HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
JANUARY 22, 2014
APPLICATION SUMMARY

NAME OF PROJECT: Smoky Mountain Surgery Center

PROJECT NUMBER: CN1308-032

ADDRESS: 1346 Papermill Way
Knoxville (Knox County), Tennessee 37909

LEGAL OWNER: Smoky Mountain Ambulatory Surgery Center, LLC
1346 Papermill Way
Knoxville (Knox County), Tennessee 37909

OPERATING ENTITY: Not Applicable

CONTACT PERSON: E. Graham Baker, Jr.
(615) 370-3380

DATE FILED: August 15, 2013

PROJECT COST: $53,000.00

FINANCING: Cash Reserves

PURPOSE OF REVIEW: The addition of interventional pain management services to a single specialty ambulatory surgical treatment center (ASTC) with one (1) procedure room

DESCRIPTION:

Smoky Mountain Surgery Center is seeking approval for the addition of interventional pain management services to its existing one operating room single specialty ambulatory surgical treatment center (ASTC) that currently only provides manipulation under anesthesia (MUA) procedures.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

Ambulatory Surgical Treatment Centers (*Revised May 23, 2013*)

The following apply:

1. Need. The minimum numbers of 884 Cases per Operating Room and 1867 Cases per Procedure Room are to be considered as baseline numbers for purposes of determining Need.[2] An applicant should demonstrate the ability to perform a minimum of 884 Cases per Operating Room and/or 1867 Cases per Procedure Room per year, except that an applicant may provide information on its projected case types and its assumptions of estimated average time and clean up and preparation time per Case if this information differs significantly from the above-stated assumptions. It is recognized that an ASTC may provide a variety of services/Cases and that as a result the estimated average time and clean up and preparation time for such services/Cases may not meet the minimum numbers set forth herein. It is also recognized that an applicant applying for an ASTC Operating Room(s) may apply for a Procedure Room, although the anticipated utilization of that Procedure Room may not meet the base guidelines contained here. Specific reasoning and explanation for the inclusion in a CON application of such a Procedure Room must be provided. An applicant that desires to limit its Cases to a specific type or types should apply for a Specialty ASTC.

   The applicant is projecting 2,700 cases in Year One (2014) and 3,100 cases in Year Two (2015). The projected cases will be limited to interventional pain management procedures.

   It appears this criterion has been met.

2. Need and Economic Efficiencies. An applicant must estimate the projected surgical hours to be utilized per year for two years based on the types of surgeries to be performed, including the preparation time between surgeries. Detailed support for estimates must be provided.

   Based on an average of 15 minutes per case, the projected surgical hours will be 13.0 hours per week or 675 hours in Year One and 14.9 hours per week or 775 hours in Year Two.

It appears this criterion has been met.

3. Need; Economic Efficiencies; Access. To determine current utilization and need, an applicant should take into account both the availability and utilization of either: a) all existing outpatient Operating Rooms and Procedure Rooms in a Service Area, including physician office based surgery rooms (when those data are officially reported and available[3]) OR b) all existing comparable outpatient Operating Rooms and Procedure Rooms based on the type of Cases to be performed. Additionally, applications should provide similar information on the availability of nearby out-of-state existing outpatient Operating Rooms and Procedure Rooms, if that data are available, and provide the source of that data. Unstaffed dedicated outpatient Operating Rooms and unstaffed dedicated outpatient Procedure Rooms are considered available for ambulatory surgery and are to be included in the inventory and in the measure of capacity.

   The applicant has provided a utilization table of all pain management ASTCs in the proposed service area for 2010, 2011 and 2012. The tables are located in attachment C.N.5.A. and C.N.5.B. of the application.

   It appears this criterion has been met.

4. Need and Economic Efficiencies. An applicant must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed, if those services are known and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above.

   There are a total of five (5) multi-specialty pain management ASTCs in the Knox County service area representing a total of twenty-four (24) ORs and two (2) procedure rooms. The five (5) multi-specialty ASTCs provided 10,234 pain management surgical cases representing 38% of overall surgical procedures in 2012. HSDA staff could not calculate current pain service area utilization using 1867 Cases per Procedure Room as the baseline numbers for purposes of determining need at 70% utilization or above. Procedure room and operating room utilization are reported together on ASTC Joint Annual Reports.

   It is not known if this criterion is met.

5. Need and Economic Efficiencies. An application for a Specialty ASTC should present its projections for the total number of cases based on its own calculations for the projected length of time per type of case, and shall provide any local, regional, or national data in support of its methodology. An applicant for a Specialty ASTC should provide its own definitions of the surgeries and/or procedures that will be performed and whether the Surgical Cases will be performed in an Operating Room or a Procedure Room. An applicant for a Specialty ASTC must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON proposal to establish a Specialty ASTC or to expand existing services of a Specialty ASTC shall not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above. An applicant that is granted a CON for a Specialty ASTC shall have the specialty or limitation placed on the CON.

   There are 2,700 cases projected in Year One and 3,100 cases in Year Two. All cases will be performed in a procedure room. None of the current multi-specialty ASTCs in Knox County provides interventional pain management services in conjunction with MUA. The applicant will only be serving patients of the Smoky Mountain Surgery Center. HSDA staff was unable to calculate current pain service area utilization using 1867 Cases per Procedure Room as the baseline numbers for purposes of determining need at 70% utilization or above. Procedure room and operating room utilization are inclusive on ASTC Joint Annual Reports and are not individually reported.

   It is not known if this criterion is met.

6. Access to ASTCs. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility.

   The majority of patients reside within 60 minutes of the facility.

   It appears this criterion has been met.

7. Access to ASTCs. An applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available

   Public bus transportation is available.

It appears this criterion has been met.

8. Access to ASTCs. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project the origin of potential patients by percentage and county of residence and, if such data are readily available, by zip code, and must note where they are currently being served. Demographics of the Service Area should be included, including the anticipated provision of services to out-of-state patients, as well as the identity of other service providers both in and out of state and the source of out-of-state data. Applicants shall document all other provider alternatives available in the Service Area. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

   The applicant states that 100% of patient projections were calculated using the Knox County service area; however historically Knox County residents have accounted for 35% of the ASTC's patients.

   It is unclear as to whether this criterion has been met.

9. Access and Economic Efficiencies. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters following completion of the project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

   Projected utilization ranges from 675 cases in the first quarter to 775 cases in the eighth quarter.

   It appears this criterion has been met.

10. Patient Safety and Quality of Care; Health Care Workforce.

    a. An applicant should be or agree to become accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization.

The applicant is certified by both Medicare and Medicaid is accredited by The Joint Commission.

It appears this criterion has been met.

b. An applicant should estimate the number of physicians by specialty that are expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel. An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.

Cynthia Niendorff, MD, Board Certified in pain medicine, will provide pain intervention services.

It appears this criterion has been met.

11 Access to ASTCs. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

There are three (3) medically underserved designated areas in Knox County.

It appears this criterion has been met.

b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program;

Since the applicant is not a hospital, this standard is not applicable to this proposed project.

c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

Medicare and the TennCare Managed Care Organization (MCO) AmeriChoice are contracted with by the applicant. The applicant has applied to AmeriGroup and plans to apply with BlueCare in the future.

It appears this criterion has been met.

d. Who is proposing to use the ASTC for patients that typically require longer preparation and scanning times. The applicant shall provide in its application information supporting the additional time required per Case and the impact on the need standard

Not applicable. The proposed pain invention procedures will average 15 minutes.

STAFF SUMMARY

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italic.

The MUA Medical Clinic of Knoxville, LLC (CN0811-112A), was originally approved at the February 25, 2009 Agency meeting for the establishment of a single-specialty one procedure room ambulatory surgical treatment center (ASTC) providing only manipulation under anesthesia (MUA) services with no actual operative surgical procedures being performed. According to the Tennessee Department of Health, Health Care Facilities web-site, MUA Medical Clinic of Knoxville, LLC changed the ASTC name to Smoky Mountain Ambulatory Surgery Center, LLC effective January 4, 2013. The applicant now proposes to add interventional pain management services to its existing ASTC by using the same one procedure room that is currently approved for MUA services. MUA procedures and interventional pain procedures will not be performed at the same time on the same patient.

Insurers required less intensive pain relief methods prior to attempting traditional MUA. These measures include interventional pain management services such as joint injections. MUA involves relaxing the patient with anesthesia, and making manual corrections to biomechanical abnormalities by stretching and manipulation. The goal of MUA is to increase the patient's range of motion and/or relief of pain, improve functional capacity, and reduce narcotic use in the treatment of pain.

An overview of the project is provided on pages 8-9 of the original application.

Project History

Note to Agency members: The following is a timeline of events that led to the filing of this application:

- ***February 2009-CN0811-112A, MUA Medical Clinic of Knoxville, was approved by the Agency to establish a single specialty ambulatory surgical treatment center (ASTC) limited to manipulation under anesthesia.***
- ***October 2011-Upon completion of the ASTC, the applicant requested a staff determination as to whether Manipulation Under Joint Anesthesia [MUJA] is part of the MUA services.***
- ***November 2011-A staff determination was issued that MUJA is part of the MUA services permitted under CN0811-112A.***

- ***November 2012-Concern arose about whether the determination had been correct. HSDA staff contacted TDH for assistance in getting the right answer to this medically complex question; TDH's Medical Director of the Board of Medical Examiners, who is also the Chairman of the Board for Licensing Health Care Facilities, recommended that HSDA staff withdraw the staff determination.***
- ***December 2012-The TDH's Medical Director of the Board of Medical Examiners recommendation led to HSDA staff's issuance of a determination that a separate CON would be needed to add pain management procedures for MUJA to be performed at the applicant's ASTC.***
- ***March 2013-After several months of dialogue with interested parties and staff's consultation with the HSDA Chair, it was decided that the questions should be decided by the HSDA Agency members after hearing from all sides in a public forum. It was also decided that until the HSDA adopts a position on this, staff would take no position; therefore, all staff determinations were rescinded.***
- ***August 2013-Rather than receive an Agency Determination, the applicant chose to file this application for the addition of pain management services. Therefore, whether MUJA has already been authorized is not an issue in whether to approve this application.***

Ownership

Smoky Mountain Surgery Center is a Tennessee registered limited liability company (LLC) formed November 7, 2008. Smoky Mountain Surgery Center is member managed and owned by four (4) members: Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, MD (25%).

In the supplemental response, the applicant indicates affiliated Lensgraf Clinic, PC (50% owner), a Tennessee registered pain clinic, is located next door to the Smokey Mountain Surgery Center at 1346 Papermill Point Way, Knoxville, TN.

Need

According to the applicant, the following demonstrates need:

- Patients with high risks of COPD, cardiovascular, uncontrolled diabetics, post-traumatic stress syndrome and intravascular problems benefit receiving interventional pain management procedures in an ASTC.
- Appropriate interventional pain management procedures minimize prescription opioid consumption.
- Reimbursement at an office level is not adequate to cover the costs of a facility comprehensive care program.
- The absorption of more TennCare and charity patients by performing procedures with its own staff in an adjoining practice-owned ASTC.

Facility Information

- The ASTC is located in subleased floor space in an existing 5,580 square building located at 1346 Papermill Point Way, Knoxville, Tennessee 37909, Suite 203, from Lensgraf Clinic, P.C.
- A floor plan drawing is included in Attachment B.IV.—Floor Plan.

Equipment

There is no major medical equipment involved with this project. The applicant will use an existing Fluoroscopy C-Arm.

Service Area Demographics

Smoky Mountain Surgery Center's declared primary service area is Knox County.

- The total population of Knox County is estimated at 448,903 residents in calendar year (CY) 2013 increasing by approximately 4.7% to 470,092 residents in CY 2017.
- The overall statewide population is projected to grow by 3.7% from 2013 to 2017.
- The latest 2013 percentage of the Knox County population enrolled in the TennCare program is approximately 14.4%, as compared to the statewide enrollment proportion of 18.8%.

Source: The University of Tennessee Center for Business and Economic Research Population Projection Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

Historical Capacity and Utilization of Multi-Specialty Pain Management ASTCs
Knox County

			2010 (Final)	2011 (Final)	2012 (final)	2012	2012	
County	ASTC	Oper. Rms/ Proc. Rms*	Cases	Cases	Cases	% of Total	Cases /Room	% change 10'-12'
Knox	Fort Sanders West Outpatient Surgery	4 / 0						
	Pain Management		3,752	2,797	3,406	83.4%		-9.2%
	Total Outpatient Cases		**6,052**	**3,687**	**4,085**		**1,021**	**-32.5%**
Knox	Knoxville Orthopaedic Surgery Ctr.	4/1						
	Pain Management		**675**	**2,519**	**2,976**	**43.5%**		**+340%**
	Total Outpatient Cases		**1,473**	**5,798**	**6,837**		**1,367**	**+364%**
Knox	Parkwest Surgery Center	5 / 1						
	Pain Management		1,495	1,045	1,039	19.3%		-30.5%
	Total Outpatient Cases		**5,935**	**5,416**	**5,393**		**899**	**-9.1%**
Knox	Physicians Surgery Center of Knoxville	5/ 0						
	Pain Management		775	794	1,071	24.4%		+38.2%
	Total Outpatient Cases		**4,090**	**3,621**	**4,398**		**880**	**+7.5%**
Knox	St. Mary's Ambulatory Surgery Center	6 / 0						
	Pain Management		1,372	1,630	1,742	28.3%		+27%
	Total Outpatient Cases		**7,353**	**6,648**	**6,160**		**1,027**	**-16.2%**
Knox	**University Ambulatory Surgery	6 / 2						
	Pain Management		2,084	1,146	**			
	Total Outpatient Cases		**5,234**	**2,785**	**			
	Service Area Totals							
	OR/PR		31/5=36	30/4=34	24/2=26			-28%
	Pain Management		10,153	9,931	10,234	38%		+.8%
	Total Outpatient Cases		**30,137**	**27,955**	**26,873**		**1,034**	**-10.8%**
	Cases per OR/PR		837	822	1,034			+23.5%

Source: Department of Health, Division of Health Statistics, Joint Annual Reports 2009-Final, 2010-Final, 2011-Final
*The area's multi-specialty ASTC operating/procedure room capacity has changed over the three reported years. OR/PR rooms based on 2012 totals
**As of February 1, 2011, University Ambulatory Surgery Center became part of the University of Tennessee Medical Center (UTMC) Campus.

Service Area Historical Utilization

The utilization table above reflects the following:

- There were no single specialty ASTCs in the service area providing pain management services in 2012. (According to a representative of PCET Surgery Center which has an outstanding CON (CN1202-009A) for an ASTC limited to pain management services, this facility opened in January 2013.)
- There are currently five (5) multi-specialty ASTCs in the service area that provide pain management services. There is only one other multi-specialty ASTC in the service area, Children's West Surgery Center, which

targets pediatric surgery. For purposes of this analysis, Children's West Surgery Center volumes are not included.

- Total pain management surgical cases increased from 10,153 in 2010 to 10,234 in 2012, a 0.8% increase.
- Knoxville Orthopaedic Surgery Center experienced the largest pain management case percentage increase of 364% from 1,473 cases in 2010 to 6,837 cases in 2012, and also the largest percentage increase of 364% in total outpatient surgeries.
- The ASTC most dependent on pain management procedures is Fort Sanders West Outpatient Surgery Center where 83.4% of is surgical cases were pain management. The next ASTC most dependent on pain management cases was Knoxville Orthopaedic Surgery Center at 43.5%.
- 10.8% decrease in multi-specialty ASTC total outpatient surgeries from 30,137 in 2010 to 26,873 in 2012
- A 23.5% overall increase in cases per OR/PR in multi-specialty ASTCs (performing pain management procedures) from 837 in 2010 to 1,034 in 2012.
- A 28% decrease in the number of ASTC multi-specialty (performing pain management procedures) OP/PRs in Knox County from 36 in 2010 to 26 in 2012. The major source of this reduction was from the conversion of University Ambulatory Surgery Center from a freestanding ASTC to being an outpatient department of UT Medical Center.

Project Cost

Major costs are:

- Legal, Administrative (Excluding CON Filing Fee), Consultant- $50,000, or 94.4% of cost
- CON Filing Fee- $3,000, or 5.6% of the total cost

Financing

All costs associated with this project are administrative and have been paid with cash reserves.

Historical Data Chart

The historical data chart for the current Smoky Mountain Surgery Center was provided by the applicant.

- For YTD October 2013 the applicant is experiencing a net loss of ($28,023).
- Net operating income increased from ($16,840) in 2011 to $307,738 in 2012.
- Average annual Net Operating Income (NOI) was approximately 37.8% of annual net operating revenue for the year 2012.

Projected Data Chart

The applicant projects $6,480,000.00 in total gross revenue on 2,700 pain management cases during the first year of operation and $7,440,000 on 3,100 pain management cases in Year Two (approximately $2,400 per case). The Projected Data Chart reflects the following:

- Net operating income less capital expenditures for the applicant will equal $512,400 in Year One increasing to $597,040 in Year Two.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to reach $1,488,000 or approximately 20% of total gross revenue in Year Two.
- Charity care at approximately 5.0% of total gross revenue in Year One and 5.0% in Year Two equaling to $324,000 and $372,000, respectively.
- Charity Care calculates to 135 cases in Year One and 155 cases in Year Two.
- The projected data chart for the entire facility (pain management and MUA cases) projected a net income of $685,140 based on 2,800 patients in Year 1 and $750,735 based on 3,215 patients in Year 2.

Charges

In Year One of the proposed project, the average pain management charges are as follows:

- The proposed average gross charge is $2,400/case in 2014.
- The average deduction is $1,920/case, producing an average net charge of $480/procedure.

Medicare/TennCare Payor Mix

- TennCare- Charges will equal $486,000 in Year One representing 7.5% of total gross revenue.
- Medicare- Charges will equal $4,600,800 in Year One representing 71% of total gross revenue.

Staffing

No additional staff is required for the addition of pain management services of Smokey Mountain Surgery Center. The applicant's proposes to utilize existing ASTC direct patient care staff in Year One:

- One (1) FTE Registered Nurse and
- One (1) FTE Licensed Practical Nurse and
- One (1) FTE Radiology Technician

Licensure/Accreditation

Smoky Mountain Surgery Center, LLC is licensed as an ASTC by the Tennessee Department of Health, Division of Health Care Facilities. A letter dated February 10, 2011 from the Tennessee Department of Health indicated the facility to be in compliance in all areas as a result of an on-site initial state licensure inspection completed on February 10, 2011.

Smokey Mountain Surgery Center is accredited by The Joint Commission for a three year period which began September 18, 2011. The last Joint Commission accreditation activity occurred on September 18, 2011 with no areas for improvement identified.

Corporate documentation, real estate lease, and detailed demographic information are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years. The applicant projects providing pain management services in February 2014.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER KNOX COUNTY FACILITIES:

There are no Letters of Intent, denied or pending applications for other Davidson County providers proposing this type of service.

Outstanding Certificates of Need

PCET Surgery Center, CN1202-009A, has an outstanding Certificate of Need which will expire on July 1, 2014. The CON was approved at the May 23, 2012 Agency meeting for the establishment of a single-specialty ambulatory surgical treatment center (ASTC) in a medical office building. Use of this facility is limited to patients of Pain Consultants of East Tennessee, PLLC, and an established physician practice that is moving to an office suite adjoining this project. The facility will be licensed by the Tennessee Department of Health as an ambulatory surgical treatment center limited to pain management with one (1) surgical procedure room and one (1) operating room. The CON was approved with the following limitations/conditions: 1.) Limited to pain management; 2.) Limited to patients of Pain Consultants of East Tennessee, PLLC; and 3.) Limited to one (1)

LETTER OF INTENT

2013 AUG 8 PM 1 43

LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the *Knoxville New Sentinel* which is a newspaper of general
(Name of Newspaper)

circulation in Knox County, Tennessee, on or before August 10, 2013 for one day.
(County) (Month / day) (Year)

==========

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §68-11-1601, et seq., and the Rules of the Health Services and Development Agency, that Smoky Mountain Ambulatory Surgery Center, LLC ("Applicant"), 1338 Papermill Pointe Way, Knoxville, Tennessee 37909-1903, owned and managed by itself, intends to file an application for a Certificate of Need for the addition of interventional pain management services at its ASTC. The Applicant currently provides manipulation under anesthesia ("MUA") services. This new service will be provided in the same one procedure room which is currently licensed. There are no beds and no major medical equipment involved with this project. No other health services will be initiated or discontinued. It is proposed that Medicare, TennCare, commercially insured, and private-pay patients will be served by the ASTC, which will be licensed by the Tennessee Department of Health. The estimated project cost is anticipated to be approximately $200,000.00.

