



**Project # 151008-B
Pittsford Pain Center LLC**

Program: Diagnostic and Treatment Center **County:** Monroe
Purpose: Establishment and Construction **Acknowledged:** January 14, 2015

Executive Summary

Description

Pittsford Pain Center, LLC, a to-be-formed New York limited liability company, requests approval to develop a single-specialty Article 28 freestanding ambulatory surgery center (FASC) to provide pain management services. The Center will be located in leased space at 727 Linden Avenue, Pittsford (Monroe County), and will consist of four operating rooms.

The proposed members of Pittsford Pain Center, LLC and their ownership percentages are as follows:

Ajai Nemani, M.D.	47.50%
Roser Ng, M.D.	47.50%
Heritage Ambulatory Surgery Center Alliance	5.00%

The members of Heritage Ambulatory Surgery Center Alliance, LLC are as follows:

Robert Tiso, M.D.	37.50%
Eric Tallarico, M.D.	5.00%
Joseph Catania, M.D.	37.50%
Nameer Haider	20.00%

The two physician owners, Ajai Nemani, M.D. and Roger Ng, M.D., currently provide pain management services in their individual offices located in Rochester. The Heritage Ambulatory Surgery Center Alliance (HASCA) provides administrative and consulting services to ambulatory surgery centers.

OPCHSM Recommendation

Contingent Approval with an expiration of the operating certificate five (5) years from the date of its issuance.

Need Summary

The vast majority of procedures to be performed at Pittsford Pain Center, LLC are presently being performed in physicians' private offices. (Fewer than 50 per year are performed elsewhere, mostly in freestanding ASCs.)

The number of projected procedures is 6,001 in Year 1, with Medicaid at 3.5% and charity care at 2.0%.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Project costs of \$404,698 will be met as follows: Equity of \$44,698 and a bank loan of \$360,000 at an interest rate of 5% for a five year term.

Budget:

Revenues	\$6,231,234
Expenses	<u>4,827,355</u>
Net Income	\$1,403,879

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner, and contingent approval is recommended.

Recommendations

Health Systems Agency

The Finger Lakes HSA recommends Disapproval of this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five (5) years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department to provide annual reports to DOH beginning in the second year of operation. These reports should include:
 - a. Data showing actual utilization including procedures;
 - b. Data showing breakdown of visits by payer source;
 - c. Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - d. Data showing number of emergency transfers to a hospital;
 - e. Data showing percentage of charity care provided; and
 - f. Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
4. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
6. Submission of an executed Administrative Services Agreement, acceptable to the Department. [HSP]
7. Submission of an executed administrative service agreement, acceptable to the Department. [BFA]
8. Submission of an executed building lease, acceptable to the Department. [BFA]
9. Submission of an executed loan commitment, acceptable to the Department. [BFA]
10. Submission of an executed working capital loan commitment, acceptable to the Department. [BFA]
11. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-03 (See Attached). [AER]
12. Submission of a photocopy of the executed Operating Agreement of Pittsford Pain Center, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the executed Lease Agreement between N & N Real Estate Holding Rochester LLC and the applicant, acceptable to the Department. [CSL]

Approval conditional upon:

1. The project must be completed within three years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, prior to the applicant's request for, and the Department's granting approval for the start of construction (See Attached). [AER]
7. The applicant shall start construction on or before 09/15/2015 and complete construction by 05/15/2016 upon the filing of Final Construction Documents in accordance with 10NYCRR section 710.7. In accordance with 10 NYCRR Part 710.2(b)(5), if construction is not started on or before the start date, this shall constitute abandonment of the approval. In accordance with Part 710.10(a), this approval shall be deemed cancelled, withdrawn and annulled without further action by the commissioner. [AER]

Council Action Date

June 11, 2015

Need Analysis

Project Description

Pittsford Pain Center, LLC, a to-be-formed New York limited liability company, is seeking approval to establish and construct a freestanding ambulatory surgery center to provide single specialty pain management surgery services at 727 Linden Avenue, Pittsford, 14534, in Monroe County.

Analysis

The primary service area consists of Monroe County. Monroe County has a total of five freestanding multi-specialty ASCs. The table below shows the number of patients utilizing Ambulatory Surgery Centers in Monroe County for 2012 & 2013 (Source: SPARCS).

