his practice does not exceed the 50 percent threshold in any given week.

3. Letter of Intent

A letter of intent between The Bahama Clinic and Southern Illinois Gastrointestinal Endoscopy Center, LLC is attached at Attachment – 1.

4. Colonoscopy Assist Program

In our previous response to the State Board's request for additional information, we submitted information regarding Southern Illinois G.I. Specialists Colonoscopy Assist Program



Mr. Michael Constantino
May 16, 2016
Page 4

and Upper GI Endoscopy Assist Program, which will be implemented at Southern Illinois Gastrointestinal Endoscopy Center. Dr. Makhdoom is committed to improving access to colonoscopy and EGD. As evidence of that commitment, a copy of the full page advertisement detailing the Colonoscopy Assist Program and Upper GI Endoscopy Assist Program that ran in The Southern Illinoisan on Saturday, April 9, 2016 is attached at Attachment – 2.

Thank you for your assistance on this matter. If you have any questions or need any additional information regarding Southern Illinois Gastrointestinal Endoscopy Center, please feel free to contact me

Sincerely,

A handwritten signature in black ink that reads 'Anne M. Cooper'.

Anne M. Cooper

Attachments

cc: Juan Morado, Jr.

NON-BINDING REAL ESTATE LEASE LETTER OF INTENT

Dr. Zahoor Makhdoom, M.D.
Manager
Southern Illinois Gastrointestinal Endoscopy Center, LLC
1100 West Diann Lane
Carbondale, Illinois 62901

**Re: Letter of Intent – Southern Illinois Gastrointestinal Endoscopy Center, LLC
Lease**

Dear Dr. Makhdoom:

This Non-Binding Letter of Intent sets forth the material terms and conditions pursuant to which The Bahama Clinic, LLC ("Lessor") is prepared to lease space in the medical office building located at 1100 West Diann Lane, Carbondale, Illinois 62901 ("Subject Property") to Southern Illinois Gastrointestinal Endoscopy Center, LLC ("Lessee"). This letter shall serve as a Non-Binding Letter of Intent to lease the Subject Property.

Proposed Terms and Conditions

Space: 1,085 gross square feet of clinical space and 2,137 gross square feet of non-clinical support space to be located adjacent to the Southern Illinois G.I. Specialists, L.L.C. office.

Lease Term: Initial term will be ten (10) years effective upon the later of the completion of construction or lessee occupancy. Lessor will grant Lessee two (2) renewal options each for a period of five (5) years.

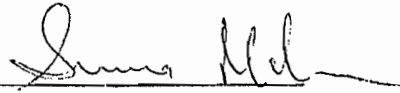
Lease Rate: The lease rate will be based upon the full amortization of the capitalized tenant improvements to build out the space with a reasonable rate of return. The anticipated tenant improvements are projected to be \$23.00/sq. ft.

Lease Contingency: The lease shall be contingent upon Lessee's receipt of a certificate of need permit for the establishment of an ambulatory surgical treatment center from the Illinois Health Facilities and Services Review Board.

If the above terms and conditions are acceptable, please indicate your acceptance by executing a copy of this letter and returning it to me.

Sincerely,

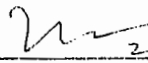
THE BAHAMA CLINIC, LLC

By: 

Its: Authorized Agent

AGREED TO AND ACCEPTED THIS 5TH DAY OF MAY, 2016:

SOUTHERN ILLINOIS GASTROINTESTINAL
ENDOSCOPY CENTER, LLC

By:  2

Zahoor Makhdoom, M.D.

Manager

53075667.1



The Joint Commission Southern Illinois GI Specialists, LLC
Z. Makhdoom, MD, FACG, FASGE, AGAF
 Accreditation Accredited 2011, 2014 Board Certified Gastroenterologist
 Office Based Surgery



ASGE Approved Unit for High Quality and Excellence
 2011, 2014

COLONOSCOPY ASSIST PROGRAM

What is the Colonoscopy Assist program for the uninsured?

If you are uninsured, the Colonoscopy Assist program offers colonoscopy procedures at a much discounted rate of \$1500. Please read this page in its entirety for additional details.

Why is the cost of a colonoscopy lower through the program?

We started this program on the principle that more people will get screened if the procedure is made affordable. In the State of Illinois only 35% of the population is being screened and when they are diagnosed with colon cancer it is usually in the later stages with 33% of those diagnosed dying due to colon cancer. The cost of a colonoscopy is low through the program to encourage uninsured individuals to get screened.

What does the \$1500 flat rate include?

The \$1500 flat rate is truly an all-inclusive rate. It includes all costs related to the procedure. There are no hidden charges or fine print and there is virtually no situation where you could see an additional charge. The price includes:

- Physician fees
- Facility fees including nursing costs
- Sedation/Anesthesia costs
- Removal of polyps (if applicable)
- Pathology costs (lab fees)
- NO HIDDEN FEES

What does the \$1500 flat rate NOT include?