The anticipated date of filing the application is: August 15, 2013.

The contact person for this project is E. Graham Baker, Jr., (Contact Name) Attorney (Title)

who may be reached at: his office located at (Company Name) 2021 Richard Jones Rd. Suite 350 (Address)

Nashville (City) TN (State) 37215 (Zip Code) 615 /370-3380 (Area Code / Phone Number)

E. Graham Baker, Jr. (Signature) August 08 2013 (Date) graham@grahambaker.net (E-mail Address)

==========

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Frost Building
161 Rosa L. Parks Blvd., 3rd Floor
Nashville, Tennessee 37243

==========

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

==========

* The project description must address the following factors:

1. General project description, including services to be provided or affected.
2. Location of facility: street address, and city/town.
3. Total number of beds affected, licensure proposed for such beds, and intended uses.

COPY-Application

Smoky Mountain Surgery Ctr.

CN1308-032

2013 AUG 15 PM 2 35

CERTIFICATE OF NEED APPLICATION

for the

Addition of Interventional Pain Management Services
to an existing ASTC

by

Smoky Mountain Ambulatory Surgery Center, LLC
1346 Papermill Point Way
Knoxville, Knox County, TN 37909

STATE OF TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY
Frost Building
161 Rosa L. Parks Blvd., 3rd Floor
Nashville, Tennessee 37243
615/741-2364

Filing Date: August 15, 2013

SECTION A: APPLICANT PROFILE

19

1. Name of Facility, Agency or Institution

2013 AUG 15 PM 2 35

Smoky Mountain Ambulatory Surgery Center, LLC
Name

1346 Papermill Point Way — Knox
Street or Route — County

Knoxville, — TN — 37909
City — State — Zip Code

2. Contact Person Available for Responses to Questions

E. Graham Baker, Jr. — Attorney
Name — Title

Weeks & Anderson — graham@grahambaker.net
Company Name — e-mail address

2021 Richard Jones Road, Suite 350 — Nashville, — TN — 37215
Street or Route — City — State — Zip Code

Attorney — 615/370-3380 — 615/221-0080
Association with Owner — Phone Number — Fax Number

3. Owner of the Facility, Agency, or Institution

Smoky Mountain Ambulatory Surgery Center, LLC — 865/673-5000
Name — Phone Number

1346 Papermill Point Way — Knox
Street or Route — County

Knoxville, — TN — 37909
City — State — Zip Code

4. Type of Ownership of Control (Check One)

A. Sole Proprietorship ____
B. Partnership ____
C. Limited Partnership ____
D. Corporation (For-Profit) ____
E. Corporation (Not-for-Profit) ____
F. Governmental (State of Tenn. or Political Subdivision) ____
G. Joint Venture ____
H. Limited Liability Company __x__
I. Other (Specify) _____ ____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS. See *Attachment A.4*.

SECTION A:

APPLICANT PROFILE

Please enter all Section A responses' on this form. All questions must be answered. If an item does not apply, please indicate "N/A". ***Attach appropriate documentation as an Appendix at the end of the application and reference the applicable Item Number on the attachment.***

Section A, Item 1: Facility Name must be applicant facility's name and address must be the site of the proposed project.

Response: Smoky Mountain Ambulatory Surgery Center, LLC is the Applicant. See Response to A.1. The Applicant is located at 1346 Papermill Pointe Way, Knox County, TN 37909.

Section A, Item 3: Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence, if applicable, from the Tennessee Secretary of State.

Response: See *Attachment A.4.*

Section A, Item 4: Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% or more ownership interest. In addition, please document the financial interest of the applicant, and the applicant's parent company/owner in any other health care institution as defined in Tennessee Code Annotated, §68-11-1602 in Tennessee. At a minimum, please provide the name, address, current status of licensure/certification, and percentage of ownership for each health care institution identified.

Response: The Applicant is owned by Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, M.D. (25%). The LLC is member-managed. There is no organization chart.

Neither the Applicant nor any of the above entities own any other health care institution in Tennessee, as defined in TCA §68-11-1602.

Section A, Item 5: For new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment methodology and schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract

Please describe the management entity's experience in providing management services for the type of the facility, which is the same or similar to the applicant facility. Please describe the ownership structure of the management entity.

Response: The Applicant will be managed by itself.

Section A, Item 6: For applicants or applicant's parent company/owner that currently own the building/land for the project location, attach a copy of the tide/deed. For applicants or applicant's parent company/owner that currently lease the building/land for the project location, attach a copy of the fully executed lease agreement. For projects where the location of the project has not been secured, attach a fully executed document including Option to Purchase Agreement, Option to Lease Agreement, or other appropriate documentation. Option to Purchase Agreements must include anticipated purchase price. Lease/Option to Lease Agreements must include the actual/anticipated term of the agreement and actual/anticipated lease expense. The legal interests described herein must be valid on the date of the Agency's consideration of the certificate of need application.

Response: The Applicant is owned by Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, M.D. (25%). The LLC is member-managed. There is no organization chart.

The Applicant's site is leased office space, and the landlord is D.F.S. Properties. Lensgraf Clinic, P.C. leases the space, and the Applicant sub-leases space from Lensgraf Clinic, P.C. The specialty ASTC is located at 1346 Papermill Point Way, Knoxville, Knox County, Tennessee 37909.

Attachment A.6 is a copy of the lease between the landlord and Lensgraf Clinic, P.C., and a *Attachment A.6.1* is an assignment of that lease to the Applicant. Please note the lease runs through 2015.

5. Name of Management/Operating Entity (If Applicable)

Name

Street or Route | County

City | State | Zip Code

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS. Not applicable.

6. Legal Interest in the Site of the Institution (Check One)

A.	Ownership	____	D.	Option to Lease	____
B.	Option to Purchase	____	E.	Other (Specify)	
C.	Lease of 5 Years	x		_____	____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS. See *Attachments A.6 & A.6.1.*

7. Type of Institution (Check as appropriate--more than one response may apply.)

A.	Hospital	____	I.	Nursing Home	____
B.	Ambulatory Surgical Treatment Center (Multi-Specialty)	____	J.	Outpatient Diagnostic Center	____
		____	K.	Recuperation Center	____
C.	ASTC	X	L.	Rehabilitation Facility	____
D.	Home Health Agency	____	M.	Residential Hospice	____
E.	Hospice	____	N.	Non-Residential Methadone Facility	____
F.	Mental Health Hospital	____			
G.	Mental Health Residential Treatment Facility	____	O.	Birthing Center	____
			P.	Other Outpatient Facility (Specify) _____	____
H.	Mental Retardation Institutional Habilitation Facility (ICF/MR)	____	Q.	Other (Specify) specialty ASTC	X

8. Purpose of Review (Check as appropriate--more than one response may apply.)

A.	New Institution	____	H.	Change In Bed Complement (Please note the type of change by underlining the appropriate response: Increase, Decrease Designation, Distribution Conversion, Relocation)	____
B.	Replacement/Existing Facility	____			
C.	Modification/Existing Facility	X			
D.	Initiation of Health Care Service as defined in TCA § 68-11-1607(4)				
E.	Specify _____	____	I.	Change of Location	____
F.	Discontinuance of OB Services	____	J.	Other (Specify) add interventional pain mgmt services	X
G.	Acquisition of Equipment	____			____

9. Bed Complement Data

23

Please indicate current and proposed distribution and certification of facility beds.

Response: Not applicable, as no beds are involved in this application.

	Current Beds Licensed	Current Beds CON*	Staffed Beds	Beds Proposed	TOTAL Beds at Completion
A. Medical					
B. Surgical					
C. Long-Term Care Hospital					
D Obstetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolescent Psychiatric					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid Certified)					
M. Nursing Facility Level 1 (Medicaid only)					
N. Nursing Facility Level 2 (Medicare only)					
O. Nursing Facility Level 2 (dually-certified)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child & Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

*CON Beds approved but not yet in service

10. **Medicare Provider Number** 103G492884
Certification Type Specialty ASTC

11. **Medicaid Provider Number** 1526056
Certification Type Specialty ASTC

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**

Response: This is an existing facility, certified for both Medicare and Medicaid. See *Attachment A.12.*

13. ***Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.* Will this project involve the treatment of TennCare participants? Yes If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted *or plans to contract. Discuss any out-of-network relationships in place with MCOs/BHOs in the area.***

Response: The Applicant has contracts with AmeriChoice, BlueCare and TennCare Select.

NOTE: *Section B is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. Section C addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.*

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Response: Smoky Mountain Ambulatory Surgery Center, LLC ("Applicant"), 1346 Papermill Pointe Way, Knoxville, Knox County, Tennessee 37909, owned and managed by itself, files this application for a Certificate of Need for the addition of interventional pain management services at its ASTC. The Applicant currently provides manipulation under anesthesia ("MUA") services. This new service will be provided in the same one procedure room which is currently licensed. There are no beds and no major medical equipment involved with this project. No other health services will be initiated or discontinued. It is proposed that Medicare, TennCare, commercially insured, and private-pay patients will be served by the ASTC, which will be licensed by the Tennessee Department of Health. The estimated project cost is anticipated to be approximately $53,000.00, which includes the $3,000.00 filing fee.

Smoky Mountain Ambulatory Surgery Center, LLC is the Applicant. See Response to A.1. The Applicant is currently located at 1346 Papermill Pointe Way, Knoxville, Knox County, Tennessee 37909.

The Applicant is owned by Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, M.D. (25%). The LLC is member-managed.

The Applicant's site is leased office space, and the landlord is D.F.S. Properties. Lensgraf Clinic, P.C. leases the space, and the Applicant sub-leases space from Lensgraf Clinic, P.C. The specialty ASTC is located at 1346 Papermill Point Way, Knoxville, Knox County, Tennessee 37909.

Physicians have expressed concern about the treatment of chronic pain. Chronic pain has both chemical and mechanical components. Such treatment is difficult, sometimes ineffective, and has risks. These risks include narcotic abuse, misuse and diversion, and infection (such as Epidural Steroid Injections). There appears to be general consensus that a procedure that could significantly lower pain scores, improve functional capacity, and reduce narcotic use would be invaluable in the treatment of chronic pain. Manipulation under Anesthesia ("MUA") is such a procedure, and the Applicant is already approved for this service.

MUA is a modality which has been used by practitioners (doctors of chiropractic, doctors of osteopathic medicine, and medical doctors) since the early 1930s. The process involves relaxing the patient (with anesthesia), and making corrections to biomechanical abnormalities by stretching and manipulation. Following the procedure, the patient gains a range of motion and/or relief of pain.

The Applicant is forced by insurers to attempt less intensive pain relief methods prior to attempting traditional MUA. These measures include interventional pain management services such as joint injections. The HSDA originally determined that such procedures were included under MUA, and the Applicant provided such procedures for some time. Later, the HSDA determined that the Applicant is not approved for such interventional pain management services. Since the Applicant cannot conduct the MUA procedures for which it has already been approved without attempting interventional pain management procedures first, this application is being filed.

Project Costs: There are no costs, other than administrative, for this project. The facility, as approved and licensed, will not require any modification. The FMV and lease costs for the ASTC have already gone through CON when the ASTC was approved. Equipment is already in place.

Staff: The Applicant will utilize existing staff, including an administrator ($25K - $30K annually), a receptionist ($15K - $20K), RN ($30K-$35K), and an LPN ($20K - $25K). No additional staff will be needed for this project.

Charges: The Applicant anticipates an average gross charge per patient in Year 1 of operation of $2,400, with an average deduction of $1,920, for an average net charge of $480 per patient. Interventional pain management procedures can be performed in physician's offices, in hospitals, and in other approved facilities. However, it is difficult, and almost impossible, to arrive at comparable charges for such services since such charges are not reported on Joint Annual Reports. The Applicant has made an attempt to compare these charges, as will be discussed later in the application.

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

Medicare and TennCare Revenue Projections: It is anticipated that 71% of our patients will be Medicare, 7.5% will be Medicaid, and 21.5% will be commercial patients.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of $5 million) and other facility projects (construction cost in excess of $2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

Response: Smoky Mountain Ambulatory Surgery Center, LLC ("Applicant"), 1346 Papermill Pointe Way, Knoxville, Knox County, Tennessee 37909, owned and managed by itself, files this application for a Certificate of Need for the addition of interventional pain management services at its ASTC. The Applicant currently provides manipulation under anesthesia ("MUA") services. This new service will be provided in the same one procedure room which is currently licensed. There are no beds and no major medical equipment involved with this project. No other health services will be initiated or discontinued. It is proposed that Medicare, TennCare, commercially insured, and private-pay patients will be served by the ASTC, which will be licensed by the Tennessee Department of Health. The estimated project cost is anticipated to be approximately $53,000.00, which includes the $3,000.00 filing fee.

Smoky Mountain Ambulatory Surgery Center, LLC is the Applicant. See Response to A.1. The Applicant is currently located at 1346 Papermill Pointe Way, Knoxville, Knox County, Tennessee 37909.

The Applicant is owned by Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, M.D. (25%). The LLC is member-managed.

The Applicant's site is leased office space, and the landlord is D.F.S. Properties. Lensgraf Clinic, P.C. leases the space, and the Applicant sub-leases space from Lensgraf Clinic, P.C. The specialty ASTC is located at 1346 Papermill Point Way, Knoxville, Knox County, Tennessee 37909.

Physicians have expressed concern about the treatment of chronic pain. Chronic pain has both chemical and mechanical components. Such treatment is difficult, sometimes ineffective, and has risks. These risks include narcotic abuse, misuse and diversion, and infection (such as Epidural Steroid Injections). There appears to be general consensus that a procedure that could significantly lower pain scores, improve functional capacity, and reduce narcotic use would be invaluable in the treatment of chronic pain. Manipulation under Anesthesia ("MUA") is such a procedure, and the Applicant is already approved for this service.

MUA is a modality which has been used by practitioners (doctors of chiropractic, doctors of osteopathic medicine, and medical doctors) since the early 1930s. The process involves relaxing the patient (with

anesthesia), and making corrections to biomechanical abnormalities by stretching and manipulation. Following the procedure, the patient gains a range of motion and/or relief of pain.

The Applicant is forced by insurers to attempt less intensive pain relief methods prior to attempting traditional MUA. These measures include interventional pain management services such as joint injections. The HSDA originally determined that such procedures were included under MUA, and the Applicant provided such procedures for some time. Later, the HSDA determined that the Applicant is not approved for such interventional pain management services, and issued a cease and desist letter. Since the Applicant cannot conduct the MUA procedures for which it has already been approved without attempting interventional pain management procedures first, this application is being filed.

Project Costs: There are no costs, other than administrative, for this project. The facility, as approved and licensed, will not require any modification. The FMV and lease costs for the ASTC have already gone through CON when the ASTC was approved. Equipment is already in place.

Staff: The Applicant will utilize existing staff, including an administrator ($25K - $30K annually), a receptionist ($15K - $20K), RN ($30K-$35K), and an LPN ($20K - $25K). No additional staff will be needed for this project.

Charges: The Applicant anticipates an average gross charge per patient in Year 1 of operation of $2,400, with an average deduction of $1,920, for an average net charge of $480 per patient. Interventional pain management procedures can be performed in physician's offices, in hospitals, and in other approved facilities. However, it is difficult, and almost impossible, to arrive at comparable charges for such services since such charges are not reported on Joint Annual Reports. The Applicant has made an attempt to compare these charges, as will be discussed later in the application.

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

Medicare and TennCare Revenue Projections: It is anticipated that 71% of our patients will be Medicare, 7.5% will be Medicaid, and 21.5% will be commercial patients.

The current ASTC room configuration is noted on *Attachment B.IV*. Note that there is only one Procedure Room. This room is already approved, and will be utilized for interventional pain management services. It is also important to note that only one patient will be served at a time, and each patient will receive only one service during a visit. Some procedures require mild sedation, and anesthesia will be administered by either an Anesthesiologist or a CRNA working for an Anesthesiologist. Patients must have medical clearance for anesthesia. Also, patients have to have had testing for the procedure (standard testing is CBS/Diff and sometimes an SMA6). If the patient is over 50 years of age, they will need an EKG; if the patient has a history of respiratory difficulty, a Chest X-Ray will be required. Finally, a pregnancy test will be given to female patients.

Both the person administering anesthesia and the recovery room nurse must be ACLS certified in life support. Following the procedure, each patient will go to the Recovery Room for gentle stretching and physical therapy, including Interferential (electrical stimulation) therapy, and then ice. Following this, the patient will have a massage prior to discharge.

Following the procedure, most patients are fully capable of ambulation. However, in some instances it may be advised that someone (either our staff, a family member, or friend) drive the patient to their destination in order for the patient to receive rest and relaxation.

The Applicant has worked with both the HSDA and the Tennessee Department of Health, Division of Licensing Health Care Facilities, to coordinate useful licensing requirements and utilization standards for facilities such as have been approved for this ASTC. Representatives of the Applicant have met with a representative of the Board for Licensing Health Care Facilities in this regard. For example, please see *Attachment C.N.5* for a copy of working protocols for MUA procedures.

According to the Tennessee Department of Labor and Workforce Development, there are no published reports available indicating the personnel positions required for the operation of a specialty ASTC. As the publishing of such information might be considered a violation of Anti-Trust, existing ASTCs cannot get together and decide on what salaries to pay for these positions. Our existing salaries will be commensurate with both abilities and the marketplace, and the Applicant will maintain that staff. *Attachment C.OD.3* contains affiliated health care workers data.

The Applicant works with area training programs to allow students to rotate though our facility to complete clinical training requirements. Further, doctors have been trained in the clinic, and this process will continue.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Response: Not applicable, as no beds are involved in this project.

C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

Response: Not applicable.

D. Describe the need to change location or replace an existing facility.

Response: Not applicable.

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of $1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For fixed-site major medical equipment (not replacing existing equipment):

a. Describe the new equipment, including:

1. Total cost; (As defined by Agency Rule)
2. Expected useful life;
3. List of clinical applications to be provided; and
4. Documentation of FDA approval.

b. Provide current and proposed schedules of operations.

Response: Not applicable.

2. For mobile major medical equipment:
a. List all sites that will be served;
b. Provide current and/or proposed schedule of operations;
c. Provide the lease or contract cost.
d. Provide the fair market value of the equipment; and
e. List the owner for the equipment.

Response: Not applicable.

3. Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Response: Not applicable.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. **Size of site (*in acres*)**
2. **Location of structure on the site; and**
3. **Location of the proposed construction.**
4. **Names of streets, roads or highway that cross or border the site.**

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Response:

1. The site on which the medical building is located is approximately 3.77 Acres.

2. See *Attachment B.III.2.*

3. There is no construction.

4. The ASTC is located in existing space at 1346 Papermill Pointe Way, Knoxville, Knox County, Tennessee 37909. The site has easy access to downtown Knoxville, including I-40, which runs adjacent to and parallel with Papermill Pointe Way.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Response: Buses run on Papermill Pointe Way, and private taxis are also available.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: *DO NOT SUBMIT BLUEPRINTS*. Simple line drawings should be submitted and need not be drawn to scale.

Response: Please see *Attachment B.IV*, which contains a footprint of that section of the first floor of the medical office building where the ASTC is located.

V. For a Home Health Agency or Hospice, identify:

1. **Existing service area by County;**
2. **Proposed service area by County;**
3. **A parent or primary service provider;**
4. **Existing branches; and**
5. **Proposed branches.**

Response: Not applicable.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper*. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. **Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.**

   a. **Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.**

Response: Please see *Attachment Specific Criteria.*

   b. **Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c).**

Response: Not applicable.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

Response: There is no long-range development plan of the Applicant, other than to add interventional pain management services to this existing ASTC. The Applicant was originally approved to provide MUA services. After licensure, the Applicant began providing the service, and insurers advised the Applicant that they would not reimburse for MUA unless and until interventional pain management services were attempted first. The Applicant requested a determination from the HSDA as to whether or not such procedures were "covered" under the heading of MUA. Obviously, the Applicant felt they were covered. The HSDA agreed, and the Applicant resumed providing services in compliance with both Licensure and third party insurers. Later, the HSDA decided that the Applicant was not approved for interventional pain management procedures, and the Applicant had to shut down its operation. After several meetings and exchange of information among the interested parties, the Applicant decided to apply for interventional pain management services via this application.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

Response: The Applicant's clinical primary service area is Knox County. See *Attachment C.N.3* for a map of the proposed primary service area.