Specialty Type	Name of Facility	Patients-2012	Patients-2013
Multi	Brighton Surgery Center ,LLC	4,745	6,778
Multi	Lindsay House Surgery Center, LLC	599	674
Multi	Rochester Ambulatory Surgery Center	3,614	4,411
Multi	Unity Linden Oaks Surgery Center	4,923	5,689
Multi	Westfall Surgery Center, LLP	14,224	13,639
Total		28,105	31,191

For Monroe County, the total number of patient visits for ASC's was 28,105 in 2012 and 31,191 in 2013. This represents a 9.9% increase in the number of patients served by Ambulatory Surgery Centers in Monroe County from 2012 to 2013.

The applicant projects 6,001 procedures in Year 1 and 7,260 in Year 3. These projections are based on the current practices of participating surgeons. The table below shows the projected payor source utilization for Pittsford Pain Center.

Projections	Year 1 Procedures	Year 1 Percentage	Year 3 Procedures	Year 3 Percentage
Commercial Ins	2,064	34.4%	2,498	34.4%
Medicare	2,184	36.4%	2,642	36.4%
Medicaid	212	3.5%	256	3.5%
Private Pay	230	3.8%	278	3.8%
Charity Care	120	2.0%	145	2.0%
Other	1,191	19.8%	1,441	19.8%
Total	6,001	100.0%	7,260	100.0%

The applicant is committed to serving all persons in need without regard to ability to pay or source of payment.

Conclusion

Approval of this project will bring office-based pain management surgical procedures into an Article 28 Ambulatory Surgery Center serving the communities of Monroe County.

Recommendation

From a need perspective, contingent approval is recommended for a limited period of five years.

Program Analysis

Project Proposal

Pittsford Pain Center, LLC seeks approval to establish and construct a single specialty ambulatory surgery center at 727 Linden Avenue, Pittsford (Monroe County) which will provide pain management services.

Proposed Operator	Pittsford Pain Center, LLC
Site Address	727 Linden Avenue, Pittsford (Monroe County)
Surgical Specialties	Pain Management
Operating Rooms	4 (Class B)
Procedure Rooms	0
Hours of Operation	Monday through Friday from 7:30 am to 4:00 pm
Staffing (1st / 3rd Year)	14.6 FTEs / 17.4 FTEs
Medical Director	Ajai K. Nemani, MD
Emergency, In-Patient & Backup Support Services Agreement and Distance	Expected to be provided by Rochester General Hospital 12 miles / 16 minutes
On-call service	24/7 on-call service to connect patients to the facility's on-call physician during hours when the facility is closed.

Character and Competence

The members of Pittsford Pain Center, LLC are:

Name	Membership
Individual Physicians	95%
Ajai Nemani, MD (47.50%)	
Roger R. Ng, MD (47.50%)	
Heritage Ambulatory Surgery Center Alliance, LLC	5%
Robert L. Tiso, MD (37.50%)	
Joseph A. Catania, MD (37.50%)	
Eric Tallarico, MD (5.00%)	
Nameer Haider, MD (20.00%)	

The proposed Center's ownership is comprised of two physicians, Drs. Nemani and Ng—both practicing physicians (Board Certified in Anesthesiology and Pain Medicine) who will perform procedures at the Center, and Heritage Ambulatory Surgery Center Alliance, which is comprised of four physicians who will provide administrative and consulting services to the Center.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Drs. Tallarico and Tiso each disclosed one open malpractice case. Dr. Catania disclosed one settled and three (3) open malpractice cases.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Integration with Community Resources

The proposed ASC will establish and maintain a list of physicians in and around the facility's location who are accepting new patients. The list will be available to any patient who does not have a primary care physician. Pain management services will be provided to all who are referred to the physicians credentialed by the ASC, without regard to their ability to pay.

The center intends on utilizing an electronic medical record. Another goal of the ASC is to integrate into a Regional Health Information Organization (RHIO) and/or Health Information Exchange (HIE). Additionally, the applicant is open to becoming a part of an Accountable Care Organization or Medical Home, based on regulatory and market demands.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Administrative Services Agreement

The applicant has submitted a draft administrative services agreement, which is summarized below:

Facility:	Pittsford Pain Center, LLC
Contractor:	Heritage Ambulatory Surgery Center Alliance, LLC
Term:	Two years with automatic renewal of successive terms of one year.
Services Provided:	The Contractor shall provide the following services: billing and collection services, detailed revenue analysis on monthly and annual collections, manage the EMR /Billing system software and vendor relationship, provide decision support reporting out of the EMR and Billing system, provide facility level financial statements in format consistent with all HASCA facilities, complete and file the NYS ACHF Cost Report required for all Article 28 facilities in NYS, attend member meetings to monitor compliance with Medicare and NYS DOH requirements, provide information systems consulting services as needed to ensure interface of systems is maintained and provide guidance on Center policies related to HIPAA compliance, HITECH Security and a Corporate Compliance Plan.
Fee:	Year One - \$190,000
	Year Two - \$250,000
	Year Three - \$250,000
	Year Four - \$257,500
	Year Five - \$265,225

