



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: PriMed Gastroenterology, LLC

Docket Number: 01-551

Project Title: Establish an Endoscopy Suite

Statutory Reference: Section 19a-638, Connecticut General Statutes

Filing Date: January 24, 2002

Hearing Date: March 5, 2002

Presiding Officer: Raymond J. Gorman, Commissioner

Informal Participants: St. Vincent's Medical Center
Bridgeport Hospital

Decision Date: April 16, 2002

Default Date: April 24, 2002

Staff: Susan Cole
Laurie K. Greci

Project Description: PriMed Gastroenterology, LLC ("Applicant") proposes to establish an endoscopy suite to be located at 888 White Plains Road, Trumbull, Connecticut, at a total capital expenditure of \$590,000.

Nature of Proceeding: On January 24, 2002, the Office of Health Care Access ("OHCA") received the Applicant's Certificate of Need ("CON") application seeking

authorization to establish an endoscopy suite to be located at 888 White Plains Road, Trumbull, Connecticut, at a total capital expenditure of \$590,000. The Applicant is a health care facility or institution as defined by Section 19a-630, of the Connecticut General Statutes (“C.G.S.”).

A public hearing was held on March 5, 2002. The Applicant was notified of the date, time, and place of the hearing and a notice to the public was published prior to the hearing in the *Connecticut Post* (Bridgeport) and the *Northeast Minority News*. Commissioner Raymond J. Gorman served as the presiding officer for this case. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-638, C.G.S.

St. Vincent’s Hospital and Medical Center petitioned for Intervenor Status and the Presiding Officer designated St. Vincent’s Medical Center an Informal Participant. Bridgeport Hospital petitioned for Informal Participant Status and the Presiding Officer designated Bridgeport Hospital an Informal Participant.

The Presiding Officer heard testimony from witnesses for the Applicant and the Informal Participants and in rendering this decision, considered the entire record of the proceeding. OHCA’s authority to review and approve, modify or deny this application is established by Section 19a-638, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

FINDINGS OF FACT

Clear Public Need

Contribution of the Proposal to the Quality and Accessibility of Health Care Delivery in the Region Impact on the Applicant’s Current Utilization Statistics

1. PriMed, LLC (“PriMed”) is an integrated internal medicine-based group with 47 physicians located throughout the greater Bridgeport area, with admitting privileges at Bridgeport Hospital and St. Vincent’s Medical Center. (*December 26, 2001 CON Application, page 7*)
2. The Applicant physicians have the following specialties: internal medicine, family practice, pediatrics, cardiology, geriatric, infectious disease, hematology, gastroenterology, rheumatology and physical medicine and rehabilitation. (*December 26, 2001 CON Application, page 9*)
3. The Applicant operates from fifteen offices in Bridgeport, Fairfield, Shelton, Stratford and Trumbull. (*December 26, 2001 CON Application, page 8*)

4. PriMed Gastroenterology, LLC (“Applicant” or “PG”), is a single-member limited liability company that was formed for the single purpose of establishing the proposed endoscopy suite (“facility”). PriMed is the sole member in PG. *(December 26, CON Application, page 8)*
5. The Applicant proposes to establish a two-room GI/Endoscopy facility in a leased space of approximately 4,720 square feet on the second floor of the building located at 888 White Plains Road, Trumbull, Connecticut. *(December 26, 2001, CON Application, pages 8 and 47)*
6. Three PriMed physicians, who specialize in gastroenterology, will perform the procedures in the new endoscopy suite; a fourth gastroenterologist will be added in summer 2002. *(December 26, 2001, CON Application, page 9)*
7. Only PriMed physicians will have access to the endoscopy suite, and only gastro-diagnostic services will be performed in the suite. The services will be provided only to patients of PrimMed’s private medical practice. *(October 5, 2001, Attachment to CON Determination Form)*
8. CON Determination Report Number 01-U3, issued on November 1, 2001, states the following:

“OHCA finds that PriMed is a multi-specialty limited liability corporation. As such, the establishment of an endoscopy suite represents an additional function or service by a freestanding outpatient ambulatory surgical facility. Therefore, Certificate of Need authorization is required pursuant to Section 19a-638 of the Connecticut General Statutes.” *(CON Determination Report Number 01-U3, November 1, 2001)*
9. Currently endoscopy procedures are performed at Bridgeport Hospital, Saint Vincent’s Medical Center and a HealthSouth facility in Bridgeport. *(December 26, 2001 CON Application, page 9)*
10. PriMed’s core service area is comprised of the following towns: Bridgeport, Easton, Fairfield, Milford, Monroe, Shelton, Stratford, and Trumbull. *(December 26, 2001, CON Application, page 9)*
11. PriMed has approximately 99,541 patients that reside within the core service area. PriMed has a total caseload of over 114,000 patients. *(December 26, 2001, CON Application, page 9)*
12. The Applicant based the need for the proposed endoscopy suite on the following:
 - a. Increased demand for screening colonoscopies (AMA, Medicare reimbursement as of 7/1/2001).
 - b. Increased number of clients aged 50 and older.
 - c. Research that indicates traditional screening methods are insufficiently sensitive as compared to colonoscopy.
 - d. Insufficient supply of ambulatory facilities in which to perform colonoscopies. *(December 26, 2001 CON Application. Pages 10-17)*

13. Screening asymptomatic persons for colorectal cancer can reduce mortality from the disease. Traditional screening methods, including fecal occult-blood test with rehydration and sigmoidoscopy, are not as sensitive as colonoscopy. *(December 26, 2001 CON Application. Page 11)*
14. The American Medical Association and the American College of Gastroenterology recommend that all persons, age 50 and over, having no other risk of colon cancer but age, should be screened using colonoscopy every ten years. *(December 26, 2001 CON Application. Pages 13)*
15. Beginning on July 1, 2001, Medicare has provided coverage for screening colonoscopies.
16. Public Act No. 01-171 of the State of Connecticut requires group health insurance policies to provide coverage for colorectal screening, commercial health plans also provide coverage for colonoscopies. *(December 26, 2001 CON Application. Pages 13)*
17. PriMed's patient population has a higher than average percentage of patients age 50 or above, with 43% of its patients aged 50 or above as compared to 32% for the general population in the towns of the its core service area. *(December 26, 2001 CON Application. Pages 13)*
18. PriMed's core service area population has 42,865 patients age 50 and above. Each year, assuming one in ten patients request a colonoscopy, over 4,200 colonoscopies may be performed. As PriMed's patient population ages, each progressive year will add an additional 2,000 patients as candidates for a screening colonoscopy. *(December 26, 2001 CON Application. Page 13)*
19. The projected numbers of ambulatory endoscopic procedures to be performed in the first three years by the Applicant are approximately:

Year	Projected Procedure Volume
2002	3,521
2003	4,000
2004	4,600

(December 26, 2001, CON Application, page 12)

20. The number of procedure rooms in current facilities and the hours of availability to PriMed physicians are given below:

Facility	Number of FTE Procedure Rooms	Hours Currently Available to PriMed Physicians
Bridgeport Hospital	5.0	6
St. Vincent's Medical Center	3.0	28
HealthSouth Ambulatory Surgical Center	0.5	12

FTE = Full Time Equivalent, 8 hours per day, 5 days per week (December 26, 2001 CON Application. Page 14 and Statement of Bridgeport Hospital, March 5, 2002)

21. At present, PriMed physicians have a total of 46 hours available to them to perform endoscopic procedures. However, the hours of availability will not meet the expected increase in demand. (December 26, 2001 CON Application. Pages 14 and 15)
22. In 2001, nearly half of Dr. Alan Landau's PriMed patients waiting for elective colonoscopies experienced a procedure delay of 30 days or more. (December 26, 2001 CON Application. Page 15)
23. The shortage of procedure rooms will cause considerable delays in scheduling appointments, causing inconvenience and anxiety for patients. (December 26, 2001 CON Application. Page 15)
24. The delays for patients receiving screening colonoscopies are directly the result of insufficient capacity to meet demand. (December 26, 2001 CON Application. Page 16) (December 26, 2001 CON Application. Page 14)
25. The Applicant states that no patients will be denied endoscopy services based on ability to pay. (January 24, 2002 Completeness Responses, page 3)
26. PriMed has experienced a bad debt expense that averages 2.5% over the past three years. The Applicant anticipates that the bad debt expense of the proposed facility will approximate this rate. (January 24, 2002 Completeness Responses, page 3)
27. PriMed's current and projected payer mix is as follows: (December 26, 2001 CON Application, page 24)