Consultations - A physician will briefly talk to you prior to your procedure and after the procedure and this is included in the program. However, if a patient would like a formal pre-procedure consultation or follow-up consultation they will be responsible for charges associated with any consults they request.

How much does a colonoscopy cost on average?

Prices for colonoscopies can vary greatly depending on the city and facility you go to. You have to keep in mind that a colonoscopy results in the patient being billed by 3-4 different entities. A patient should expect bills from:

- Consultation charge/office visit
- Physician Charge
- Facility fee
- Anesthesia Fee
- Pathology Fee
- Imaging Fee (if applicable)

Without insurance, a patient should on average expect to pay \$4700 to \$12,000 for a colonoscopy and this is only the facility fee costs. A considerable savings can be achieved if you schedule through our office.

I'd like to get a colonoscopy. What is the process?

- 1) Call our appointment line at (618) 549-8006 during business hours.
- 2) A set of forms will be mailed to you for completion.
- 3) You will receive an appointment confirmation within 3-5 business days after your paperwork is completed. You will receive your prep instructions at the same time.
- 4) You go for your scheduled colonoscopy procedure.

What are the payment terms?

Payments can be made with a debit card, credit card, HAS (Health Savings Acc't) card, FSA (Flexible Spending Acc't) check or money order and are due prior to the appointment date.

Can I cancel or reschedule my appointment?

We understand that life is unpredictable. There is no obligation to go through with an appointment once scheduled. You can cancel your appointment up to one business day prior to your appointment without penalty. If you have made a payment, you will receive a full refund.

When will I get my procedure reports and results?

The physician and nursing staff will briefly inform you about the findings directly following the procedure. You will receive a copy of your report upon leaving the facility and a copy of your report, along with the pathology report, will also be sent to your primary physician within 7-10 days.

Can I use my Health Savings Account (HSA) or Flexible Spending Account (FSA) to pay for my colonoscopy?

YES. You will receive a receipt from our office that should be used when filing for your money. We highly recommend using your HAS and FSA accounts to pay for your colonoscopy.

Will the procedure hurt?

Colonoscopies do not hurt. They do make you feel uncomfortable. To make the experience pleasant, we have included sedation/anesthesia costs into the price. You most likely won't remember your procedure.

How do I get started?

Getting started is very simple, call our office to request an appointment (618) 549-8006.

UPPER GI ENDOSCOPY ASSIST PROGRAM

What is the Upper GI Endoscopy Assist program for the uninsured?

If you are uninsured, the Upper GI Assist program offers endoscopy procedures at a much discounted rate of \$900. Please read this page in its entirety for additional details.

Why is the cost of an Upper GI endoscopy lower through the program?

We started this program on the principle that more people will seek medical attention if the procedure is made affordable. This program allows patients who are uninsured to obtain an Upper GI endoscopy at a reasonable cost so that their symptoms may be addressed.

What does the \$900 flat rate include?

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How much does an Upper GI endoscopy cost on average?

Prices for Upper GI Endoscopy/EGD can vary greatly depending on the city and facility you go to. You have to keep in mind that an Upper GI Endoscopy/EGD results in the patient being billed by 3-4 different entities. A patient should expect bills from:

- Consultation charge/office visit
- Physician Charge
- Facility fee
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- 4) You go for your scheduled Upper GI Endo procedure.

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Can I use my Health Savings Account (HSA) or Flexible Spending Account (FSA) to pay for my EGD?

YES. You will receive a receipt from our office that should be used when filing for your money. We highly recommend using your HAS and FSA accounts to pay for your Upper GI Endoscopy/EGD.

Will the procedure hurt?

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Dr. Z. Makhdoom MD
 MRCP, FACG, FASGE, AGAF
 Board Certified Gastroenterologist



Andrea Baldwin, ANP-BC
Amanda Wittnam, PA-C
 Highly Experienced in Womens GI Health/Wellness

Our mission is to make colonoscopy/EGD affordable to all.
 Better outcomes occur with Education, Early Detection and Treatment.

1100 West Diann Lane, Carbondale, Illinois 62901
 (618)549-8006 SIGIS-carbondale.com Fax#(618)549-8434



The Joint Commission

Southern Illinois G

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MRCP, FACG, FASGE, AGAF
Board Certified Gastroenterologist

Our mission is to make colon
Better outcomes occur with Educat

1100 West Diann Lane, C
(618)549-8006 SIGIS-carbon

GI Specialists, LLC

MD, FACG, FASGE, AGAF

Gastroenterologist



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Andrea Baldwin, ANP-BC

Amanda Wittnam, PA-C

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