While HASCA will be providing the above noted services, the applicant retains ultimate control in all of the final decisions associated with the services and has full control over the management of the Center. The applicant shall retain, in its sole discretion, the following powers:

- Direct independent authority over the appointment and/or dismissal of the Center's management level employees and all licensed or certified health care staff;
- The right to adopt and approve the Center's operating and capital budgets;
- Independent control over, and physical possession of, the Center's books and records;
- The right to independently adopt, approve and enforce the Center's operating policies and procedures;
- Authority over the disposition of assets and authority to incur debt;
- The right to approve settlements of administrative proceedings or litigation to which the Center is a party;
- The Center or a person directly employed by and salaried by Center shall manage and personally direct the Center's day to day operations; and

- The individual responsible for the Center's financial oversight shall be employed or contracted directly by Center and shall be independent of HASCA.

Lease Rental Agreement

The applicant has submitted a draft lease rental agreement for the site that they will occupy; which is summarized below:

Premises:	9,594 square feet located at 727 Linden Avenue, Pittsford, New York
Lessor:	N & N Real Estate Holding Rochester, LLC
Lessee:	Pittsford Pain Center, LLC
Term:	10 years
Rental:	Year One - \$316,602 (\$33.00 per sq. ft.) with a 2% annual increase thereafter.
Provisions	The lessor shall be responsible for maintenance, real estate taxes and utilities.

The applicant has submitted an affidavit indicating that the lease agreement will be an arms-length lease agreement. The applicant has submitted letters from two NYS licensed real estate agents attesting to the reasonableness of the per square foot rental.

Total Project Cost and Financing

Total project cost of \$404,698, which is for moveable equipment and CON fees, is further broken down as follows:

Moveable Equipment	\$400,495
CON Fee	2,000
Additional Processing Fee	<u>2,203</u>
Total Project Cost	\$404,698

The applicant's financing plan appears as follows:

Equity	\$44,698
Bank Loan (5% interest rate, 5 year term)	\$360,000

Equity will be provided by the proposed members proportionate to their ownership interest. A letter of interest has been provided by M&T Bank attesting to the loan terms noted above for the purchase of moveable equipment.

Operating Budget

The applicant has submitted an operating budget, in 2015 dollars, during the first and third years; summarized below:

	<u>Year One</u>	<u>Year Three</u>
Revenues:	\$5,149,780	\$6,231,234
Expenses:		
Operating	\$3,628,574	\$4,397,380
Capital	<u>431,585</u>	<u>429,975</u>
Total Expenses	\$4,060,159	\$4,827,355
Net Income	\$1,089,621	\$1,403,879
Utilization (Procedures)	6,000	7,260
Cost Per Procedure	\$676.70	\$664.92

Utilization broken down by payor source during the first and third years is as follows:

	<u>Year One</u>	<u>Year Three</u>
Medicaid Managed Care	3.53%	3.53%
Medicare Fee For Service	10.03%	10.03%
Medicare Managed Care	26.37%	26.37%
Commercial Managed Care	34.40%	34.40%
Private Pay	3.83%	3.83%
Workers Compensation	19.78%	19.78%
Charity Care	2.00%	2.00%
Other	.06%	.06%
Total	100.00%	100.00%

The payor mix reflects the historical experience of the physicians in their private practice. Both physicians participate with Medicaid and Medicaid Managed Care plans in their area. Medicare enrollees (including managed care) constitute 36% of patient visits, commercial/managed care accounts for 34%, and workers compensation for 20% of current patient volume. The FASC intends to contract with all Medicaid managed care plans in its service area as well as develop agreements with Community Health Centers and Federally Qualified Health Centers located nearby, which may lead to a higher percentage of Medicaid enrollees being served.

Utilization assumptions are based on current physician procedure volumes. Expense assumptions are based on historical experience of the physicians. The applicant has submitted physician referral letters in support of utilization projections.

Capability and Feasibility

Project costs of \$404,698 will be met as follows: Equity of \$44,698 and a bank loan of \$360,000 at an interest rate of 5% for a five year term. M&T Bank has provided a letter of interest for the loan to finance the project cost.