The Applicant's ASTC is located in Knoxville (primary service area of Knox County), but the actual referring area may well extend beyond the county of situs to outlying areas. If utilization and need for this service eventually extends to other areas of the state, the owners of the Applicant may well pursue ASTC facilities in those areas. Common sense dictates that areas of higher population concentration would be targeted first. Such other sites have not been pursued at the present time, however, as the focus of the Applicant is on this particular facility.

4. A. Describe the demographics of the population to be served by this proposal.

Response: The population to be served is an urban community with rural and industrial influences. Knox County is the hub of East Tennessee, and the population numbers of some of the counties in East Tennessee are increasing at a high rate (e.g., Knox County). Knoxville/Knox County is also the hub of the Knoxville Standard Metropolitan Statistical Area (SMSA) in East Tennessee.

The following chart lists 2013, 2015 and 2017 population estimates for the county:

Population Estimates for Proposed Service Area

County	Estimated 2013 Population	Estimated 2015 Population	Estimated 2017 Population
Knox	431,991	438,060	443,016
TOTAL	431,991	438,060	443,016

Source: Population Estimates and Projections, Tennessee Counties and the State, 2010 – 2020, Office of Health Statistics, Bureau of Health Informatics, Tennessee Department of Health.

Attachment C.N.4.A contains demographic data for Knox County. This data was obtained from the US Census Bureau.

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: There are no special needs of the service area population, as contemplated by this question. The Applicant feels that there are individuals in need of interventional pain management services, in addition to the approved MUA services, however.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

Response: There are several hospitals and ASTCs in the service area that provide interventional pain management services. None of these facilities provide such services in conjunction with MUA, however. MUA protocols are included as *Attachment C.N.5*.

Attachment C.N.5.A is a list of all hospitals in the service area that report performing pain management services. None of these hospitals are exclusively dedicated to pain management.

Attachment C.N.5.B is a list of all ASTCs in the service area that report performing pain management services. None of these ASTCs are exclusively dedicated to pain management.

The fact that no existing hospitals or ASTCs are dedicated to pain management is not a derogatory statement. It merely points out the fact that the Applicant will not be able to compare our anticipated charges with the charge information from these existing providers. The Joint Annual Reports do not segregate costs/charges by service.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: There is some historical utilization as the Applicant was approved for interventional pain management services for a time, prior to the HSDA reversing that approval. In 2011, the Applicant saw 179 patients, and the number increased to 1,778 patients in 2012. In 2013, the number of patients fell to 470, as the service was shut down, per instructions from the HSDA.

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at our facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

2013 AUG 15 PM 2 35

1. **Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.**

-- **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)**

-- **The cost of any lease should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater.**

-- **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

-- **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

Response: The Project Costs Chart is completed. This Application includes administrative costs, only, as there is no construction, no renovation, and no new equipment costs. The higher of FMV and/or lease costs for the site were approved when the original ASTC was approved.

PROJECT COSTS CHART

A. Construction and equipment acquired by purchase.

2013 AUG 15 PM 2 35

1.	Architectural and Engineering Fees	
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant	50,000 .00
3.	Acquisition of Site	
4.	Preparation of Site	
5.	Construction Costs	
6.	Contingency Fund	
7.	Fixed Equipment (Not included in Construction Contract)	
8.	Moveable Equipment (List all equipment over $50,000)*	
9.	Other (Specify)	
	Subsection A Total	**50,000 .00**

B. Acquisition by gift, donation, or lease.

1.	Facility (Inclusive of Building and Land) (FMV)	.00
2.	Building Only	
3.	Land Only	
4.	Equipment (Specify)	
5.	Other (Specify)	
	Subsection B Total	**.00**

C. Financing costs and fees

1.	Interim Financing	
2.	Underwriting Costs	
3.	Reserve for One Year's Debt Service	
4.	Other (Specify)	
	Subsection C Total	**0 .00**

D.	Estimated Project Cost (A + B + C)		$ 50,000.00
E.	CON Filing Fee		$ 3,000.00
F.	Total Estimated Project Cost (D + E)	TOTAL	$ 53,000.00

2. **Identify the funding sources for this project.** 41

   a. **Please check the applicable item(s) below and briefly summarize how the project will be financed.** ***(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)***

___ **A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

___ **B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**

___ **C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.**

___ **D. Grants--Notification of intent form for grant application or notice of grant award; or**

_x_ **E. Cash Reserves--Appropriate documentation from Chief Financial Officer.**

___ **F. Other—Identify and document funding from all other sources.**

Response: The only costs for this project are administrative. Cash Reserves have been utilized to pay for these costs.

3. **Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.**

Response: The Project Costs Chart is completed. The only costs for this project are administrative. Cash Reserves have been utilized to pay for these costs. The project cost totals $53,000.

The most recent comparable ASTC approved by the HSDA was the PCET Surgery Center in Knoxville, approved at the May 23, 2012 HSDA meeting. That particular project cost was $1,396,681.

The Surgical and Pain Treatment Center of Clarksville, LLC was denied at the December 12, 2012 meeting of the HSDA, and the project cost of that project was $1,012,993.

Therefore, our project cost is extremely reasonable.

4. **Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).**

Response: Historical and Projected Data Charts are completed.

Historical Data Chart:

The Historical Data Chart is attached.

Projected Data Chart:

This chart includes projected data for interventional pain management procedures for the Applicant. Note that the Applicant anticipates positive cash flow in both years.

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (month).

Response: Not Applicable

		YTD 2013	2012	2011
A.	Utilization/Occupancy Rate (Patients)	470	1778	179
B.	Revenue from Services to Patients			
	1. Inpatient Services			
	2. Outpatient Services	1,099,224	4,713,421	593,405
	3. Emergency Services			
	4. Other Operating Revenue (Specify) _____			
	Gross Operating Revenue	**1,099,224**	**4,713,421**	**593,405**
C.	Deductions from Operating Revenue			
	1. Contractual Adjustments	839,367	3,275,356	429,041
	2. Provision for Charity Care	43,970	547,760	67,500
	3. Provision for Bad Debt	18,027	78,023	10,134
	Total Deductions	**901,364**	**3,901,139**	**506,675**
	NET OPERATING REVENUE	**197,860**	**812,282**	**86,730**
D.	Operating Expenses			
	1. Salaries and Wages	38,660	136,104	5,341
	2. Physician's Salaries and Wages	24,000	48,000	12,000
	3. Supplies	41,029	103,800	3,284
	4 . Taxes	3,240	5,528	7,348
	5 . Depreciation			
	6. Rent	36,000	36,000	36,000
	7. Interest, other than Capital			
	8. Management Fees:			
	a. Fees to Affiliates			
	b. Fees to Non-Affiliates			
	9. Other Expenses (Consulting, advertising, utilities, office supplies, insurance), equipment lease	82,954	175,112	39,597
	Total Operating Expenses	**225,883**	**504,544**	**103,570**
E.	Other Revenue (Expenses)-Net (Specify)_____			
	NET OPERATING INCOME (LOSS)	**(28,023)**	**307,738**	**(16,840)**
F.	Capital Expenditures			
	1. Retirement of Principal			
	2. Interest			
	Total Capital Expenditure			
	NET OPERATING INCOME (LOSS) LESSCAPITAL EXPENDITURES	**(28,023)**	**307,738**	**(16,840)**

PROJECTED DATA CHART

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

Give information for the two (2) years following the completion of this project. The fiscal year begins in January (month).

		Year 1	Year 2
A.	Utilization/Occupancy Rate (Patients)	2,700	3,100
	Revenue from Services to Patients		
	1. Inpatient Services		
	2. Outpatient Services	6,480,000	7,440,000
	3. Emergency Services		
	4. Other Operating Revenue (Specify)		
	Gross Operating Revenue	**6,480,000**	**7,440,000**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	4,665,600	5,356,800
	2. Provision for Charity Care	324,000	372,000
	3. Provision for Bad Debt	194,400	223,200
	Total Deductions	**5,184,000**	**5,952,000**
	NET OPERATING REVENUE	**1,296,000**	**1,488,000**
D.	Operating Expenses		
	1. Salaries and Wages	240,000	276,000
	2. Physician's Salaries and Wages	72,000	84,000
	3. Supplies	168,480	193,440
	4 . Taxes	9,000	10,350
	5 . Depreciation		
	6. Rent	39,000	39,000
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses (Specify) consulting, advertising, utilities, office supplies, insurance, equipment lease	225,120	288,170
	Total Operating Expenses	**783,600**	**890,960**
E.	Other Revenue (Expenses)-Net (Specify)	0	0
	NET OPERATING INCOME (LOSS)	**512,400**	**597,040**
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest (on Letter of Credit)		
	Total Capital Expenditure		
	NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	**512,400**	**597,040**

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am
OCT 22 '13 9:40

PROJECTED DATA CHART (ENTIRE FACILITY)

Give information for the two (2) years following the completion of this project. The fiscal year begins in January (month).

		Year 1	Year 2
A.	Utilization/Occupancy Rate (Patients)	2,800	3,215
	Revenue from Services to Patients		
	1. Inpatient Services		
	2. Outpatient Services	7,980,000	9,165,000
	3. Emergency Services		
	4. Other Operating Revenue (Specify)		
	Gross Operating Revenue	**7,980,000**	**9,165,000**
C.	Deductions from Operating Revenue		
	1. Contractual Adjustments	5,715,600	6,564,300
	2. Provision for Charity Care	406,500	466,875
	3. Provision for Bad Debt	261,900	300,825
	Total Deductions	**6,384,000**	**7,332,000**
	NET OPERATING REVENUE	**1,596,000**	**1,833,000**
D.	Operating Expenses		
	1. Salaries and Wages	322,500	373,150
	2. Physician's Salaries and Wages	72,000	84,000
	3. Supplies	186,960	215,550
	4 . Taxes	9,000	10,350
	5 . Depreciation		
	6. Rent	39,000	39,000
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses (Specify) consulting, advertising, utilities, office supplies, insurance, equipment lease	281,400	360,215
	Total Operating Expenses	**910,860**	**1,082,265**
E.	Other Revenue (Expenses)-Net (Specify)	0	0
	NET OPERATING INCOME (LOSS)	**685,140**	**750,735**
F.	Capital Expenditures		
	1. Retirement of Principal		
	2. Interest (on Letter of Credit)		
	Total Capital Expenditure		
	NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	**685,140**	**750,735**

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Response: See (rounded) figures below for Year 1:

$	2,400	Average Gross Charge per procedure
$	1,920	Average Deduction from Operating Revenue per procedure
$	480	Average Net Charge per procedure.

The above charges are facility charges, only. Doctors will bill for their services separately.

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Response: See (rounded) figures below for Year 1:

$	2,400	Average Gross Charge per procedure
$	1,920	Average Deduction from Operating Revenue per procedure
$	480	Average Net Charge per procedure.

The above charges are facility charges, only. Doctors will bill for their services separately.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: *Attachment C.N.5.A* is a list of all hospitals in the service area that report performing pain management services. None of these hospitals are exclusively dedicated to pain management.

Attachment C.N.5.B is a list of all ASTCs in the service area that report performing pain management services. None of these ASTCs are exclusively dedicated to pain management.

The fact that no existing hospitals or ASTCs are dedicated to pain management is not a derogatory statement. It merely points out the fact that the Applicant will not be able to compare our anticipated charges with the charge information from these existing providers. The Joint Annual Reports do not segregate costs/charges by service.

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Response: The Projected Data Chart indicates sufficient income to maintain cost-effectiveness, with a positive cash flow for both projected years. Obviously, income is dependent upon rendering services to a sufficient number of patients. The Applicant believes such will be the case.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Response: The Projected Data Chart indicates sufficient income to maintain cost-effectiveness, with a positive cash flow for both projected years. Obviously, income is dependent upon rendering services to a sufficient number of patients. The Applicant believes such will be the case.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

Medicare and TennCare Revenue Projections: Based on the patients seen by the Applicant when interventional pain management services were being provided, we anticipate the following patients:

Medicare	71.0%
Medicaid	7.5%
Commercial	21.5%

Based on these projections, it is anticipated that the impact on Medicare will be as follows:

$6,480,000 x 71.0% = $4,600,800.

Likewise, it is anticipated that the impact on Medicaid will be as follows:

$6,480,000 x 7.5% x 30% State Share = $145,800.

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

Response: Please see *Attachment C.EF.10* for financials of the Applicant and one of the owners. The Applicant is owned by Lensgraf Clinic, P.C. (50%), Wayne McLemore, M.D. (25%), and Cynthia Niendorff, M.D. (25%). The LLC is member-managed. As there are minimal costs for this project, and those costs have already been paid, it should be obvious that sufficient funds are available for this project.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

a. **A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

Response: There were no other viable alternatives considered.

As stated earlier, the Applicant was approved to provide MUA services. When we began the procedures, we were advised by the insurers that we had to attempt interventional pain management procedures first, or we would not be compensated for the traditional MUA procedure. We felt that interventional pain management procedures were a part of MUA, and requested a determination from the HSDA to that extent. We were approved by the HSDA to perform these procedures, and we did so. Later, the HSDA decided we could not perform such procedures and we had to cease providing them. Since we cannot be compensated for what we have already been approved for, we had to submit this application.

b. **The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.**

Response: There were no other viable alternatives considered.

As stated earlier, the Applicant was approved to provide MUA services. When we began the procedures, we were advised by the insurers that we had to attempt interventional pain management procedures first, or we would not be compensated for the traditional MUA procedure. We felt that interventional pain management procedures were a part of MUA, and requested a determination from the HSDA to that extent. We were approved by the HSDA to perform these procedures, and we did so. Later, the HSDA decided we could not perform such procedures and we had to cease providing them. Since we cannot be compensated for what we have already been approved for, we had to submit this application.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

Response: The applicant has a contractual relationship with STATCARE Medical Group, a division of Summit Medical Group, PLLC. Through this contract, patients of the Applicant can be admitted to Fort Sanders Regional Medical Center, Parkwest Medical Center, St. Mary's Medical Center, St. Mary's North Medical Center and Laughlin Memorial Hospital. See Attachment C.OD.1.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: The approval of this application should not have a material adverse impact on any health care providers in the State. There are no other facilities in our service area that are dedicated to the provision of both interventional pain management and MUA procedures, and the Applicant is not aware of any data that would indicate any existing providers (hospitals or ASTCs) are already providing these procedures.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: According to the Tennessee Department of Labor and Workforce Development, there are no published reports available indicating the personnel positions required for the operation of a specialty ASTC. As the publishing of such information might be considered a violation of Anti-Trust, existing ASTCs cannot get together and decide on what salaries to pay for these positions. It should be assumed that existing salaries will be commensurate with both abilities and the marketplace, and the Applicant will maintain that staff. *Attachment C.OD.3* contains affiliated health care workers data.

Existing staff at the Applicant's ASTC will be utilized for this service, and no new staff will be required.

The Applicant works with area training programs to allow students to rotate though our facility to complete clinical training requirements. Further, doctors have been trained in the ASTC.

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Response: According to the Tennessee Department of Labor and Workforce Development, there are no published reports available indicating the personnel positions required for the operation of a specialty ASTC. As the publishing of such information might be considered a violation of Anti-Trust, existing ASTCs cannot get together and decide on what salaries to pay for these positions. It should be assumed that existing salaries will be commensurate with both abilities and the marketplace, and the Applicant will maintain that staff. *Attachment C.OD.3* contains affiliated health care workers data.

Existing staff at the Applicant's ASTC will be utilized for this service, and no new staff will be required.

The Applicant works with area training programs to allow students to rotate though our facility to complete clinical training requirements. Further, doctors are trained in the ASTC.

5. **Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review *policies and programs, record keeping, and staff education.***

Response: The Applicant is familiar with licensing certification requirements for an ASTC, as the facility is already licensed.

6. **Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (*e.g.*, internships, residencies, etc.).**

Response: The Applicant works with area training programs to allow students to rotate though our facility to complete clinical training requirements. Further, doctors have been trained in the ASTC.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

Response: The Applicant is familiar with licensing certification requirements for an ASTC, as the facility is already licensed.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Response:

Licensure: Tennessee Department of Health.

Accreditation: Medicaid, Medicare, TennCare, JCAHO

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Response: The ASTC is licensed. Please see Attachment C.OD.7(c).

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Response: Please see Attachment C.OD.7(d), which includes both TDOH Licensure survey and JCAHO survey information.

8. **Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.**

Response: There have been no final orders or judgments as are contemplated by this question.

9. **Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project**

Response: There have been no final orders or judgments as are contemplated by this question.

10. **If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.**

Response: The Applicant will provide all data contemplated by this question.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Response: Please see attached tear sheet from *The Knoxville News Sentinel.*

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. **Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**
2. **If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph,* please state below any request for an extended schedule and document the "good cause" for such an extension.**

Form HF0004
Revised 05/03/04
Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c): 11/2013.

2013 AUG 15 PM 2 36

Assuming the CON approval becomes the final agency action on that date; indicate the number of day **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed		
2. Construction documents approved by the Tennessee Department of Health		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete (approved for occupancy (renovation)		
10. *Issuance of license	60	02/2014
11. *Initiation of service	60	02/2014
12. Final Architectural Certification of Payment		
13. Final Project Report Form (HF0055)		

*** For projects that do NOT involve construction or renovation : Please complete items 10 and 11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

2013 AUG 15 PM 2 36

E. Graham Baker, Jr., being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of his/her knowledge.

E Graham Baker, Jr

SIGNATURE/TITLE

Sworn to and subscribed before me this 15th day of August, 2013, a
(month) (year)

Notary Public in and for the County/State of Davidson/Tennessee.