Payer	2001	2002	2003
Commercial (includes HMO)	49.52%	44.28%	39.31%
Medicaid	0.78%	0.05%	0.02%
Medicare	49.02%	55.00%	60.00%
Other*	0.67%	0.67%	0.67%
Total	100.00%	100.00%	100.00%

*Includes patients without insurance (January 24, 2002 Completeness Responses, page 3)

28. Conscious sedation will be administered at the proposed facility by PriMed gastroenterologists who have attended conscious sedation courses in accordance with JCAHO standards. General or local anesthesia will not be administered at the facility. *(January 24, 2002 Completeness Responses, page 4)*
29. The Applicant has developed plans for emergency resuscitation of patients. In addition, the Applicant will discuss a formal written transfer agreement with Saint Vincent's Medical Center and Bridgeport Hospital to accommodate the emergency transfer of patients. *(January 24, 2002 Completeness Responses, page 4)*
30. Section 19a-613 of the Connecticut General Statutes authorizes OHCA to collect patient-level outpatient data from health care facilities or institutions, as defined in Section 19a-630.

Financial Feasibility of the Proposal and its Impact on the Applicant's Rates and Financial Condition
Rates Sufficient to Cover Proposed Capital and Operating Costs
Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services

31. The total capital expenditure with this proposal is \$590,000 which includes:

Item	Cost
Movable Equipment	\$250,000
Construction/Renovation	300,000
Other	40,000
Total Capital Expenditure	\$590,000

(December 26, 2001, CON Application, page 23)

32. The source of funding for the proposal is Applicant's equity. *(December 26, 2001 CON Application, page 23)*
33. The Applicant is projecting the following revenues and expenses for the first three years of the project:

Description	FY 2002	FY 2003	FY 2004
Revenue	\$902,500	\$997,500	\$1,140,000
Expenses	\$893,929	\$907,729	\$959,443
Income over/(under) Expense	\$8,571	\$89,771	\$180,557

(December 26, 2001 CON Application, page 68)

34. The Applicant's rates are sufficient to cover the operating costs with the proposal. *(CON Application, page 13)*

Consideration of Other 19a-637, C.G.S. Principles and Guidelines

The following findings are made pursuant to other principles and guidelines set forth in Section 19a-637, C.G.S.:

35. There is no State Health Plan in existence at this time. *(December 26, 2002 CON Application, page 18)*
36. The Applicant has adduced evidence that this proposal is consistent with the Applicant's long-range plan. *(December 26, 2001 CON Application, page 18)*
37. The Applicant has improved productivity and contained costs through energy conservation, reengineering, group purchasing and the application of technology. *(December 26, 2001 CON Application, page 21)*
38. The Applicant's proposal will not result in a change to the Applicant's teaching or research responsibilities. *(December 26, 2001 CON Application, page 21)*
39. There are no distinguishing characteristics of the Applicant's patient/physician mix as compared to that of other endoscopy programs. *(December 26, 2001 CON Application, page 21)*
40. The Applicant has sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. *(December 26, 2001 CON Application, page 68)*

Rationale

The need for the proposed endoscopy facility is based on increasing demand, quality and access considerations. The two-room suite will be located at 888 White Plains Road in Trumbull. The endoscopy facility will be owned by PriMed Gastroenterology, LLC ("Applicant"), which is owned by PriMed, LLC, an integrated internal medicine group. Endoscopy services at the proposed facility will be performed exclusively by gastroenterologists who are members of PriMed. No other procedures will be performed.

The project will allow the Applicant to meet the increasing demand for endoscopic procedures. There has been a rapid increase in patient demand for GI/Endoscopy procedures over the past several years. Patients are requesting screening colonoscopies in order to detect colon cancer early in its progression. Older people have a higher utilization rate of GI/Endoscopy procedures. As PriMed's patient population has a higher than average percentage of patients aged 50 or above, there is a higher demand for these services.

The increase in demand has resulted in a scheduling backlog of thirty days or more. The expansion of the facilities will help to alleviate the backlog. The Applicant's proposal is anticipated to have little to no effect on existing providers within the area, as they also are anticipated to experience an increase in demand for services.

The Applicant's proposal will improve the quality and accessibility of health care delivery in the region. Only conscious sedation will be performed; general or local anesthesia will not be administered at the proposed facility. The Applicant has developed plans for emergency resuscitation and will develop formal transfer agreements with Saint Vincent's Medical Center and Bridgeport Hospital to accommodate the emergency transfer of patients. In addition, access to the proposed facility will be available to all PriMed patients regardless of ability to pay. Over the past three years PriMed has experienced bad debt expense of 2.5%. The Applicant anticipates a similar bad debt expense at the proposed facility.