Working capital requirements are estimated at \$804,560, which is equivalent to two months of third year expenses. The applicant will finance \$360,000 at an interest rate of 5% for a five year term. A letter of interest has been provided by M&T Bank for the working capital financing. The remaining \$444,560 will be provided as equity by the proposed members of Pittsford Pain Center, LLC proportionate to their ownership interest. BFA Attachment A is the personal net worth statements of the proposed members of Pittsford Pain Management, LLC, which indicates the availability of sufficient funds for the equity contribution. BFA Attachment B is the pro forma balance sheet of Pittsford Pain Management, LLC as of the first day of operation, which indicates a positive net asset position of \$485,055.

The submitted budget indicates a net income of \$1,089,621 and \$1,403,879 during the first and third years, respectively. Revenues are based on current reimbursement rates for pain management services. The submitted budget appears reasonable.

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendation

From a financial perspective, contingent approval is recommended.

Supplemental Information

Hospital Responses

Below are presented summaries of responses by hospitals to letters from the Department asking for information on the impact of the proposed ambulatory surgery center (ASC) in their service areas.

Facility: Strong Memorial Hospital
601 Elmwood Avenue
Rochester, New York 14642

Current OR Use (% of capacity)	Surgery Cases ¹		Amb. Surg. Cases by Applicant Physicians	Reserved OR Time for Applicant Physicians
	Ambulatory	Inpatient		
53% Main site 62% Off-site	54%	46%	None	None

Strong Memorial Hospital opposes this application based on existing operating room capacity within the Strong system, the low volume of pain procedures provided in an operating room setting and concerns over the quality and management of pain cases that would be treated at the proposed ASC.

In 2012 Strong Memorial had operating expenses of \$1,083,726,520 on revenue of \$1,179,855,300 for a gain of \$96,128,780. In 2013, operating expenses totaled \$1,163,324,922 and revenue was \$1,286,605,893, for a gain of \$123,280,971. Current assets in 2012 were \$538,431,207 and current liabilities were \$231,840,446 for a working capital ratio of 2.3 to 1.0. In 2013, current assets were \$644,356,490, and current liabilities were \$220,328,133, for a working capital ratio of 2.9 to 1.0. In its fiscal year 2013, Strong Memorial incurred bad debt of \$19.3 million and provided charity care in the amount of \$37.5 million. In fiscal year 2014, the hospital incurred \$22.9 million in bad debt and provided \$37.8 million in charity care.

Facility: Highland Hospital
1000 South Avenue
Rochester, New York 14620

Current OR Use (% of capacity)	Surgery Cases		Ambulatory Surgery Cases by Applicant Physicians	Reserved OR Time for Applicant Physicians
	Ambulatory	Inpatient		
Operating Rms. 63.8%	49.0%	51.0%	Yes ²	No
Procedure Ctr. 42.1%	78.9%	21.1%		

Highland Hospital opposes the application on the grounds that there is sufficient OR capacity at Highland and elsewhere in the community to obviate the need for an additional ASC, especially in a time of growing consolidation and affiliation among providers. The hospital also states that approval of the proposed ASC

¹ Main site and off-site combined.

² Four cases in 2014

could potentially reduce current OR utilization. Highland does not quantify what effect such a reduction would have on its surgical revenues or on its community-oriented services.

In 2012 Highland Hospital had operating expenses of \$280,395,263 on revenue of \$294,378,157 for a gain of \$13,982,894. In 2013, operating expenses totaled \$297,751,531 and revenue was \$312,863,256, for a gain of \$15,111,725. Current assets in 2012 were \$112,366,882, and current liabilities were \$28,059,340 for a working capital ratio of 4.0 to 1.0. In 2013, current assets were \$127,086,005, and current liabilities were \$30,448,992, for a working capital ratio of 4.2 to 1.0. In 2012, Highland Hospital incurred bad debt of \$3.2 million and provided charity care in the amount of \$4.9 million. In 2013, the hospital incurred \$4.1 million in bad debt and provided \$5.7 million in charity care.

Facility: Rochester General Hospital -- **No Response**
1425 Portland Avenue
Rochester, New York 14621

Supplemental Information from Applicant

Need and Source of Cases: The applicant states that patients of the proposed facility would receive care from staff focused only on the provision of pain management procedures and that the better organized and more efficient nature of a new state-of-the-art ASC would result in reduced wait times, increased patient satisfaction and an overall better patient experience. Oversight by DOH will also help ensure that quality care is provided.