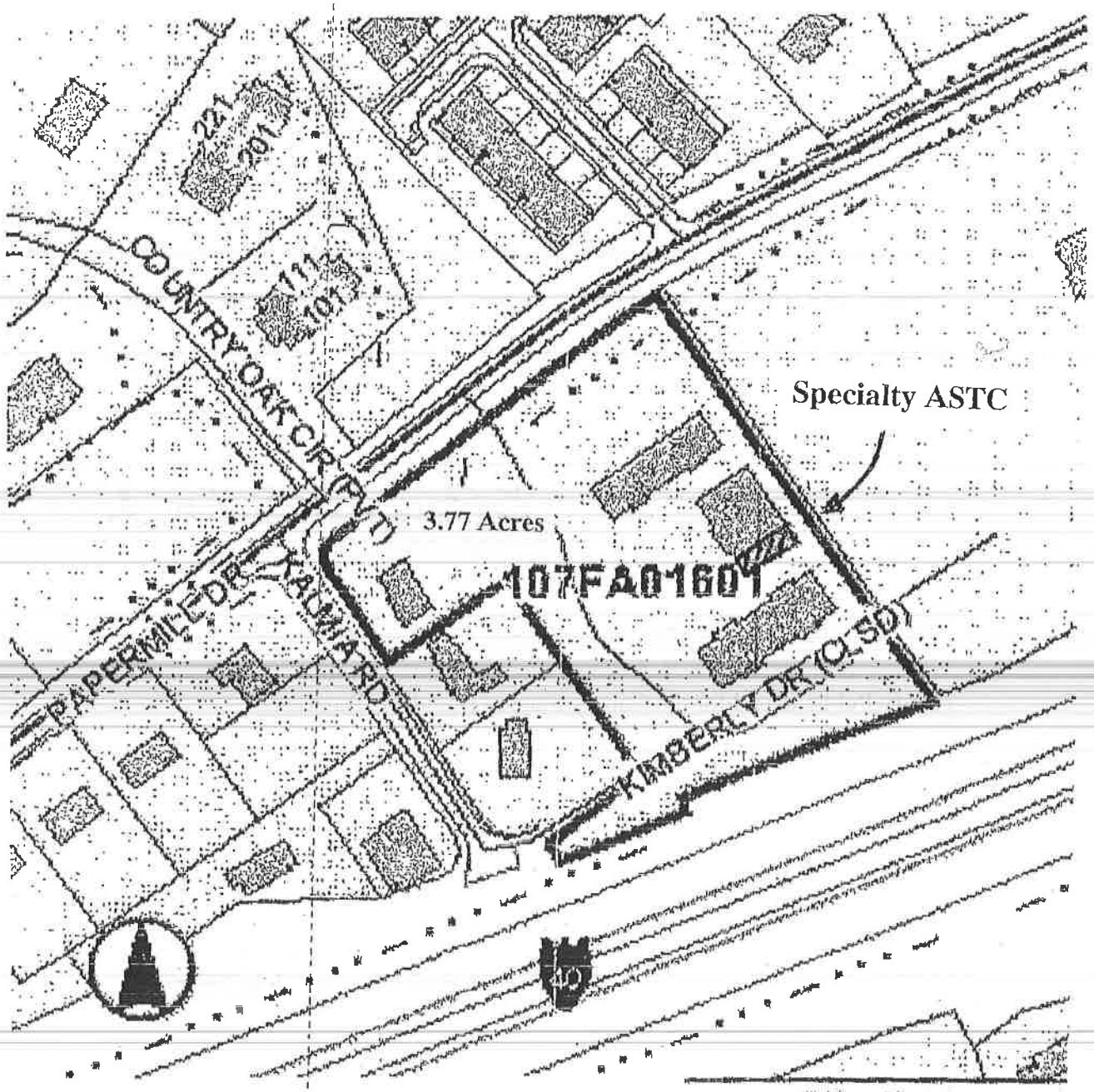
Nadean E. Poteet

NOTARY PUBLIC

NADEAN E. POTEET STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY

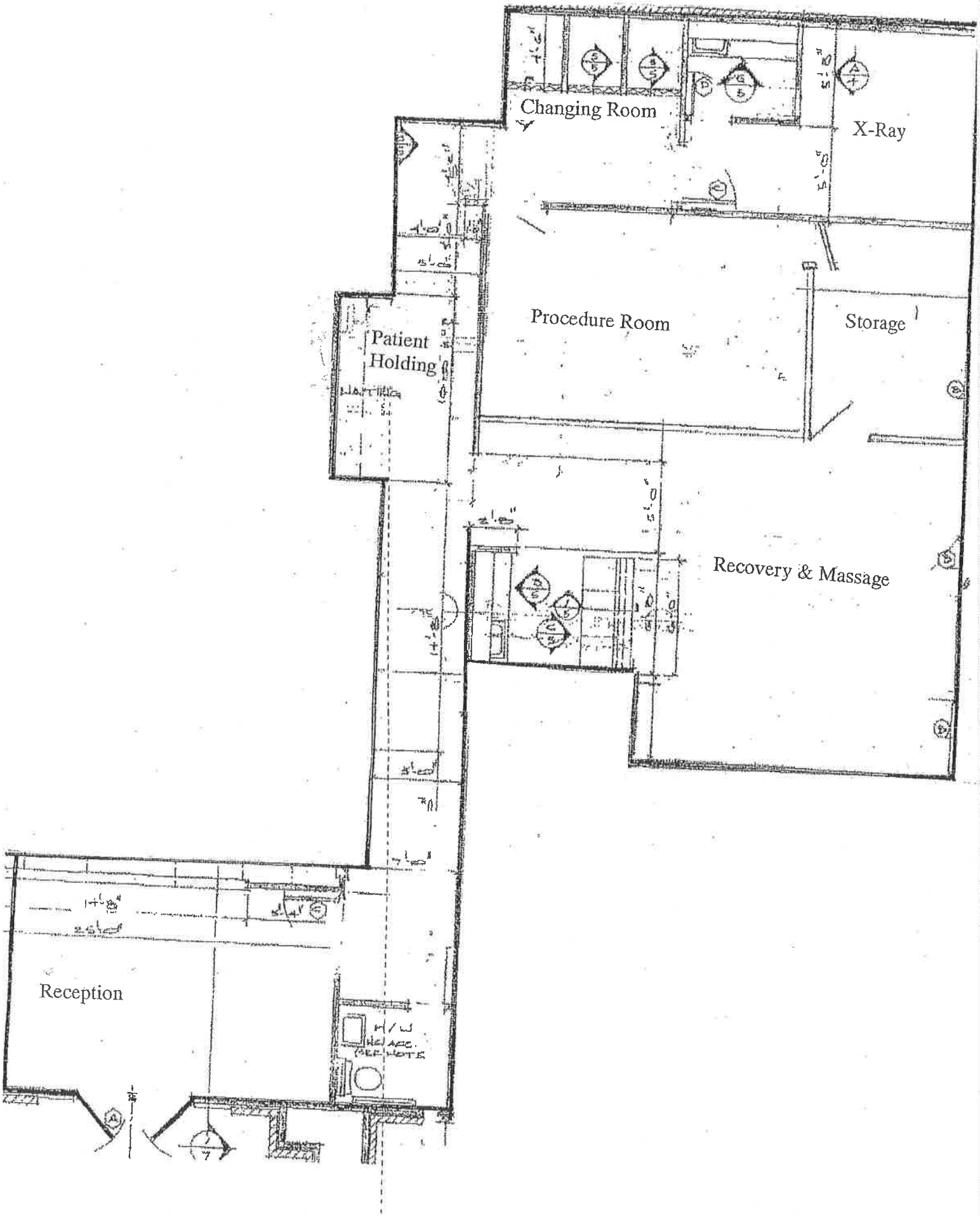
My commission expires July 3, 2017.

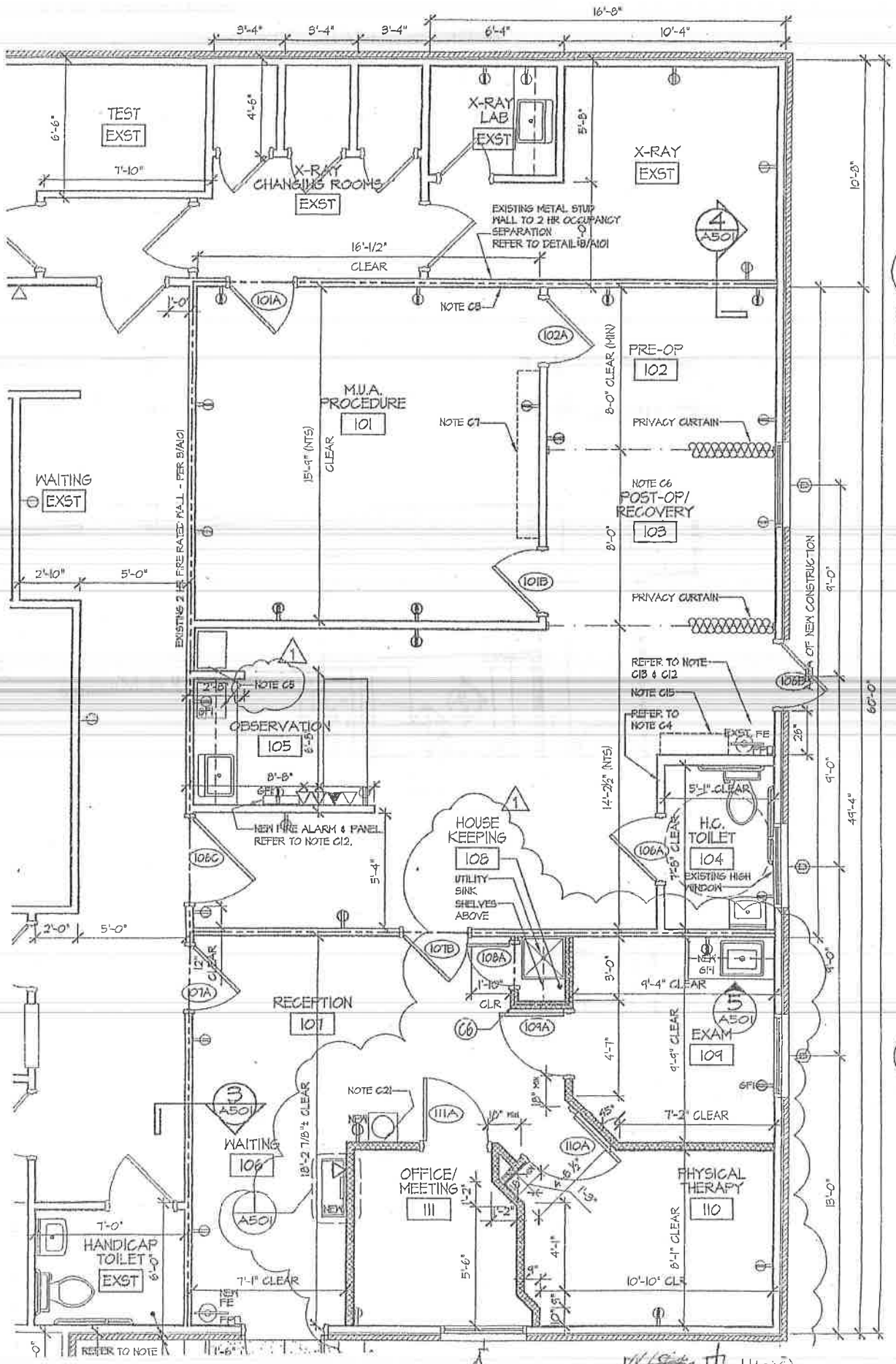
Attachment B.III.2



Map provided by KGIS - Copyright(c) 2007 0 207

Attachment B.IV





Approx 1400

ROOM NO.	F
101	M
102	P
103	P
104	T
105	O
106	W
107	R
108	H
109	E
110	P
111	O

FINISH N

1. INTERIOR SMOKE DEVE BUILDING CO (0-25, 0-450 0-450). THE PANEL TEST

2. INTERIOR TO BE SELEC

3. VINYL BA

4. PAINT GY GYPSUM BOA EXISTING FLC

5. PROVIDE

6. ALL CEILI REQUIRED BY

7. PROVIDED

8. PAINT CEI

MARK	W
101A	3
101B	3
102A	3
106A	3
106B	3
106C	4
107A	3
107B	3
107C	3
108A	2
109A	3
110A	3
111A	3

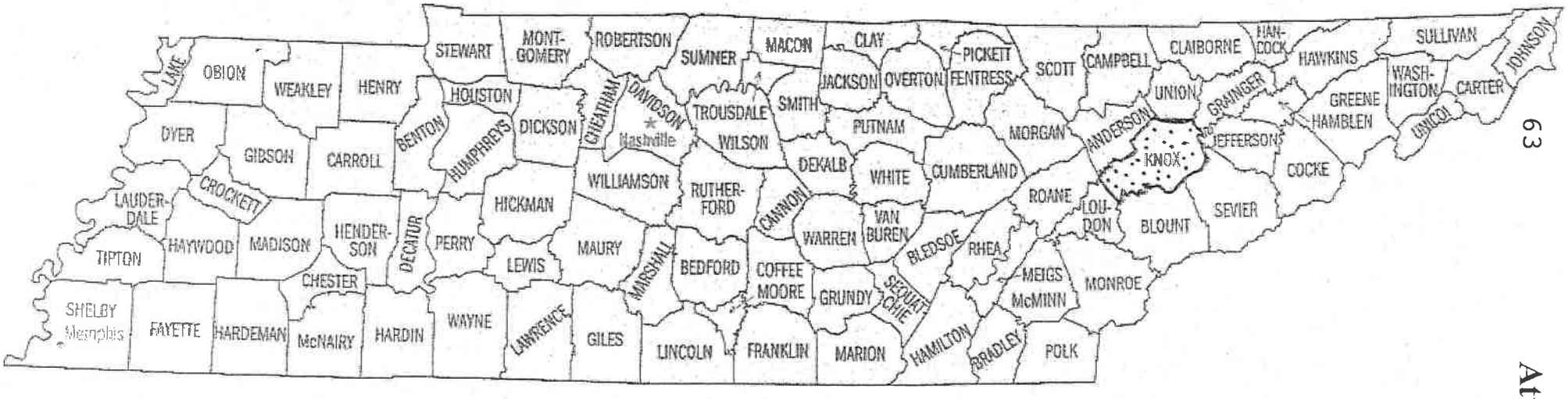
DOOR N

1. SEE SPECIFI
2. WEATHER-ST
3. INSULATED D
4. EXISTING FIR
5. EXISTING NO
6. EXISTING DO
7. MATCH EXIST
8. PROVIDE DC
9. REMOVE EXI

DOOR TYP

2" DOOR

Tennessee County Map



2013 AUG 15 PM 2 36

STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

AMBULATORY SURGICAL TREATMENT CENTERS

Determination of Need

1. **Need. The minimum numbers of 884 Cases per Operating Room and 1867 Cases per Procedure Room are to be considered as baseline numbers for purposes of determining Need. An applicant should demonstrate the ability to perform a minimum of 884 Cases per Operating Room and/or 1867 Cases per Procedure Room per year, except that an applicant may provide information on its projected case types and its assumptions of estimated average time and clean up and preparation time per Case if this information differs significantly from the above-stated assumptions. It is recognized that an ASTC may provide a variety of services/Cases and that as a result the estimated average time and clean up and preparation time for such services/Cases may not meet the minimum numbers set forth herein. It is also recognized that an applicant applying for an ASTC Operating Room(s) may apply for a Procedure Room, although the anticipated utilization of that Procedure Room may not meet the base guidelines contained here. Specific reasoning and explanation for the inclusion in a CON application of such a Procedure Room must be provided. An applicant that desires to limit its Cases to a specific type or types should apply for a Specialty ASTC.**

Response:

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

2. **Need and Economic Efficiencies. An applicant must estimate the projected surgical hours to be utilized per year for two years based on the types of surgeries to be performed, including the preparation time between surgeries. Detailed support for estimates must be provided.**

Response:

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several

doctors in the Knoxville area. Each procedure will take less than 15 minutes, including clean-up time. This is a procedure room, and needs only to be clean – not sterile.

- The ASTC will be available Monday through Friday, 8 hours per day. This means that the ASTC will be available 120,000 minutes per year (5 days x 8 hours x 60 minutes x 50 weeks), meaning that in Year 1, 44 minutes will be available for each procedure, and in Year 2, about 39 minutes will be available for each procedure. Since each procedure will take less than 15 minutes, sufficient time will be available.

3. **Need; Economic Efficiencies; Access. To determine current utilization and need, an applicant should take into account both the availability and utilization of either: a) all existing outpatient Operating Rooms and Procedure Rooms in a Service Area, including physician office based surgery rooms (when those data are officially reported and available) OR b) all existing comparable outpatient Operating Rooms and Procedure Rooms based on the type of Cases to be performed. Additionally, applications should provide similar information on the availability of nearby out-of-state existing outpatient Operating Rooms and Procedure Rooms, if that data are available, and provide the source of that data. Unstaffed dedicated outpatient Operating Rooms and unstaffed dedicated outpatient Procedure Rooms are considered available for ambulatory surgery and are to be included in the inventory and in the measure of capacity.**

Response:

Attachment C.N.5.A is a list of all hospitals in the service area that report performing pain management services. None of these hospitals are exclusively dedicated to pain management.

Attachment C.N.5.B is a list of all ASTCs in the service area that report performing pain management services. None of these ASTCs are exclusively dedicated to pain management.

The fact that no existing hospitals or ASTCs are dedicated to pain management is not a derogatory statement. It merely points out the fact that the Applicant will not be able to compare our anticipated charges with the charge information from these existing providers. The Joint Annual Reports do not segregate costs/charges by service.

The approval of this application should not have a material adverse impact on any health care providers in the State. There are no other facilities in our service area that are dedicated to the provision of both interventional pain management and MUA procedures, and the Applicant is not aware of any data that would indicate any existing providers (hospitals or ASTCs) are already providing these procedures.

4. **Need and Economic Efficiencies. An applicant must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed, if those services are known and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above.**

Response:

Attachment C.N.5.A is a list of all hospitals in the service area that report performing pain management services. None of these hospitals are exclusively dedicated to pain management.

Attachment C.N.5.B is a list of all ASTCs in the service area that report performing pain management services. None of these ASTCs are exclusively dedicated to pain management.

The fact that no existing hospitals or ASTCs are dedicated to pain management is not a derogatory statement. It merely points out the fact that the Applicant will not be able to compare our anticipated charges with the charge information from these existing providers. The Joint Annual Reports do not segregate costs/charges by service.

The approval of this application should not have a material adverse impact on any health care providers in the State. There are no other facilities in our service area that are dedicated to the provision of both interventional pain management and MUA procedures, and the Applicant is not aware of any data that would indicate any existing providers (hospitals or ASTCs) are already providing these procedures.

5. **Need and Economic Efficiencies. An application for a Specialty ASTC should present its projections for the total number of cases based on its own calculations for the projected length of time per type of case, and shall provide any local, regional, or national data in support of its methodology. An applicant for a Specialty ASTC should provide its own definitions of the surgeries and/or procedures that will be performed and whether the Surgical Cases will be performed in an Operating Room or a Procedure Room. An applicant for a Specialty ASTC must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON proposal to establish a Specialty ASTC or to expand existing services of a Specialty ASTC shall not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above. An applicant that is granted a CON for a Specialty ASTC shall have the specialty or limitation placed on the CON.**

Response:

Procedures: It is projected that 2,700 and 3,100 interventional pain management procedures will be performed in years 1 and 2, respectively. These projections are based on historical utilization at the Applicant's facility, coupled with anecdotal information retrieved from several doctors in the Knoxville area.

The ASTC will be available Monday through Friday, 8 hours per day. This means that the ASTC will be available 120,000 minutes per year (5 days x 8 hours x 60 minutes x 50 weeks), meaning that in Year 1, 44 minutes will be available for each procedure, and in Year 2, about 39 minutes will be available for each procedure. Since each procedure will take less than 15 minutes, sufficient time will be available.

Other Standards and Criteria

6. **Access to ASTCs. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility.**

Response:

The majority of patients in the service area will reside within 60 minutes average driving time to our facility.

7. **<u>Access to ASTCs</u>. An applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available.**

Response:

Buses run on Papermill Pointe Way, and private taxis are also available.

8. **<u>Access to ASTCs</u>. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project the origin of potential patients by percentage and county of residence and, if such data are readily available, by zip code, and must note where they are currently being served. Demographics of the Service Area should be included, including the anticipated provision of services to out-of-state patients, as well as the identity of other service providers both in and out of state and the source of out-of-state data. Applicants shall document all other provider alternatives available in the Service Area. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.**

Response:

The service area is Knox County.

9. **<u>Access and Economic Efficiencies</u>. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters following completion of the project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.**

Response:

It is anticipated that utilization will be as follows:

1st Quarter	675 procedures
2nd Quarter	675 procedures
3rd Quarter	675 procedures
4th Quarter	675 procedures
5th Quarter	775 procedures
6th Quarter	775 procedures
7th Quarter	775 procedures
8th Quarter	775 procedures

10. **<u>Patient Safety and Quality of Care; Health Care Workforce</u>.**

    a. **An applicant should be or agree to become accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization.**

b. **An applicant should estimate the number of physicians by specialty that are expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel. An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.**

Response:

The Applicant is licensed by the TDOH, is certified by both Medicare and Medicaid, and is accredited by JCAHO.

To date, at least 8 physicians have utilized our ASTC.

11. **Access to ASTCs. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:**

    a. **Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;**

    b. **Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program;**

    c. **Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or**

    d. **Who is proposing to use the ASTC for patients that typically require longer preparation and scanning times. The applicant shall provide in its application information supporting the additional time required per Case and the impact on the need standard.**

Response:

The Applicant agrees that every citizen should have reasonable access to health care. When we opened our ASTC, many patients (179 in 2011; 1778 in 2012, and 470 YTD in 2013) received care at our facility. We contract with AmeriChoice, BlueCare and TennCare Select, and are Medicare certified.

Policies and Procedures for Manipulation Under Anesthesia

Robert C. Gordon, D.C., FABCS, FRCCM, DAAPM

Purpose

The purpose of writing these policies and procedures is for facilities or doctors or the staff of a facility to have a guideline for providing the service of the technique of Manipulation Under Anesthesia (MUA). It will be used in conjunction with the National Academy of MUA Physicians standards and protocols, and will be used to determine the types of doctors who may use the facilities for MUA; the educational standards required for staff privileges for the use of MUA; for the patient logistical movement in the facility; the required policy for the use of the MUA procedure; the basis for clinical selection of cases for the MUA procedures; the accepted and suggested follow-up post care requirement for the MUA patients; and for the overall guidelines for the MUA procedures that may not be part of the mentioned areas above.

Educational Standards

It shall be the policy of this facility that the doctors that are performing this procedure must have achieved 36 hours of postgraduate instruction in MUA from a CCE/CME accredited Chiropractic or Medical school, and that those hours contain education in: The history of the MUA procedure; the scientific basis of the MUA procedure; the clinical application of the patients for MUA; the proper selection of the patients for MUA (use of the NAMUAP standards and protocols); two week-ends of education in MUA consisting of a didactic education and workshops, an examination both oral and written, and a second week-end which allows the doctors to be proctored on actual patients with hands on training in the MUA procedure. This standard of education has long been the standard of education for MUA since its inception, and has been taught by the original MUA instructors since the late 80's in the chiropractic profession. Since the MDs and the DOs have no formal MUA program at this time in their institutions most MDs and DOs have been taking their training from the chiropractic profession. There is a preponderance of evidence that the education of the doctors performing this procedure must follow extensive standards that have long been the standard of education to understand the full process of MUA. There is also evidence that if proper education in the area of billing and working with insurance companies is not completed properly there is no proper follow-up for graduating doctors, and therefore no education in the proper use of coding, and fee structures. This should be considered when a doctor becomes a part of a facility. The doctors that use this facility must have an idea of proper billing procedures, and must follow standards that allow for conservative billing practices as taught in the long standing older courses. The older courses still teach proper billing practices and therefore will be used as the gold standard for any doctor that has taken the training.