In order to further enhance access to endoscopic services in the greater Bridgeport area, OHCA encourages the development of a collaborative arrangement between the Applicant and the two other major providers of endoscopic services, St. Vincent's Medical Center and Bridgeport Hospital. In addition, Section 19a-613, C.G.S. authorizes OHCA to collect patient-level outpatient data from health care facilities or institutions. The submission of quarterly utilization reports to OHCA by the Applicant will provide OHCA with the data necessary to monitor the quality and accessibility of care provided at the proposed facility.

The proposal is financially feasible. The project has a total capital expenditure of \$590,000, which will be funded entirely through the Applicant's equity. The Applicant projects a gain from operations for each of the first three years of operation, which appears to be both reasonable and achievable.

Based upon the foregoing Findings of Fact and Rationale, the Certificate of Need request of PriMed Gastroenterology, LLC for the establishment of an endoscopy suite to be located at 888 White Plains Road, Trumbull, Connecticut at a capital expenditure of \$590,000 is hereby GRANTED.

ORDER

PriMed Gastroenterology, LLC is hereby authorized to establish an endoscopy suite (“facility”) to be located at 888 White Plains Road, Trumbull, Connecticut, at a total capital expenditure of \$590,000. The authorization is subject to the following conditions:

1. All gastroenterologists who perform procedures at the endoscopy suite shall be members or employees of PriMed, LLC.
2. If PriMed Gastroenterology, LLC and/or PriMed, LLC propose in the future to change the scope of services and/or permit non-PriMed members or employees to use the facility, prior approval of OHCA will be required.
3. PriMed Gastroenterology, LLC will provide OHCA with utilization reports on a quarterly basis. The data elements and the format and submission requirements are described in Attachment 1. In addition to basic data analyses, OHCA will use the submitted data to assure that residents of the greater Bridgeport area have appropriate access to the site.
4. This authorization shall expire on March 6, 2003, unless the Applicant presents evidence to OHCA that the endoscopy suite is in operation.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

April 16, 2002
Date

Signed by:
Raymond J. Gorman
Commissioner

RJG/km

Attachment 1

PriMed Gastroenterologists, LLC shall submit patient-specific data as listed and defined below for those patients that receive service, care, diagnosis or treatment at the endoscopy suites located at 888 White Plains Road, Trumbull, Connecticut. This information may be extracted from either the medical abstract or billing records or both and submitted to the Office of Health Care Access (OHCA) in accordance with this Attachment.

- I. The data are to be submitted in ASCII format on a computer disk or electronically.
- II. Column headers to be used are listed below in parentheses after the name of each data element.
- III. Data formats to be followed are listed for each data element.
- IV. The disk or file should be clearly marked with the applicant's/facility's name, file name, docket number and its contents.
- V. Accompanying the data submission, the applicant/facility must submit a full written description of the data submitted and its record layout.
- VI. Initial data shall be submitted at the end of the first quarter in which the facility begins to provide the service it is licensed for. Subsequent data for a calendar quarter shall be filed before the end of the calendar quarter following the calendar quarter in which the encounter was recorded. This data set shall contain the data records for each individual encounter from that facility during the preceding calendar quarter. For example, the data set to be filed before June 31, 2002, shall contain the data records for each individual encounter at that facility from January 1, 2002 until March 31, 2002.
- VII. All data collected by OHCA will be subject to the laws and regulations of the State of Connecticut and the Office of Health Care Access regarding its collection, use, and confidentiality.

Patient Data Elements

1. Medical Record Number (mrn) – unique patient identification number assigned to each patient for whom services are provided by a facility that distinguishes by itself the encounter of an individual patient from the encounter of all other patients for that facility. **Format: string (20, zero filled to left if fewer than 20 characters)**
2. Patient Control Number (patcont) – unique number assigned by the facility to each patient's individual encounter that distinguishes the medical and billing records of the encounter. **Format: string (20, zero filled to left if fewer than 20 characters)**

3. Date of birth (dob) – the month, day, and year of birth of the patient whose encounter is being recorded. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

4. Sex (sex) – patient’s sex, to be numerically coded as follows:

- a. Male = 1
- b. Female = 2
- c. Undetermined = 3

Format: string (1)