Staff Recruitment and Retention: Staff will be drawn from among the current staff of the office practices of the applicant physicians.

Office-Based Cases: The applicant states that virtually all of the projected cases for the proposed ASC are currently performed in the office practices of the applicant physicians. Of those that are not (fewer than 50 per year), most are performed in freestanding ASCs.

DOH Comment

The comments from the responding hospitals do not describe a specific adverse impact of the proposed ASC on the facilities' surgical revenues or community-oriented programs. Nor does any such adverse impact seem likely, given that virtually all the procedures projected for the ASC are currently performed in office-based settings and that the applicant physicians have performed only a negligible number of cases at one of the responding hospitals. The Department concludes that the comments from area hospitals provide no basis for reconsideration of the recommendation for approval of the proposed ASC based on public need, financial feasibility and owner/operator character and competence.

Finger Lakes HSA Review & Recommendation

MEMO

TO: CON Project File

RE: CON Project 151008 – Pain Management ASC

DATE: March 20, 2015

Service Location:

727 Linden Avenue
Pittsford, NY 14534

Description:

Interventional Pain Management of Rochester, LLC proposes to develop a single-specialty ambulatory surgery center (ASC) to provide pain management services.

Projected Changes to Community Capacity:

Community Capacity

There are four pain management centers currently operating in Monroe County:

1. Center for Pain Management at RGH
2. University of Rochester Pain Treatment Center at Sawgrass
3. University of Rochester Neuromedicine Pain Management Center at Strong
4. Highland Hospital Pain Management Center

FLHSA has access to a multi-payer claims database consisting of claims data from two major commercial insurers in the region. Because many of the proposed procedures are performed outside of the hospital setting, staff utilized this database as the primary source of information for this review. This database contains commercial, Medicare Advantage, and Managed Medicaid claims for Excellus Blue Cross Blue Shield and MVP for patients living in the twelve counties that make up the Finger Lakes region³. In reviewing the proposed services to be provided at the new facility, we reviewed claims data for January 2010- June 2014 for the region and the two physicians proposing to utilize the new facility.

The applicant has provided the top five (5) projected procedures at the new facility by CPT code, those procedures are located in Table 1. These procedures are expected to account for 85% of ASC's total projected procedure volume.

³ Chemung, Genesee, Livingston, Monroe, Ontario, Orleans, Schuyler, Seneca, Steuben, Wayne Wyoming, and Yates Counties

Table 1. Projected Procedures by Volume, Year 1 and Year 3

CPT	Description	Projected Volume Y1	Projected Volume Y3
64483	Injection(s), anesthetic agent and/or steroid transforaminal epidural, with imaging guidance (fluoro or CT); lumbar or sacral, single level	2,449	2,964
62311	Injection(s) of diagnostic or therapeutic substance(s), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	928	1,123
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet joint with image guidance, lumbar or sacral; single level	891	1,078
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance; lumbar or sacral, single facet joint	450	544
62310	Injection(s), of diagnostic or therapeutic substance(s) not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral	944	1,142

Even with this source of information, total community capacity is difficult to determine. The procedures being proposed at the new facility are often performed in the office setting and can be performed by physicians of numerous specialties. Claims data indicate that of the top 5 projected procedures at the new facility 35% are performed in the office. 57% of procedures are performed in an outpatient surgery setting while only 4% are performed in an ambulatory surgery center or as inpatient procedures. It is unlikely that additional outpatient surgical capacity would result in a shift from inpatient to outpatient for these procedures.

The proposing physicians are currently performing nearly all of the proposed procedures in the office setting. ½ of 1% of the applicant's top five procedures proposed at the new facility have been performed in an outpatient surgery or ambulatory surgical center setting.

Community Need

The applicant cites that 195,000 persons in the five county region the ASC proposes to serve will be affected by chronic pain. Staff estimates that there are approximately 117,000 individuals in Monroe County (proposed site's primary service area) over the age of 18 with chronic pain using an estimate of 30.7% of the population.⁴ However, this number does not reflect the number of individuals that will seek treatment or that will meet criteria for the interventions to be provided at the proposed center

The applicant indicates that wait times for patients at offices of both physicians proposing to utilize the new facility are between four and six weeks. It is unknown if there are other practices in the region experiencing similar wait times. The issues apparent with determining community capacity are mirrored regarding community need. Our estimation of need will rely on the evidence apparent in the literature and the applicant's estimated wait times.