Proper Patient Selection

It shall be the policy of the facility that the proper selection of patients for this procedure should be foremost in the mind of the practitioner of MUA. Proper selection of the patient is the purest form of proper outcomes, and the essence of a good MUA program is the highest recovery rate possible from those patients selected to undergo MUA. The use of the National Academy of

MUA Physicians is a good start for this section. Other algorithms that follow standard care for various conditions may also be formatted to fit this particular section, and may be included in additional appendixes within this policies and procedures protocols.

Clinical Efficacy of Manipulation Under Anesthesia(MUA)

It has long been the practice of the doctor involved in physical medicine and chiropractic that the movement, mobilization, manipulation, and adjusting of joints, joint capsules, and surrounding holding elements (muscles, ligaments, and tendons) of aberrant articulations can decrease the patients pain and increase range of motion. Literature and reference of all kinds for many years has contended, and research has proven that to relocate abnormal articulations and correct misalignment from biomechanical abnormalities creates an atmosphere of correction and recovery from which patients respond very well. The chiropractic profession, as well as the osteopathic profession, have long stood behind these practices, and the medical profession in most recent years have also given credence to mobilization and manipulation as a real alternative to other frequently used methods of medical pharmacologic intervention or surgery.

Manipulation under anesthesia is a modality which has been used by all of the above mentioned practitioners since the early 30's to bring about the correction of biomechanical abnormalities that would only respond minimally to conservative office based manual therapy in its various forms. The object and therefore the clinical justification for the use of MUA is simply to relax the patient and then make the corrections in the biomechanical abnormality by means of stretching mobilization and manipulation of the articulations that are involved in the abnormal mechanical alteration. If the right anesthesia is introduced in a proper environment that allows the patient to respond, but be less apprehensive and have less discomfort, the practitioner who has MUA certificate training is better able to make corrections such that the patient gains back range of motion and therefore is relieve of neurological stressors that cause painful response while they are being compressed. To make more out of this than this simple statement is complicating a very well received and very well used procedure that causes many recoveries that would not respond if not for this procedure being used.

Clinically we are basically taking arthrokinectic dysfunctional anatomy which is causing fibroblastic proliferative changes (adhesions) to be formed, altering them, and giving back normal movement and in the process decreasing pain and dysfunction.

Patient Selection Criteria

In conjunction with the National Academy of MUA Physicians and following their standards and protocols the following would be indicated but may not be limited to: Following the standards of proper care as outlined by the NAMUAP standards and protocols which calls for a minimum of 4-6 weeks of conservative manual therapy care:

1. The patient must exhibit pain and or muscle spasm/contracture documented by three of the following:
   a. Observation
   b. Palpation

c. Visual analog scale
d. Measurement (algometry)
e. History
f. Objective testing such as MRI, CT, EMG, Surface EMG, Mechanical Dermatomal alteration, or other well established diagnostic testing modalities.
g. Standardized pain questionnaire such as Oswestry or Roland Morris

2. The patient must also be diagnosed as having a primary neuromusculoskeletal complaint as the primary cause of the patients complaint using the standard MUA protocols for MUA patient selection criteria (NAMUAP).

3. The patient's diagnosed condition must interfere with the patient's **activities of daily living** as outlined in the history and physical, and fall within the standard **indications** for MUA, as referenced in: "Manipulation Under Anesthesia, Concepts In Theory and Application", R. Gordon, April 2005, Taylor and Francis, and the NAUMAP standards and protocols.

4. Sufficient care has been rendered prior to MUA selection as referenced above.

5. The patient has been informed of other treatments that might also be available, but has chosen to proceed with the MUA procedure after adequate explanation of the risks and benefits.

Medical Clearance and Standardized Review

Medical clearance is required for MUA just like medical clearance is required for any procedure completed under anesthesia. The requirements for medical clearance vary for each state, and each facility and the anesthesiologists requirements before anesthesia is provided. This determines what the standard testing will be required before the patient undergoes MUA. In general the class one patient will be required to have a physical examination involving all systems, heart, respiratory system, liver, abdomen, eyes nose and throat, and complete musculoskeletal and neurological work up. Blood work that is required is usually minimal (ex. SMAC 6) just to rule out any problems that might prevent excretion of medicines and slow metabolism etc.. Most facilities also require that the patients over 40-50 undergo an EKG, and if respiratory problems are suspected, or asthma, a chest x-ray. Since we only choose patients that fall within the class 1 or with evaluation class 2 anesthesia criteria, these tests are fairly routine in most facilities.

The other requirement is for medical supervision and oversight. Medical presence should be part of the team approach for MUA. It should be remembered that this not a one type of physician procedure. This is a team procedure and cannot be accomplished by one or even two practitioners. We teach in class that this is not a chiropractic procedure but rather a procedure that chiropractic physicians take part in. In order for this procedure to be completed there needs to be a medical clearance physician as mentioned above, there needs to be anesthesia clearance and an anesthesia practitioner involved, there needs to be medial oversight, there needs to be two

trained MUA practitioners to perform the procedure, and there needs to be nursing supervision of the patient during and after the procedure in recovery before the patient is sent home.

Treatment Protocols

1. The following must be considered when considering the treatment and the numbers of treatments necessary to achieve the desired results in the MUA field:

   a. Chronicity
   b. Length of current conservative therapy program
   c. Patients age
   d. Numbers of previous injuries to the same area
   e. Level of unimproved pain
   f. Patient acceptance
   g. Muscle contracture (beyond splinting)
   h. Interference with activities of daily living (ADLs)
   i. Augmentation of adhesion build up, esp. with failed back surgery
   j. Possible surgical intervention if MUA is not tried at this juncture of the patient's recovery. Serial MUA considered to prevent surgery where one procedure might still make the patient a surgical candidate, three or four MUAs might prevent the surgical intervention (ref. NAMUAP).

2. The usual and customary protocols for MUA have been to provide serial fashion MUA, where the procedure is repeated in three successive days. This approach over the years has proven to be very beneficial to the patient, and has been clinically justified by the referenced fact that when correcting adhesion build up, if collagen fibers are not addressed during remodeling in an intensive format, which is what MUA does, then adhesions (or fibroblastic proliferative tissue) begins to reform in 24-48 hours. It is the contention by the MUA community that if we were to allow for one MUA to be performed, and then waited a week to do another one etc., then the process of reformation and remodeling would not take place, but rather the adhesion would reform again. In doing that we would be constantly working to control the reformation of the adhesions that had formed over the period of time since the patient was injured. It has been shown doing MUA in serial fashion and based on the references that performing multiple MUAs and then following the MUAs with immediate post MUA care to be described later in these policies and procedures, that the adhesions do not form back as before as evidenced by the patient gaining considerable range of motion and decreased pain and in many cases an 80 to 90% recovery with the proper patient selection.

3. Post MUA Care – is without a doubt, one of the most important phases of the MUA procedure. With the fibroblastic proliferative tissues altered in an intensified manner, the joints, joint capsules, and the surround holding elements must undergo continuous motion and joint manipulation/adjusting to help reform those collagen fibers in order to maintain the status of improvement that was achieved during the MUA procedure. In the past, post care was carried on in a normal conservative fashion, however, it is now believed that immediate intensified post care consisting of immediate same day therapy using the exact

same stretches that were used during the MUA procedure, followed by 7-10 days of continuous motion, mobilization and manipulation with minimal resistance, followed by 2 weeks of pre-rehabilitation using slight to moderate resistive forces, and then 4 weeks of formal circuit training rehabilitation will give the best outcomes. This regime has been used over and over by the MUA community, and has been found to be the best approach to maintaining the improvement that was achieved during the MUA procedure itself. Since the end result of this procedure is recovery from the conditions that were chosen to receive the MUA procedure, and to maintain the status post recovery, the patient has to undergo changes in their life style, and feel a sense of accomplishment in not only the therapy that was administered using the MUA procedure, but in their own benefit by their participation in the recovery process.

Operative Procedure (this report is a guideline and sample for the full spine procedure referenced in the textbook, "Manipulation Under Anesthesia, Concepts In Theory and Application; R. Gordon....it is not meant to replace standard documentation specifically dictated for each procedure for each day the patient undergoes MUA.) Also note that extra spinal techniques have not been presented but should be dictated for each area treated.

PROCEDURES PERFORMED:

1. Manipulation of the hip joint requiring general anesthesia, **RIGHT & LEFT; CPT 27275 x 2 – 51**
2. Manipulation under anesthesia, shoulder joint, **RIGHT & LEFT; CPT 23700 x 2 – 51**
3. Manipulation of the spine requiring anesthesia, **CERVICAL, THORACIC, & LUMBAR regions; CPT 22505 x 3 – 51**

PRE-OP DIAGNOSIS: **(Example)**

1. Displacement of Thoracic and/or Lumbar IVD without Myelopathy **(ICD-9 722.1)**
2. Displacement of cervical IVD without Myelopathy **(ICD-9 722.0)**
3. Myalgia and Myositis; cervical, thoracic, lumbar, bilateral shoulder/peri-scapular musculature, pelvic girdle musculature, and bilateral hip regions **(ICD-9 729.1)**
4. Spasm of muscle/muscle hypertonicity; cervical, thoracic, lumbar, bilateral shoulder/peri-scapular musculature, pelvic girdle musculature, and bilateral hip regions **(ICD-9 728.85)**

POST-OP DIAGNOSIS:
Same as Pre-op Diagnosis

INFORMED CONSENT:
After adequate explanation of the medical, surgical, and procedural options, this patient has decided to proceed with the recommended spinal Manipulation Under Anesthesia. The patient has been informed that more than one procedure may be necessary to achieve satisfactory results.

INDICATION:
Upon review of the patient's history and supplied medical records the patient has been found a good candidate for manipulation under anesthesia. The standards of protocol being followed are set forth by the National Academy of MUA Physicians.

COMMENTS:
The patient understands the essence of the diagnosis and the reasons for MUA. The associated risks of the procedure, including anesthesia complications, fracture, vascular accident, disc herniation, and post-procedure discomfort, were thoroughly discussed with the patient. Alternatives to the procedure, including the course of the

condition without MUA were discussed. The patient understands the chances of success from undergoing MUA and that no guarantees are made or implied regarding outcome. The patient has given both verbal and written informed consent for the listed procedure.

THE PROCEDURE IN DETAIL:

The patient's pain level today was 8 out of a possible 10 (10 being the worst imaginable pain)

The patient was draped in appropriate gowning and was taken by gurney to the operative area and asked to lie supine on the operative table. The patient was then placed on the appropriate monitors for this procedure. When the patient and I were ready, the anesthesiologist administered the appropriate medications to assist the patient into twilight sedation using medications which allow the stretching, mobilization, and adjustments necessary for the completion of the outcome desired.

THE CERVICAL SPINE:

The patient's arms were crossed and the patient was approached from the rostral end of the table. Long axis traction was applied to the patient's cervical spine and musculature while counter-traction was applied by the co-attending doctor. The co-attending doctor was positioned to stabilize the patient's shoulders in order to use this counter-traction maneuver. Traction in the same manner was then applied into a controlled lateral coronal plane bilaterally, and then in an oblique manner by rotating the patient's head to 45 degrees and elevating the head toward the patient's chest. This was also accomplished bilaterally. At no time was the patient taken past the physiological barrier. The patient's head was then brought into a neutral posture and cervical flexion was achieved to traction the cervical paravertebral muscles. The cervical spine was then taken into a lateral traction maneuver to achieve specific closed reduction manipulation of vertebral elements at the cervical spine on the right side and again using the same technique on the left side of the cervical spine. During this maneuver, a low velocity thrust was achieved after taking the vertebrae slightly past the elastic barrier of resistance. Cavitations were achieved.

SHOULDER THORACIC LIFT:

With the patient in the supine position, the doctor distracts the right arm straight/superior cephalad to end range. This is accomplished on both sides to release thoracic elements before the thoracic adjustment.

SHOULDER:

With the patient in the supine position the doctor stands on the side of involvement. The doctor takes the patient's arm in the bent arm position and tractions up away from the patient's body and tucks the extremity into the doctor's abdominal area. The doctor has contact at the crook of the patient's bent arm and support contact on the patient's lateral shoulder area over the mid deltoid area. In this position, the attending doctor then walks the extremity forward into forward flexion noting range of motion and patient's resistance. Once the extremity and thus the shoulder was taken into forward flexion the next move was to leave the contact hand in place and do an adduction traction over the doctor's hand toward the middle of the patient' body. The next move was then to relocate position so that internal and external ranges of motion are performed. The attending doctor can take the shoulder through simple external and internal ranges of motion on the first day and then become more aggressive on the following days by contacting the upper extremity up near the axial and doing internal and external rotation closer to the body.

The next part of the procedure is the same forward flexion maneuver with the arm straight. Traction is accomplished by contacting the wrist, tucking the arm in close to the doctor, and then walking the arm forward into forward flexion. Then the same adduction move is accomplished with the doctor keeping the arm straight and tractioning the arm over his or her hand toward mid line of the body. Next the doctor stands at the head of the patient and lowers the patient's arm to his side. Forward flexion in then accomplished with a knife edge contact at the acromioclavicular humeral joint area. Traction is made during forward flexion into the knife edge and a slight thrust into the joint is made.

The attending doctor then assumes the forward position and tractions the arm up and away and at the same time rotates his hip into the axillary area. This opens up the joint space and the doctor contacts the lateral border of the clavicle and administers three short toggle thrusts into the area with a pisiform contact. The thrusts are not directed into the clavicle but the line of drive is more toward the lateral clavicle and the medial border of the humerus.

The patient is then placed in the side lying position and circumduction clockwise and counterclockwise is accomplished by contacting the head of the humerus. This maneuver is accomplished by the doctor cupping the hands with interwoven fingers around the head of the humerus and the movements are very small and deliberate.

Once all these maneuvers are accomplished the doctor then completes the A to P manipulative procedure. Contact is at the cephalad border of the pectoralis major with support for the scapula and at the anterior aspect of the humeral glenoid cavity joint. The thrust is a motion that mimics the relocation of the head of the humerus into the glenoid cavity. The movement is up and over the shoulder with respect to line of drive.

THE THORACIC SPINE:
With the patient in the supine position on the operative table, the upper extremities were flexed at the elbow and crossed over the patient's chest to achieve maximum traction to the patient's thoracic spine. The co-attending doctor held the patient's arms in the proper position and assisted in rolling the patient for the adjustive procedure. With the help of the first assistant, the patient was rolled onto their side, selection was made for the contact point and the patient was rolled back over the doctor's hand. The elastic barrier of the resistance was found, and a low velocity thrust was achieved using a specific closed reduction anterior to posterior manipulative procedure. This same procedure was repeated at the upper, middle, and lower thoracic regions.

MEDIAL SCAPULAR BORDER LIFT:
With the patient in the side lying position, the patient's lower arm is moved behind the patient to allow relaxation of the scapular muscles. With the assistance of the co-attending doctor, the attending doctor reaches into the medial scapular area and lifts both vertically and laterally to separate subscapular adhesions.

THE LUMBAR SPINE:
With the patient supine on the procedure table, the primary physician addressed the patient's lower extremities which were elevated alternatively in a straight leg raising manner to until resistance due to adhesions and/or nocioceptive response by the patient. Linear force is used to increase the hip flexion gradually during this maneuver. Simultaneously, the co-attending physician applies a myofacial release technique to the calf and posterior thigh musculature. Each lower extremity was independently bent at the knee and tractioned cephalad in a neutral sagittal plane, lateral oblique cephalad traction, and medial oblique cephalad traction maneuver. The primary physician then approximated the opposite single knee from their position from neutral to medial slightly beyond the elastic barrier of resistance, allowing for a piriformis myofascial release as well. This was repeated with the opposite lower extremity. Following this, a Patrick-Fabere maneuver was performed up to and slightly beyond the elastic barrier of resistance.

PIRIFORMIS BOW-STRING STRETCH:
With the patient in the supine posture and following the adductor stretch, the patient's knee is held slightly past medial and the attending doctor contacts the knee with their hand. The force is applied toward the table with the help of the co-attending doctor and the piriformis muscle is then massaged. The force down the femur into the pelvic basin allows for relaxation of the piriformis muscle across the obturator foramina.

With the co-attending physician stabilizing the pelvis and femoral head, the attending physician extended the right lower extremity in the saggital plane, and while applying controlled traction radically stretched the para-articular holding elements of the right hip by means of gradually describing an approximately 30-35 degree horizontal arc. The lower extremity was then traction straight caudad and internal rotation was accomplished. Using traction, the lower extremity was gradually stretched into a horizontal arch to approximately 30 degrees. This procedure was then repeated using external rotation to stretch the para-articular holding elements of the hips bilaterally. These procedures were then repeated on the opposite lower extremity.

With the patient's lower extremities kept in hip and knee flexion, the patient's torso was secured by the co-attending doctor and the lumbar fasciae and musculature elongated obliquely to the right of mid-line, in a controlled manner up to and beyond the elastic barrier of resistance. Cavitation was noted. This was repeated on the opposite side.

The patient is then repositioned in the supine posture and the same lateral knee movement is repeated bilaterally only this time there is more of a torsion traction movement up toward the head and then laterally away from the main trunk thereby stretching the lumbar holding elements of the spinal motion units. This posture is proving to

show potential disc decompression as evidenced by pre and post MRI studies that have been completed for research purposes.

With the use of under sheets, the patient was carefully placed in the side lying decubitus position and positioned so that the lumbar spine overlay the kidney plate to the point where the lumbar spine attained the horizontal and was de-rotated to avoid facet imbrications.

ILIOPSOAS STRETCH:
With the patient in the side lying position, the upper leg is bent at the knee and distracted in a horizontal manner to stretch the iliopsoas muscle. The leg is then extended more caudad at a 30 degree angle to stretch the TFL.

The patient's body was stabilized by the first assistant. The knee and hip of the upper leg were flexed and the lower leg stabilized in the extended position by the co-attending doctor. Segmental localization of the appropriate lumbar motion-units was made by the attending physician and the elastic barrier of resistance found. A low velocity impulse thrust was applied achieving cavitation. This procedure was then repeated for the sacroiliac joint. The posterior superior iliac spine and lumbar spine was then adjusted on the opposite side with the patient in the same position as above.

The patient was then repositioned supine by means of the under sheets. With appropriate assistance, the patient was transferred from the procedure table to the gurney and was returned to the recovery room, where appropriate monitoring equipment was utilized to monitor vital signs. The IV was maintained up to the point where the patient was fully alert and stable. The patient was then transferred to a sitting recovery position and given fluids and a light snack. Following this, the patient was discharged with appropriate home instructions.

COMPLICATIONS:
The patient tolerated the procedure well with no untoward incident or complication.

SUMMARY:
The patient tolerated the procedure well and without complications and recovered from the general anesthesia without difficulty.

SUMMARY:
The patient underwent MUA of the axial spine and extremities. The patient tolerated the procedure well; there were no intra-operative or post-operative complications. The patient was able to achieve increased motion post MUA without significant muscle guarding. With the improvement of range of motion, it is medically reasonable to opine that this patient's fibro-adhesive conditions were significantly impacted, increasing the potential for appropriate neuromuscular re-education of affected myofacial structures and before having re-establishment of collagen deposition during the healing phase.

PATIENT INSTRUCTIONS:
The patient will receive post MUA therapy in the doctor's office or P.T. suite to include heating the area of involvement; stretching of the involved areas just as they were stretched during the MUA procedure; followed by interferential in a hertz range of 80-120 and 0-10 with cryotherapy for a duration of no longer than 20 minutes. This will be completed each day after the MUA procedure.

PROGNOSIS:
The patient under went post MUA examination and considering the patient's overall improvement in function and diminishing pain, it is opined, absent further injury, that the patient's prognosis is considered to be good. The patient will continue with the next procedure based on the improvement noticed during the post examination and in keeping with the recommendations of the serial pattern of MUAs as per standing orders. This follows standards and protocols as established by the National Academy of MUA Physicians. The patient has been instructed that periodic exacerbations or remissions may be experienced. These may be adequately managed by means of palliative care and with the recommended post MUA therapy.