5. If available, Race (race1, race2, race3, race4, race5, race6) – patient-identified designation(s) of one or more categories from the following list, and numerically coded as follows:

- a. White = 1
- b. Black/African American = 2
- c. American Indian/Alaska Native = 3
- d. Native Hawaiian/Other Pacific Island = 4
(e.g., Native Hawaiian, Guamanian or Chamorro, Samoan, Other Pacific Islander.)
- e. Asian = 5
(e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, other Asian)
- f. Some other race = 6

Format: string (1)

6. If available, Ethnicity (pat_eth) –patient-identified cultural origin listed below, as from time to time amended, and numerically coded as follows:

- a. Hispanic/Latino = 1
(i.e., Mexican, Puerto Rican, Cuban or other Hispanic or Latino)
- b. Non-Hispanic/Latino = 2

Format: string (1)

7. Zip Code (patzip) - the zip code of the patient’s primary residence. **Format: string (5)**

8. Date that Procedure was Scheduled (Booking Date) – means the month, day, and year on which the procedure or service was scheduled for a patient by the provider. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

9. Date of Encounter or Service (doe) – means the month, day, and year of the procedure or service for the encounter being recorded. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

10. Principal Diagnosis (dx1) – the ICD-9-CM code for the condition which is established after the study to be chiefly responsible for the encounter being recorded. **Format: String (5, do not include decimal place -- decimal place is implied)**
11. Secondary Diagnoses (dx2 through dx10) – the ICD-9-CM codes for the conditions, exclusive to the principal diagnosis, which exist at the time the patient was treated or which developed subsequently to the treatment and which affect the patient’s treatment for the encounter being recorded. Diagnoses which are associated with an earlier encounter and which have no bearing on the current encounter shall not be recorded as secondary diagnoses. **Format: String (5, do not include decimal place -- decimal place is implied)**
12. E-code (ecode) – The ICD-9-CM codes for external cause of injury, poisoning or adverse effect. **Format: string (5, do not include decimal place -- decimal place is implied)**
13. Principle Procedure (px1) - the CPT-4/HCPCS code for the procedure most closely related to the principal diagnosis that is performed for the definitive treatment of the patient. **Format: string (5)**
14. Secondary Procedure (px2 through px10) – the CPT-4/HCPCS codes for other significant procedures. **Format – string (5)**
15. Modifier (mod1 through mod10) – means by which a physician indicates that a service or procedure performed has been altered by some specific circumstance but not changed in definition or code. **Format: string (2)**
16. Payment sources (Primary (ppayer), Secondary (spayer) and Tertiary (tpayer)) - the major payment sources that were expected at the time the dataset was completed, from the categories listed below:
 - a. Self pay = A
 - b. Worker's Compensation = B
 - c. Medicare = C
 - d. Medicaid = D
 - e. Other Federal Program = E
 - f. Commercial Insurance Company = F
 - g. Blue Cross = G
 - h. CHAMPUS = H
 - i. Other = I
 - j. Title V = Q
 - k. No Charge = R
 - l. HMO = S
 - m. PPO = T**Format: string (1)**

17. Payer Identification (payer1, payer2, payer3) – the insured’s group number that identifies the payer organization from which the facility expects, at the time of the encounter, some payment for the bill. Up to three payer organizations shall be reported in the order of their expected contributions to the payment of the facility’s bill. **Format: string (5, zero filled to left if fewer than 5 characters)**
18. Encounter type (etype) – indicates the priority of the encounter.
- | | | |
|-------------|---|---|
| a. Emergent | = | 1 |
| b. Urgent | = | 2 |
| c. Elective | = | 3 |
- Format: string (1)**
19. Referring Physician (rphysid) -- State license number of the physician that referred the patient to the service/treatment/procedure rendered. **Format: string (6)**
20. Operating Physician (physid) – State license number identifying the provider who performed the service/treatment/procedure. **Format: string (6)**
21. Charges (chrg_tot) – Total charges for this encounter. **Format: numeric (8)**
22. Disposition (pstat) – the circumstances of the patient’s discharge, categories of which are defined below and from time to time amended:
- | | | |
|--|---|---|
| a. Discharged home | = | 1 |
| b. Referred for medical treatment | = | 2 |
| c. Transferred to another health care facility | = | 3 |
| d. Expired | = | 4 |
| e. Other | = | 5 |
- Format: string (1)**