⁴ Johannes, C; Le, T; Zhou X. The Prevalence of Chronic Pain in United States Adults: Results of an Internet-Based Survey. The Journal of Pain. 2010;11(11):1230-1239

There are no national guidelines for wait times for patients with chronic pain. The most current literature found⁵ indicates that patient wait times of 6 months or longer are medically unacceptable. This study also found that only one country had any benchmarks for wait times (United Kingdom, 13 weeks). It should be noted that in many countries wait times for cancer patients are dramatically reduced / eliminated. Wait times in the United States are estimated in one study to be three to four weeks with the local example of Strong Memorial Hospital having a policy of trying to keep wait times to less than two weeks⁶.

Although no national guidelines exist, The Centers for Medicare and Medicaid Services has developed local coverage determinations (LCD's) regarding the facet joint (spinal) injections which are proposed to account for 28% of the practice at the new ASC. The LCD which covers our area prescribes very specific timelines and limits for the application of this treatment modality. The LCD does not require that procedures are completed in an outpatient or ambulatory surgery setting, but does require fluoroscopic guidance. Additionally the LCD notes that "... the evidence of clinical efficacy and utility has not been well-established in the medical literature, which is replete with non-comparable and inadequately designed studies. Further, there is a singular dearth of long-term outcomes reports."⁷ There is some national concern about the abuse of these procedures.

National data indicate that the wait times at Dr. Ng and Dr. Nemani's practices are typical of pain management practices across the United States. The wait times listed for United States practices are the shortest of the countries surveyed in the previously noted study. There is no definitive evidence that these wait times result in poorer patient outcomes.

Need Conclusion

It is unclear how the conversion to Article 28 status will improve patient wait times, other than by improving patient flow and efficiency, which could be achieved without the costs associated Article 28 status.

It is not apparent that there is community need for a single specialty Ambulatory Surgical Center for the purposes of pain management.

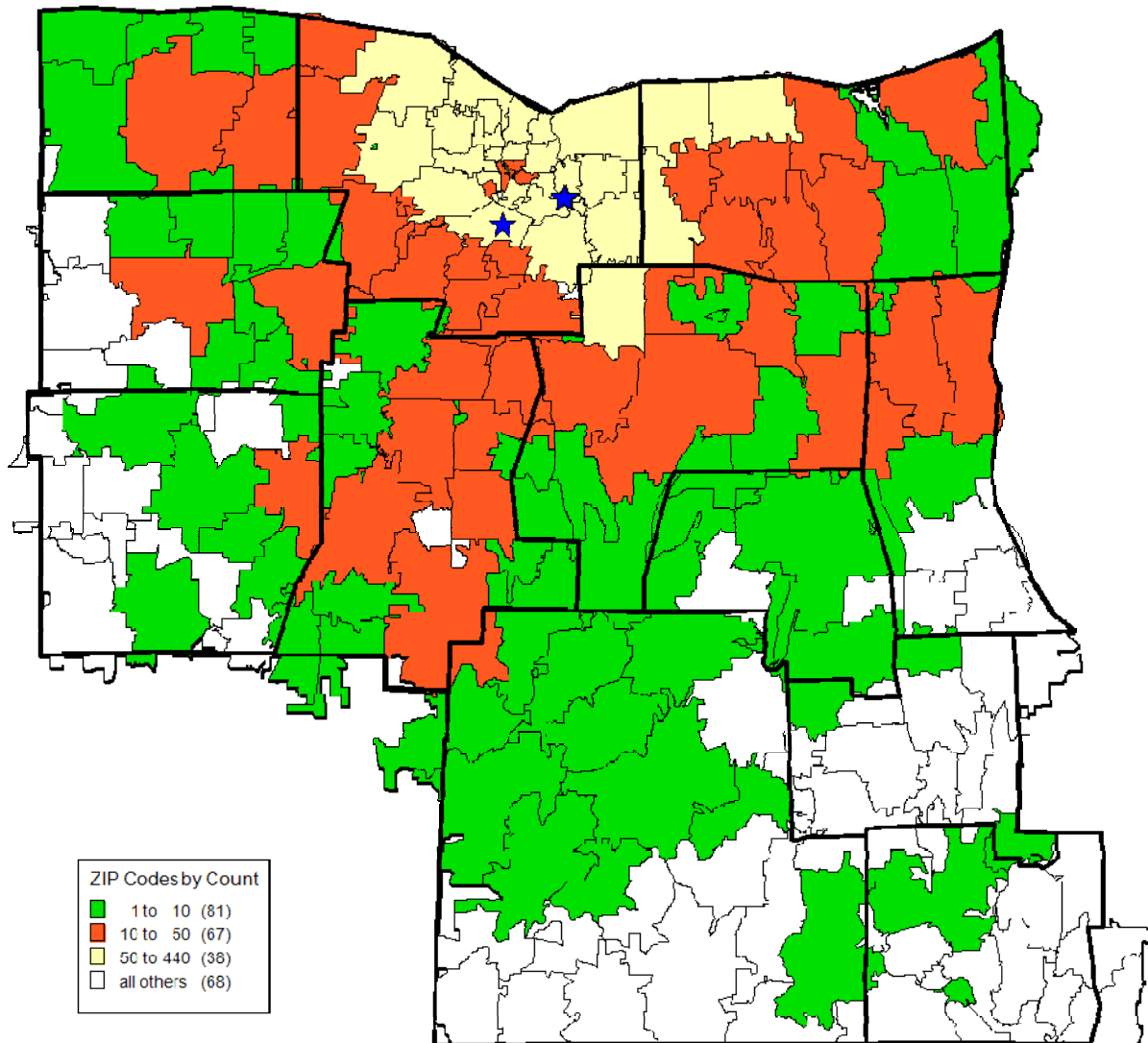
⁵ Lynch, ME; Campbell, F; Clark, A; et al. A systematic review of the effect of waiting for treatment for chronic pain. *Pain*. 2008;136:97-116.