Recommendations For Pre and Post Instructions to The MUA Patient

Pre MUA Instructions:

The patient should get a good nights sleep; the patient needs to be NPO 8-12 hours before the procedure due to the administration of anesthesia; the patient should not eat a heavy meal the night before the procedure is completed the following day; medications that are taken normally are usually taken with a sip of water the morning of the procedure (these recommendations are determined by the anesthesiologist in charge of the procedure, i.e for hypertension etc.); the patient must have undergone a medical clearance for anesthesia by an MD or a DO who is familiar with the procedure that is being performed so that an accurate opinion of the patient tolerating the anesthesia is obtained prior to undergoing MUA; the patient **must** have transportation other than themselves from the facility where the procedure is being performed back to their home. No one will be allowed to leave the facility without proper transportation; the patient should be out of work the days that the procedure is being administered. This procedure involves the administration of an anesthesia and the patient should not be signing anything important, making decisions, nor driving any vehicle while they are under the effects of the anesthesia which could affect them most of the day of the procedure.

Post MUA Instructions:

The post MUA instructions are based on what the treating physician wants the patient to do. However, the generalized post MUA instructions consist of returning to a semi-normal to normal diet. By this we mean that on the days of the MUA when a second or third MUA are completed the next day we recommend that a light diet be followed. Once the MUAs have been completed then the patient can return to their normal diet with recommendations from their treating physician. On the days of the procedure, we recommend that the patient be seen at the treating doctor's office later that same day if possible. With late afternoon MUA procedures being completed this is not practical, but when procedures are completed in the morning the patient should return to the office in the afternoon for post MUA care same day. We recommend that ice be used by the patient, and that they follow the instructions of the anesthesiologist, or medical treating doctor as far as post MUA medications. The patient should rest the days of the procedures, and should not being doing anything strenuous. Doing strenuous exercise or movements could cause harm to the patients until given permission to do these types of activities by their treating physician. Again, if the patient is going to undergo the next in a series of MUAs, the patient should be NPO 8-12 hours before the next days MUAs. Over the years we have not had any lingering effects from anesthesia when multiple MUAs are completed on three successive days.

Recommendations For Post MUA Therapy and Rehabilitation

The treating physician is ultimately responsible for the post MUA care. Our recommendation is that since we are attempting, and in most cases accomplishing the altering of adhesions (fibroblastic proliferative collagen tissue) from reforming in and about the joints and holding elements, that continued regular stretching should be started immediately after the MUAs. We recommend that if possible these stretches be the same as during the MUA procedure, and that

they be performed on the same day as the MUA with no manual adjustive therapy. Once the final MUA is completed, we recommend continuing with the stretching process that has already begun, but that now the adjustive techniques also be added. This process should ideally be performed on a daily basis for 7-10 days following the MUA procedures. We then recommend 2 weeks of pre-rehabilitation which would involve the beginning of continued movement with slight resistive strengthening. This is still not the time for conditioning and strengthening, but a time for the patient to start rebuilding the strength that was lost from injury, and from the process of the MUA procedure where weakening occurs as part of the corrections that take place as a result of performing this procedure. This is then followed by between 4 and 6 weeks of formal rehabilitation. It is this part of the post recovery phase of MUA where the patient claims his or her recovery and strengthens the body to return to their normal pre-injury physical capacity and activities of daily living. We recommend circuit training which not only helps the patient regain strength, but is also enjoyable to accomplish. Encouragement for re-strengthening should be foremost on the treating physicians mind at this point so that the patient will want to continue with their fitness program when they are dismissed from formal treatment.

Service Area
Hospital - Pain Management

Attachment C.N.5.A

2009	I/P	O/P
Baptist Hospital West	1	1,690
Parkwest Medical Ctr.	11	254
St. Mary's Medical Ctr.	21	30,907
St. Mary's Medical Ctr. North	9	15,244
Select Specialty Hospital Knox.	280	0
Select Specialty Hospital North Knox.	152	0
University of TN Memorial Hospital	0	0
Total	474	48,095

2010	I/P	O/P
Baptist Hospital West	0	888
Parkwest Medical Ctr.	11	320
St. Mary's Medical Ctr.	16	30,628
St. Mary's Medical Ctr. North	10	14,917
Select Specialty Hospital Knox.	0	0
Select Specialty Hospital North Knox.	0	0
University of TN Memorial Hospital	0	0
Total	37	46,753

2011	I/P	O/P
Baptist Hospital West	0	67
Parkwest Medical Ctr.	9	341
St. Mary's Medical Ctr.	24	35,540
St. Mary's Medical Ctr. North	4	14,240
Select Specialty Hospital Knox.	0	0
Select Specialty Hospital North Knox.	0	0
University of TN Memorial Hospital	0	1,782
Total	37	51,970

Source: 2009, 2010 & 2011 JAR, Schedule D - Services

Service Area ASTC's
Pain Management

2009	Co.	ORs	PRs	T RM	PM Pts	Total Pts	Pt %	PM Proc	Total Proc	Proc %	Proc./RM
Fort Sanders West Outpatient Surgery Ctr.	Knox	4	0	4	4,141	6,979	59.3%	8,939	14,552	61.4%	3,638
Knoxville Orthopedaedic Surgery Ctr	Knox	*	*	*	*	*	*	*	*	*	*
Parkwest Surgery Ctr	Knox	5	1	6	1,090	5,812	18.8%	2,550	13,514	18.9%	2,252
Physicians Surgery Ctr of Knoxville	Knox	6	1	7	709	4,229	16.8%	1,620	8,414	19.3%	1,202
St. Mary's Ambulatory Surgery Ctr	Knox	6	0	6	1,469	7,585	19.4%	1,469	7,585	19.4%	1,264
University Ambulatory Surgical Ctr	Knox	6	2	8	2,318	5,535	41.9%	4,391	10,623	41.3%	1,328
Total		27	4	31	9,727	30,140	32.3%	18,969	54,688	34.7%	1,764

Legend : ORs = Number of Operating Rooms
PRs = Number of Procedure Rooms
T RM = Total Number of Operating Rooms plus Procedure Rooms
PM Pts = Number of Pain Management Patients
Total Pts = Total Number of patients seen during year
Pt % = Pain Management patients as a Percentage of Total patients
PM Proc = Number of Pain Management Procedures
Total Proc. = Total Number of Procedures Performed during year
Proc % = Pain Management Procedures as a Percentage of Total Procedures
Proc/RM = Total Proc. / T RM

* No JAR

Source: 2009 JAR, Schedule D - Availability and Utilization of Service

Supplemental C.N.5.B
SUPPLEMENTAL - # 1
OCTOBER 2
9:40am

Service Area ASTC's
Pain Management

2010	Co.	ORs	PRs	T RM	PM Pts	Total Pts	Pt %	PM Proc	Total Proc	Proc %	Proc./RM
Fort Sanders West Outpatient Surgery Ctr.	Knox	4	0	4	3,752	6,052	62.0%	7,915	11,669	67.8%	2,917
Knoxville Orthopedaedic Surgery Ctr	Knox	4	1	5	675	1,473	45.8%	1,684	3,426	49.2%	685
Parkwest Surgery Ctr	Knox	5	1	6	1,495	5,935	25.2%	2,986	13,484	22.1%	2,247
Physicians Surgery Ctr of Knoxville	Knox	6	1	7	775	4,090	18.9%	1,864	9,068	20.6%	1,295
St. Mary's Ambulatory Surgery Ctr	Knox	6	0	6	1,372	7,353	18.7%	1,372	7,353	18.7%	1,226
University Ambulatory Surgical Ctr	Knox	6	2	8	2,084	5,234	39.8%	4,903	10,667	46.0%	1,333
Total		31	5	36	10,153	30,137	33.7%	20,724	55,667	37.2%	1,546

Legend : ORs = Number of Operating Rooms
PRs = Number of Procedure Rooms
T RM = Total Number of Operating Rooms plus Procedure Rooms
PM Pts = Number of Pain Management Patients
Total Pts = Total Number of patients seen during year
Pt % = Pain Management patients as a Percentage of Total patients
PM Proc = Number of Pain Management Procedures
Total Proc. = Total Number of Procedures Performed during year
Proc % = Pain Management Procedures as a Percentage of Total Procedures
Proc/RM = Total Proc. / T RM

* No JAR

Source: 2010 JAR, Schedule D - Availability and Utilization of Service

Service Area ASTC's
Pain Management

2011	Co.	ORs	PRs	T RM	PM Pts	Total Pts	Pt %	PM Proc	Total Proc	Proc %	Proc./RM
Fort Sanders West Outpatient Surgery Ctr.	Knox	4	0	4	2,797	3,687	75.9%	6,320	7,580	83.4%	1,895
Knoxville Orthopedaedic Surgery Ctr	Knox	4	1	5	2,519	5,798	43.4%	6,995	21,304	32.8%	4,261
Parkwest Surgery Ctr	Knox	5	1	6	1,045	5,416	19.3%	2,962	13,456	22.0%	2,243
Physicians Surgery Ctr of Knoxville	Knox	5	0	5	794	3,621	21.9%	1,794	8,014	22.4%	1,603
St. Mary's Ambulatory Surgery Ctr	Knox	6	0	6	1,630	6,648	24.5%	1,630	6,648	24.5%	1,108
University Ambulatory Surgical Ctr	Knox	6	2	8	1,146	2,785	41.1%	2,401	5,573	43.1%	697
Total		30	4	34	9,931	27,955	35.5%	22,102	62,575	35.3%	1,840

Legend : ORs = Number of Operating Rooms
PRs = Number of Procedure Rooms
T RM = Total Number of Operating Rooms plus Procedure Rooms
PM Pts = Number of Pain Management Patients
Total Pts = Total Number of patients seen during year
Pt % = Pain Management patients as a Percentage of Total patients
PM Proc = Number of Pain Management Procedures
Total Proc. = Total Number of Procedures Performed during year
Proc % = Pain Management Procedures as a Percentage of Total Procedures
Proc/RM = Total Proc. / T RM

* No JAR

Source: 2011 JAR, Schedule D - Availability and Utilization of Service

Service Area ASTC's
Pain Management

2012 - Provisional	Co.	ORs	PRs	T RM	PM Pts	Total Pts	Pt %	PM Proc	Total Proc	Proc %	Proc./RM
Fort Sanders West Outpatient Surgery Ctr.	Knox	4	0	4	3,406	4,085	83.4%	7,791	8,801	88.5%	2,200
Knoxville Orthopedaedic Surgery Ctr	Knox	4	1	5	2,976	6,837	43.5%	9,005	19,414	46.4%	3,883
Parkwest Surgery Ctr	Knox	5	1	6	1,039	5,393	19.3%	1,039	5,393	19.3%	899
Physicians Surgery Ctr of Knoxville	Knox	5	0	5	1,071	4,398	24.4%	2,884	11,087	26.0%	2,217
St. Mary's Ambulatory Surgery Ctr	Knox	6	0	6	1,742	6,160	28.3%	1,742	6,160	28.3%	1,027
University Ambulatory Surgical Ctr	Knox	*	*	*	*	*	*	*	*	*	*
Total		24	2	26	10,234	26,873	38.1%	22,461	50,855	44.2%	1,956

Legend : ORs = Number of Operating Rooms
PRs = Number of Procedure Rooms
T RM = Total Number of Operating Rooms plus Procedure Rooms
PM Pts = Number of Pain Management Patients
Total Pts = Total Number of patients seen during year
Pt % = Pain Management patients as a Percentage of Total patients
PM Proc = Number of Pain Management Procedures
Total Proc. = Total Number of Procedures Performed during year
Proc % = Pain Management Procedures as a Percentage of Total Procedures
Proc/RM = Total Proc. / T RM

* No JAR

Source: 2012 - Provisional JAR, Schedule D - Availability and Utilization of Service

Attachment C.EF.10

3:18 PM
08/09/13
Cash Basis

LENSGRAF CLINIC, PC
Profit & Loss
January through June 2013

	Jan - Jun 13
Ordinary Income/Expense	
Income	
PROFESSIONAL FEES COLLECTED	1,943,873.49
Refunds	-10,462.79
Total Income	1,933,410.70
Expense	
ACCOUNTING	3,745.00
Advertising and Promotion	167,273.73
AMORTIZATION	767.00
ANSWERING SERVICE	2,685.85
BANK CHARGES	3,472.01
BILLING EXPENSES	43,485.78
Computer and Internet Expenses	617.91
Continuing Education	991.00
CONTRIBUTIONS	175.00
Depreciation Expense	7,460.00
DUES & PUBLICATIONS	2,053.75
INSURANCE	46,264.14
INTEREST	2,557.08
JANITORIAL SERVICES	6,082.74
Laboratory Fees	7,764.00
LAUNDRY & UNIFORMS	5,064.79
LEGAL & COLLECTIONS	17,773.45
LICENSES	2,991.00
MEALS & ENTERTAINMENT	22,519.41
MEDICAL SUPPLIES	188,517.80
MISCELLANEOUS	247.62
OFFICE EXPENSE	25,541.23
PAYROLL TAXES	104,915.51
POLITICAL CONTRIBUTIONS	2,000.00
POSTAGE	4,454.76
PRINTING	3,158.42
PROFESSIONAL CONSULTANTS	56,475.72
RENT - BUILDING	65,112.48
REPAIRS & MAINTENANCE	20,337.71
TAXES - OTHER	7,955.17
TELEPHONE	8,932.99
TRAVEL & SEMINARS	19,935.74
Utilities	8,960.91
WAGES	1,178,767.05
Total Expense	2,039,056.75
Net Ordinary Income	-105,646.05
Other Income/Expense	
Other Income	
STATE OF TN EHR CREDIT	64,125.51
REIMBURSED EXPENSES	138,182.79
Total Other Income	202,308.30
Net Other Income	202,308.30
Net Income	**96,662.25**

3:19 PM
08/09/13
Cash Basis

LENSGRAF CLINIC, PC
Balance Sheet
As of June 30, 2013

	Jun 30, 13
ASSETS	
Current Assets	
Checking/Savings	
PETTY CASH	450.00
OPERATING ACCOUNT	58,700.72
FIRST TENNESSEE BANK PAYRO...	1,285.56
CASH - MUA	54,816.21
MONEY MARKET FUND	121.98
ADVERTISING ACCOUNT	186.26
Total Checking/Savings	115,560.73
Other Current Assets	
PREPAID RENT	7,030.00
LOANS TO SHAREHOLDERS	25,122.12
Total Other Current Assets	32,152.12
Total Current Assets	147,712.85
Fixed Assets	
EQUIPMENT, FURN & FIXTURES	932,218.53
LEASEHOLD IMPROVEMENTS	108,679.89
Accumulated Depreciation	-652,209.25
Total Fixed Assets	388,689.17
Other Assets	
DEPOSITS	46,917.24
INTANGIBLE ASSET	30,753.10
ACCUMULATED AMORTIZATION	-8,833.00
INVESTMENTS	36,000.00
LOANS TO SHAREHOLDER	19,877.22
Total Other Assets	124,714.56
TOTAL ASSETS	**661,116.58**
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	
DUE TO AFFILIATE	60,510.42
GARNISHMENT PAYABLE	1,287.23
NOTES PAYABLE	45,621.40
FEDERAL INCOME TAX	150.93
SHAREHOLDER LOANS	55,193.21
Total Other Current Liabilities	162,763.19
Total Current Liabilities	162,763.19
Total Liabilities	162,763.19
Equity	
Capital Stock	1,000.00
PAID IN CAPITAL	12,771.50
Retained Earnings	387,919.64
Net Income	96,662.25
Total Equity	498,353.39
TOTAL LIABILITIES & EQUITY	**661,116.58**

1:36 PM
08/15/13
Cash Basis

SMOKY MOUNTAIN AMBULATORY SURGERY CENTER, LLC
Profit & Loss
January through June 2013

	Jan - Jun 13
Ordinary Income/Expense	
Income	
FEES COLLECTED	250,951.82
Total Income	250,951.82
Expense	
Advertising and Promotion	25,546.00
Bank Service Charges	34.00
BILLING EXPENSE	6,702.00
EQUIPMENT LEASE	17,400.00
Insurance Expense	7,884.51
JANITORIAL	1,610.00
Laboratory Fees	1,165.00
LAUNDRY & UNIFORMS	611.00
LEGAL EXPENSES	11,664.38
MEDICAL DIRECTOR SALARY	24,000.00
MEDICAL SUPPLIES	41,029.40
Office Supplies	5,444.34
PERSONNEL LEASE	38,660.00
RENT - LHI	10,800.00
RENT - SUBLEASE	7,200.00
Repairs and Maintenance	1,925.08
TAXES	3,240.00
Telephone Expense	1,340.00
TRAVEL & SEMINARS	282.90
Utilities	1,344.00
Total Expense	207,883.21
Net Ordinary Income	43,068.61
Net Income	43,068.61

1:37 PM
08/15/13
Cash Basis

SMOKY MOUNTAIN AMBULATORY SURGERY CENTER, LLC
Balance Sheet
As of June 30, 2013

	Jun 30, 13
ASSETS	
Current Assets	
Checking/Savings	
OPERATING ACCOUNT	54,816.21
Total Checking/Savings	54,816.21
Total Current Assets	54,816.21
Other Assets	
INTANGIBLE ASSET - CERT OF NE...	23,000.00
ACCUMULATED AMORTIZATION	-6,515.00
Total Other Assets	16,485.00
TOTAL ASSETS	71,301.21
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	
LOAN FROM MEMBER	9,867.76
Total Other Current Liabilities	9,867.76
Total Current Liabilities	9,867.76
Total Liabilities	9,867.76
Equity	
Members Equity	18,364.84
Net Income	43,068.61
Total Equity	61,433.45
TOTAL LIABILITIES & EQUITY	71,301.21

Attachment C.OD.7(d)

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
OFFICE OF HEALTH LICENSURE AND REGULATION
EAST TENNESSEE REGION
5904 LYONS VIEW PIKE, BLDG. 1
KNOXVILLE, TENNESSEE 37919

February 10, 2011

Mr. Arthur D. Lengraf, Administrator
MUA Medical Clinic of Knoxville, LLC
1338 Papermill Pointe Way
Knoxville, TN 37909

RE: Ambulatory Surgical Treatment Center

Dear Mr. Lengraf:

The East Tennessee Regional Office conducted an initial licensure survey at your facility on February 10, 2011. As a result of the survey, no deficient practice was found.

If our office may be of assistance to you, please feel free to call (865) 588-5656.

Sincerely,

Karen B. Kirby/mcd

Karen B. Kirby, R.N.
Regional Administrator
East TN Health Care Facilities

KBK:cvb

PRINTED: 02/10/2011
FORM APPROVED

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED
	TNPL535206		02/10/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MUA MEDICAL CLINIC OF KNOXVILLE, LLC	1346 PAPERMILL POINTE WAY KNOXVILLE, TN 37909

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 001	1200-8-10 Initial An Initial Licensure survey was conducted on February 10, 2011, at MUA Medical Clinic of Knoxville. No deficiencies were cited under 1200-8-10, Standards for Ambulatory Treatment Centers.	A 001		

Division of Health Care Facilities

TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

PRINTED: 02/10/2011
FORM APPROVED

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED
	TNPL535206		02/10/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MUA MEDICAL CLINIC OF KNOXVILLE, LLC	1346 PAPERMILL POINTE WAY KNOXVILLE, TN 37909

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 002	1200-8-10 No Deficiencies During the Life Safety portion of the survey conducted on February 10, 2010, no licensure deficiencies were cited under chapter 1200-8-10, Standards for Ambulatory Surgical Treatment Centers.	A 002		

Division of Health Care Facilities

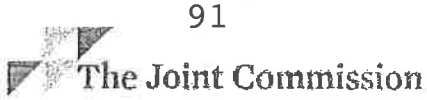
TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM 6899 CXKL11

If continuation sheet 1 of 1



MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, TN 37909

Organization Identification Number: 514649

Evidence of Standards Compliance (45 Day) Submitted: 9/18/2011

Program(s)
Ambulatory Health Care Accreditation

Executive Summary

Ambulatory Health Care Accreditation :	As a result of the accreditation activity conducted on the above date(s), there were no Requirements for Improvement identified. You will have follow-up in the area(s) indicated below: • Measure of Success (MOS) – A follow-up Measure of Success will occur in four (4) months.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission
Summary of Compliance

Program	Standard	Level of Compliance
AHC	EC.02.05.03	Compliant
AHC	NPSG.03.04.01	Compliant
AHC	PC.03.01.03	Compliant
AHC	PC.04.01.05	Compliant
AHC	UP.01.03.01	Compliant

The Joint Commission
Summary of CMS Findings

CFC: §416.42 **Tag:** Q-0060 **Deficiency:** Compliant

Corresponds to: AHC

Text: §416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

CFC Standard	Tag	Corresponds to	Deficiency
§416.42(a)(1)	Q-0061	AHC - PC.03.01.03/EP9	Compliant

CFC: §416.52 **Tag:** Q-0260 **Deficiency:** Compliant

Corresponds to: AHC

Text: §416.52 Conditions for coverage: Patient admission, assessment and discharge

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

CFC Standard	Tag	Corresponds to	Deficiency
§416.52(c)(2)	Q-0266	AHC - PC.04.01.05/EP13	Compliant

The Joint Commission

MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, TN 37909

Organization Identification Number: 514649

Evidence of Standards Compliance (60 Day) Submitted: 9/18/2011

Program(s)
Ambulatory Health Care Accreditation

Executive Summary

Ambulatory Health Care Accreditation :	As a result of the accreditation activity conducted on the above date(s), there were no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission
Summary of Compliance

Program	Standard	Level of Compliance
AHC	MM.01.01.03	Compliant
AHC	MM.01.02.01	Compliant

The Joint Commission

September 27, 2011

A D. Lensgraf
Owner
MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, TN 37909

Joint Commission ID #: 514649
Program: Ambulatory Health Care
Accreditation
Accreditation Activity: 60-day Evidence of Standards Compliance
Accreditation Activity Completed: 09/20/2011

Dear Dr. Lensgraf:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high - quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

With that goal in mind, your organization received Requirement(s) for Improvement during its recent survey. These requirements have been summarized in the Accreditation Report provided by the survey team that visited your organization.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

Sincerely,

Ann Scott Blouin RN, PhD

Ann Scott Blouin, RN, Ph.D.
Executive Vice President
Accreditation and Certification Operations

The Joint Commission

September 12, 2011

A D. Lensgraf
Owner
MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, TN 37909

Joint Commission ID #: 514649
Program: Ambulatory Health Care Accreditation
Accreditation Activity: Initial Unannounced Full Event
Accreditation Activity Completed: 09/01/2011

Dear Dr. Lensgraf:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high - quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

With that goal in mind, your organization received Requirement(s) for Improvement during its recent survey. These requirements have been summarized in the Accreditation Report provided by the survey team that visited your organization.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

Sincerely,

Ann Scott Blouin RN, PhD

Ann Scott Blouin, RN, Ph.D.
Executive Vice President
Accreditation and Certification Operations

The Joint Commission

MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, TN 37909

Organization Identification Number: 514649

Program(s)	**Survey Date(s)**
Ambulatory Health Care Accreditation	08/31/2011-09/01/2011

Executive Summary

Ambulatory Health Care Accreditation :

As a result of the accreditation activity conducted on the above date(s), Requirements for Improvement have been identified in your report.

You will have follow-up in the area(s) indicated below:

- Evidence of Standards Compliance (ESC)

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission
Summary of Findings

Evidence of DIRECT Impact Standards Compliance is due within 45 days from the day this report is posted to your organization's extranet site:

Program:	Ambulatory Health Care Accreditation Program	
Standards:	EC.02.05.03	EP5
	NPSG.03.04.01	EP1
	PC.03.01.03	EP9
	PC.04.01.05	EP13
	UP.01.03.01	EP5

Evidence of INDIRECT Impact Standards Compliance is due within 60 days from the day this report is posted to your organization's extranet site:

Program:	Ambulatory Health Care Accreditation Program	
Standards:	MM.01.01.03	EP1
	MM.01.02.01	EP1

CFC: §416.42 **Tag:** Q-0060 **Deficiency:** Standard

Corresponds to: AHC

Text: §416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

CFC Standard	Tag	Corresponds to	Deficiency
§416.42(a)(1)	Q-0061	AHC - PC.03.01.03/EP9	Standard

CFC: §416.52 **Tag:** Q-0260 **Deficiency:** Standard

Corresponds to: AHC

Text: §416.52 Conditions for coverage: Patient admission, assessment and discharge

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

CFC Standard	Tag	Corresponds to	Deficiency
§416.52(c)(2)	Q-0266	AHC - PC.04.01.05/EP13	Standard

The Joint Commission
Findings

Chapter: Environment of Care

Program: Ambulatory Health Care Accreditation

Standard: EC.02.05.03

ESC 45 days

Standard Text: The organization has a reliable emergency electrical power source.

Primary Priority Focus Area: Patient Safety

Element(s) of Performance:

5. The organization provides emergency power for the following: Equipment that could cause patient harm when it fails, including life-support systems; blood, bone, and tissue storage systems; medical air compressors; and medical and surgical vacuum systems.

Scoring Category : A
Score : Insufficient Compliance

Observation(s):

EP 5
Observed in Environment of Care Session at MUA Medical Clinic of Knoxville (1338 Papermill Pointe Way, Knoxville, TN) site.
While reviewing the ability of the facility to respond to a life threatening emergency or a patient airway issue during moderate sedation, it was determined the organization does not have an emergency electrical power source for its medical and surgical vacuum systems. The organization had pursued efforts to have this waived by the state. The only written correspondence provided by the organization reflected a state expectation for temporary back-up power as well.

Chapter: Medication Management

Program: Ambulatory Health Care Accreditation

Standard: MM.01.01.03

ESC 60 days

Standard Text: The organization safely manages high-alert and hazardous medications.

Primary Priority Focus Area: Medication Management

Element(s) of Performance:

1. The organization identifies, in writing, its high-alert and hazardous medications. * (See also EC.02.02.01, EP 8)
Footnote *: For a list of high-alert medications, see http://www./ismp.org. For a list of hazardous medications, see http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html#o.

Scoring Category : A
Score : Insufficient Compliance

Observation(s):

EP 1
Observed in Medical Management Session at MUA Medical Clinic of Knoxville (1338 Papermill Pointe Way, Knoxville, TN) site.
Observed but corrected on-site After review with the facility staff the high risk issues related to medication, it was determined there is no policy, protocol or high alert medication list currently in place. The organization accessed ISMP and have accessed the list and have identified in writing its high alert and hazardous medications.

October 4, 2011

Re: # 514649
CCN: Initial
Program: Ambulatory Surgical Center
Accreditation Expiration Date: December 02, 2014

A D. Lensgraf
Owner
MUA Medical Clinic of Knoxville,L.L.C
1338 Papermill Pointe Way
Knoxville, Tennessee 37909

Dear Dr. Lensgraf:

This letter confirms that your August 31, 2011 - September 01, 2011 unannounced initial survey was conducted for the purposes of assessing compliance with the Medicare conditions for ambulatory surgical centers through The Joint Commission's deemed status survey process.

Based upon the submission of your evidence of standards compliance on September 18, 2011, the areas of deficiency listed below have been removed. The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of September 18, 2011. We congratulate you on your effective resolution of these deficiencies.

§416.42 Surgical Services
§416.52 Patient Admission, Assessment and Discharge

The Joint Commission is also recommending your organization for Medicare certification effective September 18, 2011. Please note that the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO) makes the final determination regarding your Medicare participation and the effective date of participation in accordance with the regulations at 42 CFR 489.13. Your organization is responsible for notifying the State Survey Agency that a recommendation for Medicare certification has been made. Please provide your State agency with a copy of your accreditation report, accreditation award letter, and this Medicare recommendation letter.

This recommendation also applies to the following location(s):

MUA Medical Clinic of Knoxville
1338 Papermill Pointe Way, Knoxville, TN, 37909

We direct your attention to some important Joint Commission policies. First, your Medicare report is publicly accessible as required by the Joint Commission's agreement with the Centers for Medicare and Medicaid Services. Second, Joint Commission policy requires that you inform us of any changes in the name or ownership of your organization, or health care services you provide.

COPY-

SUPPLEMENTAL-1

Smoky Mountain Ambulatory
Surgery Ctr.

CN1308-032

OCT 22 '13 9:39

SUPPLEMENTAL- # 1
OCTOBER 22
9:40am

AFFIDAVIT

STATE OF TENNESSEE
COUNTY OF DAVIDSON

NAME OF FACILITY: Smoky Mountain Ambulatory Surgery Center, LLC (CN1308-032)

I, E. Graham Baker, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge, information and belief.

E. Graham Baker, Jr. Attorney at Law
Signature/Title

Sworn to and subscribed before me, a Notary Public, this 22nd day of October, 2013; witness my hand at office in the County of Davidson, State of Tennessee.

NOTARY PUBLIC
My Commission expires 5/3/14

ROBERT A. ANDERSON
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

1. Section A, Item 5

Please provide a response and submit a replacement page.

The facility will continue to be managed by itself, as stated. Therefore, the "Not Applicable" response on A.5 continues to be correct.

SUPPLEMENTAL- # 1
OCTOBER 28
9:40am

2. Section A, Item 12

Please indicate if there have been any discussions by the applicant with any TennCare MCO's regarding contracting for this proposed project. If so, what is the stage of discussion?

We currently have a contract with United Health (Medicaid Number 1526056), and have applied for a contract with BlueCare.

SUPPLEMENTAL- # 1
OCTOBER 28
9:40am

3. Section A, Item 13

Please discuss if there is any out-of-network relationship with AmeriGroup.

AmeriGroup has requested we join them, and we have made an application.

SUPPLEMENTAL- # 1
OCTOBER 2012
9:40am

4. Section B, Project Description, Item I

Please explain why the applicant chose to file this application rather than request an Agency determination regarding whether MUJA fell under the umbrella of MUA.

We were advised by the HSDA that we needed to file a new CON in order to perform any type of injections in the surgery center.

Please provide a brief description of the service area, need and funding for the proposed project.

The Applicant's clinical primary service area is Knox County. See *Attachment C.N.3* for a map of the proposed primary service area. Also, see *Attachment C.OD.3* for basic wage information for Knox County. Knoxville is an urban area, and Knox County has both urban and rural influences.

The Applicant's ASTC is located in Knoxville (primary service area of Knox County), but the actual referring area may well extend beyond the county of situs to outlying areas. All projections were based on Knox County residents, however.

Physicians have expressed concern about the treatment of chronic pain. Chronic pain has both chemical and mechanical components. Such treatment is difficult, sometimes ineffective, and has risks. These risks include narcotic abuse, misuse and diversion, and infection (such as Epidural Steroid Injections). There appears to be general consensus that a procedure that could significantly lower pain scores, improve functional capacity, and reduce narcotic use would be invaluable in the treatment of chronic pain. Manipulation under Anesthesia ("MUA") is such a procedure, and the Applicant is already approved for this service.

MUA is a modality which has been used by practitioners (doctors of chiropractic, doctors of osteopathic medicine, and medical doctors) since the early 1930s. The process involves relaxing the patient (with anesthesia), and making corrections to biomechanical abnormalities by stretching and manipulation. Following the procedure, the patient gains a range of motion and/or relief of pain.

The Applicant is forced by insurers to attempt less intensive pain relief methods prior to attempting traditional MUA. These measures include interventional pain management services such as joint injections. The HSDA originally determined that such procedures were included under MUA, and the Applicant provided such procedures for some time. Later, the HSDA determined that the Applicant is not approved for such interventional pain management services. Since the Applicant cannot conduct the MUA procedures for which it has already been approved without attempting interventional pain management procedures first, this application is being filed.

This Application includes administrative costs, only, and there is no construction or renovation. We will be using the same ASTC that has already been approved for the Applicant. The higher of FMV and/or lease costs for the site were approved when the original ASTC was approved. Cash reserves have been utilized to pay for these nominal costs. No additional funding is required.

SUPPLEMENTAL- # 1
OCTOBER 28
9:40am

The applicant states they are forced by insurers to attempt less intensive pain relief methods prior to attempting traditional MUA. Please provide any documentation in the form of correspondence, policies and procedures, provider manuals, clinical criteria, etc. from insurance companies that support this statement.

Please see the following attachments:

UHC-MUA Policy;
BCBST-MUA;
Medical Necessity Guidelines;
Smoky Mountain Ambulatory Surgery Center Protocols;
Addendum to Policies and Procedures;
Pain Management Agreement Medication Protocols; and
a two page excerpt from AETNA's MUA/MUJA guidelines.

Since the applicant will only be performing interventional pain management services, has the applicant requested and received any waivers from the Tennessee Department of Health, Board of Healthcare Licensing Facilities regarding operating rooms?

Our ASTC is currently approved as a clean room with approved anesthesia with no open surgery. When our existing ASTC was originally approved, we obtained minimal waivers, such as no requirement for an electrical generator since we were not performing traditional surgery, but were performing manual procedures. We do not anticipate further waivers as a result of this application.

There appears to be an existing state registered licensed pain management clinic at the applicant's address. Please clarify the applicant's relation to that clinic and if the proposed project will be registered separately with the State of Tennessee as a registered pain clinic.

There are two separate facilities, with two separate addresses and entrances. Lensgraf Clinic, PC, a currently registered pain management clinic, is located at 1346 Papermill Point Way. Lensgraf Clinic, PC is part owner (50%) of Smoky Mountain Ambulatory Surgery, LLC, the Applicant, along with Cynthia Neindorf, M.D., Anesthesiologist (25%), and Wayne McLemore, M.D., Orthopedic Surgeon (25%).

Smoky Mountain Ambulatory Surgery Center, LLC, is located next door at 1338 Papermill Point Way. Since Lensgraf Clinic, PC (the affiliated clinic) is certified in pain management, we would see no need to have the applicant be certified in pain management as patients will not be receiving prescriptions at the Applicant's ASTC.

Will all patients having a pain management injection also receive a MUA procedure or are there occasions where a patient will have a pain management procedure and no MUA procedure or occasions where a patient will have no pain management procedure but receive a MUA procedure? If these several scenarios are possible please breakout the expected percentage of patients that will fall into each category.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

MUA procedures and interventional pain management procedures will not be performed at the same time on the same patient. If interventional pain management is not successful, a patient may undergo traditional MUA treatment later.

A review of our patient files indicates that approximately 30% of our patients will have improved results with interventional pain management procedures and will then not require the more traditional MUA, thereby avoiding possible complications of anesthesia.

Patients that may go directly to MUA first would be those who have previously received interventional pain management with little or no success. It would not be appropriate medical procedure to continue procedures that are ineffective.

With that said, and from a clinical standpoint, we will utilize any procedure for which we are qualified and approved in order to provide appropriate services to our patients in order to reduce inflammation and break down scar tissue in order to increase the patient's range of motion. Such procedures would involve traditional MUA and interventional pain management.

On page 9 of the application the applicant lists the Medicare and TennCare revenue projections. However, what is listed is the percentage of patients not the percentage of revenue. Please clarify.

We listed the percentage of patients, as this is the estimated percentage that will be referred for procedures in the surgery center. The percentage of revenue from Medicare is less than commercial, and the percentage of revenue from Medicaid is less than both. As a practical matter, it is almost impossible to predict the exact amount of revenue from each payor source. However, based on prior experience of collection percentages for each, we could reasonably project our Medicare net revenue to be 60%, our Medicaid net revenue to be 5%, and our commercial net revenue to be 35%.

Are interventional pain management procedures being performed now by the applicant or affiliated entity in an office setting at 1346 Papermill Pont Way Knoxville, TN 37919

They are being performed by an affiliated entity, Lensgraf Clinic, PC.

Our patient population is primarily Medicare disability and Medicaid, a population that has high incidents of COPD, cardiovascular, uncontrolled diabetics, obesity, posttraumatic stress syndrome along with EKG's that reveal intravascular problems of numerous natures that preclude by half their being able to safely receive procedures in a clinical setting verses an ASTC. This is one of the reasons for filing this application. Further, we agree with the summary notes regarding a similar CON application (issued in April, 2012) filed by Dr. Joe Browder in Knoxville. We have a staff of nurse practitioners and a full time psychologist for cognitive behavioral treatments, and will offer Knoxville's second integrated, multi-disciplinary program that addresses both physical and psychological aspects of pain management and has developed an opoiods-restricted treatment plan for its patients. A key component of our application is provision of appropriate surgical procedures to minimize prescription opoiods consumption.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

The second need to consolidate procedures at a licensed ASTC involves reimbursement. For many procedures, reimbursement at an office level is not adequate to cover the costs of a comprehensive care program such as will be provided at our facility. The national and state standard for these procedures is to perform them in a licensed facility where reimbursement is sufficient to cover costs of at least anesthesia and supplies. Reimbursement at a practice-owned ASTC will be sufficient to avoid losses on some procedures, and to fund new program enhancements that cannot now be afforded and with contracted physical therapist staff to assess outcomes after surgery, a "proof of efficacy" increasingly required by insurers. Another anticipated enhancement is to be able to absorb more TennCare and charity patients than in past years by performing all procedures with its own staff in an adjoining practice-owned ASTC. By doing so, surgical staff competencies and productivity will be maximized.

While performing procedures such as RF Ablation, Medial and Facet blocks, ESI SI joint injections along various other injections to manage pain, it is more to improve joint range of motion, reduce scar tissue, and reduce inflammation as part of a ligament rejuvenation. Since ligaments have no elasticity, it is important to follow such treatment with MUA for muscle and joint stability, followed with physical medicine.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

5. Section B, Project Description, Item II A

Please clarify if the applicant is describing the development of the proposal since the project appears to not have any renovation or construction cost.

Yes. As stated, all costs for this project are administrative costs, only. This application is for a new service at an existing ASTC. There is no renovation or construction cost associated with this application. No additional funds are required.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

6. Section C, Need Item 1

Please discuss how the proposed project will relate to the 5 Principles for Achieving Better Health found in the State Health Plan."

HEALTHY LIVES. The affiliate clinic (that has been referred to in conjunction with the applicant) currently offers behavioral health with an on-site social worker doing evaluations, group consults for healthy life styles, review of at home activities, exercises, as well as on site physical therapy and weight loss, physical medicine and Chiropractic. The Applicant will offer a safe environment for treatment of (for example) patients with obesity, hypertension, and diabetic problems that put them at risk, as opposed to performing procedures in a private clinic. Physical medicine and chiropractic will also be available at our affiliate. A private clinic may not have the ability to manage a case that could code during a procedure. Thus, the two (private clinic and ASTC) working together increases the promotion of healthy lives for our patients.

ACCESS TO CARE. As quoted from Dr. Joe Browder testimony, whose recent CON was approved two miles from our facility, "...there was a 200 percent need for pain procedure facility's in his area" -- and we would agree with that. More especially, we will be providing MUA/MUJA, which his ASTC does not perform MUA/MUJA. Plus, we intend to use this for our patients only, unless requested to open this to all physicians, with our same philosophy of treatment for all, regardless of ability to pay. This will result in more access to care that does not exist in other facilities in Knoxville. We will also provide more medical care for the disabled.

ECONOMIC EFFICIENCY. With the two affiliated groups, Lensgraf Clinic, PC and Smoky Mountain Surgery Center, LLC working together, treatment is more efficient. Our review indicates that this association reduces both costs and patient waiting time for treatment. This is a more efficient way to interact with each physician, who will have immediate access to patient care when needed. Having this affiliation will also bring an ASTC to service that will be willing to absorb some of the costs that will not be covered by the various carriers. We have a standard of care to keep the patient no matter what, and trust at the end of the day that patient satisfaction will continue to increase.

QUALITY OF CARE. Our procedures are safe, and there have been no reported complaints to any of the boards as to patient harm or dissatisfaction as a result of treatment provided.

Our procedures are effective. Internal survey results show high patient satisfaction for procedures that have been above described. Part of this is the result of careful patient selection. With the multiple Physicians on the staff of Lensgraf Clinic, the waiting time is greatly reduced verses having to be referred out and wait.

The services we provide are patient-centered. All of our staff are patient-oriented -- from on-staff social workers to our various physicians and mid-levels -- and are carefully understanding of each patients' needs. We are more patient-centered by the affiliation of the applicant and the Lensgraf Clinic, PC that sees primary care patients through a family practice managed by James Foster, M.D., an Internist, and a Medical Director who is a Neurosurgeon.

We provide timely services. As addressed above there are few if any delays for treatment due to mutual staffing and timely weekly staff meeting regarding patient management.

Our services are efficient: Being able to share equipment, supplies, ideas, and energy of the two entities reduces the staff size and space required for our patients.