⁶ L Lynch, ME; Campbell, F; Clark, A; et al. Waiting for treatment for chronic pain – a survey of existing benchmarks: Toward establishing evidence-based benchmarks for medically acceptable waiting times. *Pain Research and Management*. 2007;112(4):245-248

⁷ National Government Services LCD L35336. Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy 12/16/2014

Projected Changes to Community Access:

The ASC does not appear to significantly alter geographic access for the practices' respective patient population. The proposed center is 1.2 miles from Dr. Nemani's office and 10.0 miles from Dr. Ng's current office location. Below is a map of the physician's current patient population by ZIP code (from claims data).



The applicant projects 3.5% of patient volume to be from Medicaid Managed care and projects no utilization from Medicaid FFS patients. The relatively low volume of Medicaid patients is concerning in that access may be limited by ability to pay at the new ASC.

Project Cost & Revenue:

Pittsford Pain Center, LLC proposes to establish a new 9,594 square foot single-specialty Ambulatory Surgical Center to provide pain management services. The new facility is to contain four operating rooms with eight (8) pre-operative and ten (10) post-operative recovery beds. The floor plan also contains a central supply, consult room, decontamination and separate clean and soiled linen space.

Capital costs are expected to be \$400,495. The entirety of the cost is for moveable equipment, suggesting that other renovation costs are being covered by the building developer and are included in the lease expense. \$175,000 is allotted for two C-Arm imaging devices. \$50,000 will be used to install an EMR system in two rooms. The remainder of the costs are for various surgical and / or office infrastructure.

Incremental operating costs are anticipated to be \$4,827,355 by year three, with an incremental operating revenue of \$6,231,234. Table 2 outlines total project costs. Staffing is anticipated to increase by 17.4 FTE's by year three. New staffing will include 8 RNs 3 LPNs as well as management, technician, clerical and medical assistants. The applicants indicate that it is unlikely that current office staff will be re-allocated or repurposed for the new facility.

Table 2. Project Costs

	Current Year	Year 1 Incremental	Year 3 Incremental
Project Capital Cost	\$400,495	N/A	N/A
Operating Cost	\$0	\$4,060,159	\$4,827,355
Operating Revenue	\$0	\$5,149,780	\$6,231,234

Project financing will be accomplished with a \$360,000 bank loan at an interest rate of 5% with a five (5) year term and the remainder paid for in cash (\$44,698). The space for the facility will be rented with a lease term of ten (10) years.

There are significant incremental operating costs associated with this project. Staff have submitted questions to the applicant asking to identify the amount of incremental operating revenue that is expected due to the shift from office to ASC based procedures. While unable to provide this information, the applicant has made laudable efforts to identify the cost increases associated with the shift and has provided Medicare proposed reimbursements and anticipated revenues for the five (5) procedures noted previously. Utilizing this information we are able to estimate that incremental revenue for these procedures is anticipated to be \$2.26M per year.

Table 3. Medicare Proposed Payments by Setting
**2015 Medicare Proposed Total
 Payment Per Procedure**

CPT Code	Office	ASC
64483	\$222.46	\$485.53
62311	\$225.32	\$461.88
64493	\$175.17	\$464.03
64635	\$424.86	\$1,055.34
62310	\$244.67	\$481.95

Table 4. Estimated Revenue Increase due to Change in Place of Service

CPT Code	Expected Office Reimbursement	Expected ASC Reimbursement	Difference	Proposed Number of Procedures	Estimated Difference in Total Revenue
64483	\$202	\$566	\$364	2,449	\$891,436
62311	\$231	\$728	\$497	928	\$461,216
64493	\$181	\$566	\$385	891	\$343,035
64635	\$399	\$943	\$544	450	\$244,800
62310	\$214	\$561	\$347	944	\$327,568
TOTAL DIFFERENCE IN REVENUE					\$2,268,055

Comments:

The applicant had the opportunity to present the same proposal to the Community Technology Assessment Advisory Board (CTAAB). CTAAB consists of employers, consumers, clinicians, health systems and health insurance representatives and has a 20 year history of making recommendations to the payer community regarding issues of health technology and community capacity. This board considered the needs analysis conducted by Finger Lakes Health Systems Agency (FLHSA), the CON application materials, and the applicant’s presentation to the Board.

Based on the information available, CTAAB concluded there is not a need for the proposed capacity and cited the following reasons:

- There is no demonstrated community need for additional Pain Management Capacity
 - Wait times at the physician offices do not appear to be atypical for that specialty
 - While defining total capacity is difficult, there is no evidence that current capacity is not meeting patient needs
- There are significant incremental costs associated with the project and no evidence of improved outcomes for patients
- Increases in efficiency and quality could be achieved without article 28 status.
- There is no demonstrated improvement in access
 - Geographic access is not significantly altered
 - There is limited access projected for the Managed Medicaid population, with no access indicated for the Medicaid FFS population.

This recommendation was communicated to the Rochester payer community.

Recommendation - Disapproval

Contingencies: N/A

Conditions: N/A

Attachments

BFA Attachment A Personal Net Worth Statement
BFA Attachment B Pro Forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of June, 2015 having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a single specialty ambulatory surgery center to provide pain management services at 727 Linden Avenue, Pittsford, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:

FACILITY/APPLICANT:

151008 B

Pittsford Pain Center LLC

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five (5) years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a signed agreement with an outside independent entity satisfactory to the Department to provide annual reports to DOH beginning in the second year of operation. These reports should include:
 - a. Data showing actual utilization including procedures;
 - b. Data showing breakdown of visits by payer source;
 - c. Data showing number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
 - d. Data showing number of emergency transfers to a hospital;
 - e. Data showing percentage of charity care provided; and
 - f. Number of nosocomial infections recorded during the year in question. [RNR]
3. Submission of a statement, acceptable to the Department, that the applicant will consider creating or entering into an integrated system of care that will reduce the fragmentation of the delivery system, provide coordinated care for patients, and reduce inappropriate utilization of services. The applicant will agree to submit a report to the Department beginning in the second year of operation and each year thereafter detailing these efforts and the results. [RNR]
4. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to assure that charity care is available to those who cannot afford to pay. [RNR]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
6. Submission of an executed Administrative Services Agreement, acceptable to the Department. [HSP]
7. Submission of an executed administrative service agreement, acceptable to the Department. [BFA]
8. Submission of an executed building lease, acceptable to the Department. [BFA]
9. Submission of an executed loan commitment, acceptable to the Department. [BFA]
10. Submission of an executed working capital loan commitment, acceptable to the Department. [BFA]
11. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-03 (See Attached). [AER]

12. Submission of a photocopy of the executed Operating Agreement of Pittsford Pain Center, LLC, acceptable to the Department. [CSL]
13. Submission of a photocopy of the executed Lease Agreement between N & N Real Estate Holding Rochester LLC and the applicant, acceptable to the Department. [CSL]

APPROVAL CONDITIONAL UPON:

1. The project must be completed within three years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities. [HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]
5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, prior to the applicant's request for, and the Department's granting approval for the start of construction (See Attached). [AER]
7. The applicant shall start construction on or before 09/15/2015 and complete construction by 05/15/2016 upon the filing of Final Construction Documents in accordance with 10NYCRR section 710.7. In accordance with 10 NYCRR Part 710.2(b)(5), if construction is not started on or before the start date, this shall constitute abandonment of the approval. In accordance with Part 710.10(a), this approval shall be deemed cancelled, withdrawn and annulled without further action by the commissioner. [AER]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON*.