SUPPLEMENTAL- # 1
OCTOBER 2
9:40am

And our services are equitable. The affiliate and applicant owners have a long history of working with the underserved, through three generations: Arthur D. Lensgraf, D.C. practiced in the socioeconomically underserved area of East Knoxville on Magnolia Avenue for over 30 years with Donald Thompson, M.D. Dr Derek Lensgraf joined the practice 15 years ago and continues that tradition. Upon Dr. Thompson's passing, the practice was centralized where it now is joined by Dr. Elizabeth Lensgraf who had been managing a practice. This combined practice in the central city continues today to see many patients less fortunate that others.

HEALTH CARE WORKFORCE. The affiliate Lensgraf Clinic, PC has a history of development, recruitment, and retention of staff. The Applicant has similar owners to the affiliate clinic, and the same staff process will continue in the ASTC. "The collaboration and consideration of all health professional in creating practices and policies addressing workforce's issues" has been applied in multiple locations such as Chattanooga (Hamilton County Medical Center) and Johnson City (Washington County Medical Center) with a workforce of over a hundred employees. This experience and history will enable the applicant to aid its patients in attaining quality healthcare from providers at all levels and all specialties.

7. **Section C, Need, Item 1.a., Service Specific Criteria-ASTC (Item 1) and Section C. Need, Item 6**

The applicant projects 2,700 and 3,100 interventional pain management procedures in Year One and Year Two.

Is it possible for a patient to have more than one pain management procedure per visit? If yes, please provide the projected utilization based on patient visits/cases, since ASTC utilization standards are now based on cases.

While it is possible for a patient to have more than one pain management procedure per visit, such is not customary, and our projections are for one procedure per visit. Therefore, the term "procedures" in our application should actually have been "cases" as defined by the new ASTC Guidelines. Our projections are for one pain management procedure per visit, and one procedure is one case.

Please explain how procedures based on historical utilization were determined. Is it based on the MUJA procedures performed prior to the HSDA ruling? Please provide the details of the methodology used.

Cases based on historical utilization were determined using reports generated by our EHR system to obtain actual number of patients, actual number of procedures, and actual number of cases (patient visits) for the periods of time requested.

Our methodology was based on training, certifications, and clinical hours of experience of each patient's results, during pre- and post-treatment, and case reviews with other Physicians with similar experience. We experienced a fifty percent (50%) to sixty percent (60%) increase in patient satisfaction when utilizing various interventional pain procedures back when we were approved for such, verses when not performed. During the time period we were advised by the HSDA to cease performing interventional pain management, patient satisfaction dropped dramatically.

Please explain what you mean by anecdotal information from physicians. Please give some specific examples.

Physicians have informally (anecdotally) advised us of numerous accounts of patients having such pain that most of the patients felt they were beyond help, and would just half to live with the pain or take drugs the rest of their lives. Actual numbers of patients were not retained.

Of these procedures how many are based on historical utilization and how many from anecdotal information from doctors in the Knoxville area.

While these figures could hypothetically include anecdotal information as to potential referrals, the reasonableness of these projections is merited by historical information and current experience. As stated in response to #10 below, based on our patient files from when we were providing interventional pain management procedures, over 50% of Lensgraf Clinic, PC's new patients were seen in the ASTC. Using even a current experience of 175 new patients per month and the number of visits historically experienced by a new patient in one month, we are able to arrive at a projected case number of 2,700 cases in Year 1. We used a reasonable Year 2 growth rate of 15% to arrive at 3,100 cases in that year. These estimates are conservative as they do not even include repeat visits by existing patients.

In addition, please clarify if the mentioned Knoxville doctors have verbally committed or have provided letters stating they will refer to the proposed project.

Most of the Physicians listed are Chiropractic Physicians, and there is not another ASTC with the specialty of MUA and interventional pain management procedures. They have verbally committed to referring patients to our ASTC, and some of them will be writing letters of support.

D.C. applicants are traditionally denied admitting privileges when requesting application to perform MUA at other ASTCs. This is true even though the MUA procedures are performed by a multi-disciplinary team involving a medical partner (M.D. or D.O.). For several years prior to requesting our own ASTC, our D.C., D.O., and M.D. that wanted to perform these procedures were denied, and in most cases existing facilities would not even give them an application form. There is also a DC who has applied and been accepted to our ASTC from Chattanooga that has and will continue to bring his patients to our facility because no ASTC in his area would accept him or his patients. Previously, this Chattanooga physician was taking his patients to Atlanta.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

8. Section C, Need, Item 1.a, Service Specific Criteria-ASTC (4) Need and Economic Efficiencies

Please address the following statement as related to this proposal:

"A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed, if those services are known and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above."

As stated, there are no comparable ASTCs in Knoxville that restrict their services to what we will provide (MUA/MUJA/interventional pain management) and will accept patients from M.D.s, D.O.s and D.C.s for these procedures. According to the latest JAR information (2012, Provisional), there are six ASTCs in Knoxville. Apparently, none of these facilities limit their procedures to pain management (since none of the existing ASTCs report 100% of their patients receive pain management). The highest percentage of pain management patients was at Fort Sanders West Outpatient Surgery Center, for which 59.3% of its patients involved pain management. That facility averaged 3,658 total procedures per room (see *Attachment C.N.5.B*). This amount (3,658) is about 96% higher than the stated Guideline amount of 1,867 cases per room. Any comparison of total outpatient surgery utilization is fruitless, since there is no way to establish "comparable services" as suggested in the Guidelines.

9. Section C, Need, Item 1.a, Service Specific Criteria-ASTC (6) Other Standards and Criteria

Please document that a majority of patients reside within 60 minutes average drive time to the applicant's facility.

The ASTC is located in Knoxville. Knoxville is in the geographic center of Knox County, which is our only service area. Knox County is approximately 33 miles wide (East to West), and approximately 22 miles high (North to South). Surely, the majority of patients in Knox County reside within 60 minutes average drive time to our ASTC.

SUPPLEMENTAL- # 1
OCTOBER 28
9:40am

10. Section C, Need, Item 1.a,Service Specific Criteria-ASTC (9) Other Standards and Criteria

Please clearly state the specific methodology and assumptions by which the utilization for the first 8 quarters is projected.

Over 50% of Lensgraf Clinic, PC's new patients were seen in the ASTC. Using even a current experience of 175 new patients per month and the number of visits historically experienced by a new patient in one month, we are able to arrive at a projected case number of 2,700 cases in Year 1. We used a reasonable Year 2 growth rate of 15% to arrive at 3,100 cases in that year. These estimates are conservative as they do not even include repeat visits by existing patients.

As for our quarterly assumptions, we simply divided the projected number of annual procedures by 4 and reported that number, by quarter. Any other manner of projecting how many procedures, by quarter for 8 successive quarters, would be speculative. As we have some history of providing the service, we made the logical assumption that there would not be so much of a "ramping-up" time frame for this service and could simply resume services for which we were earlier approved.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

11. Section C, Need, Item 1.a,Service Specific Criteria-ASTC (10) Other Standards and Criteria

Please list the physicians that will provide pain intervention services in the proposed ASTC and their qualifications/certification/specialties

Cynthia Niendorff, M.D., Board Certified Anesthesiologist.

Please identify the Medical Director and his/her qualifications.

Cynthia Niendorff, M.D., Board Certified Anesthesiologist.

Please address question 10 (b).

We anticipate the existing physicians, listed above and below, will continue to utilize the ASTC. As stated, our ASTC is licensed and accredited by the Joint Commission (JCAHO), and as such, we already have sufficient staff to add this type of service. In fact, we already had been certified by JCAHO to perform injections, based on our existing staff and policies/procedures. Obviously, we are applying for CON approval to resume these services, but JCAHO has already certified us for these services. Therefore, no additional staff will be needed.

Physicians anticipated to utilize and/or referred to our ASTC are as follows:

Fred Bennett, M.D.
Scott McClain, M.D.
Richard Boyer, M.D.
Todd B. Abel, M.D.
Cynthia Niendorff, M.D.
Wayne McLemore, M.D.
Robert Odell, Jr., M.D.
Gary O'Shaughnessy, D.O.
James Foster, M.D.
Evan Willing, D.C.
Ronald Patrick, D.C.
Russell Smith, D.C.
Shantel Lafontaine, D.C.
Derrick Kimble, D.C.
Derek Lensgraf, D.C.
Elizabeth Lensgraf, D.C.
J. Scott Brown, D.C.
A. Douglas Lensgraf, D.C.
Charles H. Means, D.C.
Daniel McMahan, D.C.
D. Sean Newport, D.C.
W. David Forth, D.C.

NOTE: various CVs and Letters of Support are included.

Please identify the eight physicians that have used the existing ASTC.

Physicians that have utilized and/or referred to our ASTC are as follows:

Fred Bennett, M.D.
Scott McClain, M.D.
Richard Boyer, M.D.
Todd B. Abel, M.D.
Cynthia Niendorff, M.D.
Wayne McLemore, M.D.
Robert Odell, Jr., M.D.
Gary O'Shaughnessy, D.O.
James Foster, M.D.
Evan Willing, D.C.
Ronald Patrick, D.C.
Russell Smith, D.C.
Shantel Lafontaine, D.C.
Derrick Kimble, D.C.
Derek Lensgraf, D.C.
Elizabeth Lensgraf, D.C.
J. Scott Brown, D.C.
A. Douglas Lensgraf, D.C.
Charles H. Means, D.C.
Daniel McMahan, D.C.
D. Sean Newport, D.C.
W. David Forth, D.C.

NOTE: various CVs and Letters of Support are included.

Please document that the applicant has a contract for anesthesiology services.

Cynthia Niendorff, M.D. (Board Certified Anesthesiologist), Jonathan Vice, CRNA, Walter Geldrich, CRNA, and Jacob Geldrich, CRNA are all under contract to provide anesthesiology services.

Please identify the TennCare MCOs with which the anesthesiology service contracts.

BlueCare, AmeriChoice, Tennessee Medicaid

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

12. Section C, Need, Item 1.a, Service Specific Criteria-ASTC (11) Other Standards and Criteria, Access to ASTCs

Please indicate if there are any designated medically underserved areas in the proposed service area as designated by the United States Health Resources and Services Administration.

Yes. Please see *Supplemental Medically Underserved Areas*.

The applicant has listed insurance plans that have contracted with the applicant. Please indicate if the listed insurance companies will contract with the applicant for interventional pain management services.

Yes.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

13. Section C, Need, Item 3.

Please provide the projected number and percentage of patients by county of residence.

The ASTC is located in Knoxville. Knoxville is in the geographic center of Knox County, which is our service area. All patients, 100%, will be from Knox County. The Application states that we anticipate 2,700 patients in Year 1. We anticipate that all will live in, and originate from, Knox County.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

14. Section C, Need, Item 4.A.

Your response to this item is noted. Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area.

Variable	Knox	Service Area	TN
2013 Age 65+	61,335	61,335	904,587
2015 Age 65+	65,118	65,118	960,158
Age 65+, % Change	6.2%	6.2%	6.1%
2015 Age 65+, % Total	14.9%	14.9%	14.7%
2013 Total Pop.	431,991	431,991	6,414,297
2015 Total Pop.	438,060	438,060	6,530,459
Total Pop. % Change	1.4%	1.4%	1.8%
TennCare Enrollees 2012	62,766	62,766	1,206,538
TennCare Enrollees as a % of Total Pop.	14.5%	14.5%	18.8%
Median Age	32.7	32.7	41.3
Median Household Income 2007-2011	47,277	47,277	43,989
Below Poverty Level % 2007-2011	13.7%	13.7%	16.9%

Again, the reason the numbers are the same for both Knox County and Service Area (in the above chart), is that Knox County is the only county in our proposed service area.

15. Section C, Need Item 5

Please indicate if there are unimplemented CONs of similar institutions in the service area.

There are none, to our knowledge.

The last three years of JAR data in attachment C.N.5.B. include 2012 provisional data. Please also include final 2009 Joint Annual Report data in this chart.

Please see *Supplemental C.N.5.B*, which shows requested 2009 utilization data for all ASTCs in the service area.

There is no way to compare financial data (gross and net charges) with existing facilities, as there are no existing facilities with comparable services. All existing ASTCs provide services unlike what we will be providing, because none of them limit their services to pain management services, according to the Joint Annual Reports.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

16. Section C, Economic Feasibility, Project Costs Chart

Please indicate if the applicant already has fluoroscopic equipment for injections. If not, does the applicant intend to purchase fluoroscopic equipment?

We do have a fluoroscope.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

17. Economic Feasibility, Item 2, Project Funding

Please provide documentation from the Chief Financial Officer of adequate cash reserves to pay for project costs.

As stated, our ASTC is already licensed, and no renovation is necessary to add this service. In addition, all equipment needed is already purchased and in place (as we had been performing these procedures with prior HSDA approval). All costs associated with this project are administrative, only, and have already been paid. No more cash is needed to pay for this project.

SUPPLEMENTAL- # 1
OCTOBER 21
9:40am

18. Economic Feasibility, Item 4, Historical Data Chart and Projected Data Chart

The historical data chart and projected data charts have management fees assigned. Please identify the management company.

Please pardon this error. The line item at D.8.a. in the Historical and Projected Data Charts, previously identified as "Fees to Affiliates" under Management Fees, should have been further explained to be Equipment Lease costs to an affiliate. We thought it most prudent to separately identify these costs as an explanation of our minimal capitalized equipment expenditures. This lease is with our Affiliate, Lensgraf Clinic, P.C., who owns some of the equipment utilized in our facility. We are internally managed and do not pay management fees to any company.

Replacement pages 27-R and 28-R are attached. These minimal amounts have been deleted from Lines D.8.a.in the respective charts, and added to Line D.9 in both charts. The explanation for Line D.9 has been updated to include "equipment lease."

A Medical Director is listed on the Projected Data Chart at a cost of $72,000 per year. Please clarify if this is a part-time or full-time position.

The Medical Director for the facility is available full time during the operating hours of the ASTC. However, she also provides services as an Anesthesiologist in the ASTC and at our other two Clinics. Therefore, her salary as Medical Director was allocated, based on her time and duties as such at the ASTC.

Please provide a Projected Data Chart for the total facility.

Please see attached Projected Data Chart (Entire Facility), as requested. This chart combines the numbers from the Projected Data Chart originally included with this application with projections for the more traditional MUA procedures. Please note that as we have been providing the more traditional MUA procedures at our ASTC, our projections for future utilization of this service is different from what was submitted in that original application in 2008. As the resulting numbers in this new chart include both traditional MUA (for which we are already approved) and interventional pain management (for which we are requesting), the combination of these numbers does not yield anything that can be compared to existing ASTCs, as there are no comparable ASTCs in the service area.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

19. Section C., Economic Feasibility, Item 10

The applicant balance sheet reflects a current ratio of .90:1 and $115,000 in cash. Please verify the applicant has adequate cash to meet short term obligations.

The current facility is meeting all of its financial obligations, and there will be no additional financial increases by obtaining a CON for interventional pain management procedures.

Two of the items listed in Current Liabilities on the Balance Sheet (Due to Affiliate and Shareholder Loans) are listed as such due to Accounting financial statement preparation rules in the absence of promissory notes. In reality, these items would be deferred for several years if necessary and excluded from Current Liabilities. Also, the line item of Notes Payable includes $38,000 for a LOC loan that can be and has been renewed annually if necessary, as well as moved to a term loan. If adjustment is made to Current Liabilities for these items to be only 20% (5 year notes) of their total balances, then the current ratio becomes 2.9:1. Also, given the fluctuation in collections and expenditures timing on a cash basis financial statement, the cash balance at a particular time can vary widely and has typically been higher.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

20. Section C, Economic Feasibility, Item 6.B

Please indicate the top 10 projected CPT reimbursed procedures for this proposed project.

CPT Code	Brief Description
64640	Radiofrequency ablation of upper extremity; shoulder adhesive capsulitis
64555	Peripheral Nerve Neurostimulator
64635	Radiofrequency ablation-destruction of nerve by neurolysis lumbar one level
64633	Radiofrequency ablation-destruction of nerve by neurolysis-cervical one level
62311	Epidural steroid injection lumbar
62310	Epidural steroid injection cervical or thoracic
64493	Facet Injection Lumbar one level
64490	Facet injection cervical one level
64494	Facet injection lumbar second level
23700	Adhesive Capsulitis, frozen shoulder
64491	Facet injection cervical second level.

21. Section C, Orderly Development, Item 3

Please provide the anticipated staffing pattern for the proposed project. Also, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor and Workforce Development and/or other documented sources.

We will use the following existing support staff: RN, MA/Receptionist, RT (Radiology Tech). We pay our RN $34/hr and the prevailing wage pattern is approximately $31/hr. We pay our MA $13/hour and the prevailing wage pattern is approximately $13.80. We pay our RT $24/hr and the prevailing wage pattern is approximately $23.50. No additional staff is required for the addition of this service.

SUPPLEMENTAL- # 1
OCTOBER 20
UHC-MUA Policy 9:40am

MEDICAL POLICY

MANIPULATION UNDER ANESTHESIA

Policy Number: 2012T0515F
Effective Date: May 1, 2012

Table of Contents

	Page
COVERAGE RATIONALE	1
BACKGROUND	2
CLINICAL EVIDENCE	3
U.S. FOOD AND DRUG ADMINISTRATION	9
CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)	9
APPLICABLE CODES	9
REFERENCES	16
POLICY HISTORY/REVISION INFORMATION	18

Related Medical Policies:
None

Related Coverage Determination Guidelines:
None

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this medical policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the Milliman Care Guidelines®, to assist us in administering health benefits. The Milliman Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

Manipulation under anesthesia (MUA) is proven for:
- Elbow joint for arthrofibrosis following elbow surgery or fracture
- Knee joint for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture
- Pelvis for acute traumatic fracture or dislocation
- Shoulder joint for adhesive capsulitis (e.g. frozen shoulder)

Manipulation under anesthesia is unproven for:
- Ankle
- Finger*
- Hip joint or adhesive capsulitis of the hip
- Knee joint for any condition other than for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture
- Pelvis for diastasis or subluxation

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

- Shoulder for any condition other than adhesive capsulitis (frozen shoulder)
- Spine
- Temporomandibular joint (TMJ)
- Toe
- Wrist

Published studies which are available are of relatively small sample size, short-term outcomes and lack of randomization or a control group.

* This policy does not apply to manipulation of the finger on the day following the injection of collagenase clostridium histolyticum (Xiaflex®) to treat Dupuytren's contracture.

Manipulation under anesthesia is unproven for serial manipulations for any body part or multiple body joints for the management of acute or chronic pain conditions. There is a lack of peer-reviewed published evidence supporting the need for multiple, repeat sessions of MUA for multiple body joints.

BACKGROUND

Manipulation under anesthesia (MUA) is a non-invasive procedure which combines manual manipulation of a joint or the spine with an anesthetic. In patients who are unable to tolerate manual procedures due to pain, spasm, muscle contractures, or guarding may benefit from the use of an anesthetic agent prior to manipulation. Anesthetics may include intravenous general anesthesia or mild sedation, injection of an anesthetic to the affected area, oral medication such as muscle relaxants, inhaled anesthetics, or any other type of anesthetic medication therapy. Because the patient's protective reflex mechanism is, absent under anesthesia, manipulation using a combination of specific short lever manipulations, passive stretches, and specific articular and postural kinesthetic maneuvers in order to break up fibrous adhesions and scar tissue around the joint, spine and surrounding tissue is made less difficult. Manipulation procedures can be performed under either: general anesthesia, mild sedation, or local injection of an anesthetic agent to the affected area (Reid, 2002).

Manipulation under anesthesia (MUA) may be accompanied by fluoroscopically-guided intra-articular injections with corticosteroid agents to reduce inflammation or manipulation under joint anesthesia/analgesia (MUJA). Manipulation under epidural anesthesia (MUEA) employs an epidural, segmental anesthetic, often with simultaneous epidural steroid injections, followed by spinal manipulation therapy. Other therapies may combine manipulation with cortisone injections into paraspinal tissues or joint spaces.

Spinal manipulation under anesthesia (SMUA) consists of spinal manipulation and stretching procedures performed on the patient after an anesthetic is administered (e.g., mild sedation, general anesthesia) and may be recommended when standard chiropractic care and other conservative measures have been unsuccessful. This is typically performed by chiropractors, osteopathic physicians, and orthopedic physicians along with an anesthesiologist. Theoretically, SMUA is thought to stretch the joint capsules to break up adhesions within the spinal column to allow for greater mobility and reduced back pain; however, this has not been proven in the peer-reviewed literature.

Note: Unless otherwise specified, this policy does not address closed reduction of a fracture or joint dislocation.

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

CLINICAL EVIDENCE

Manipulation under anesthesia may be performed for a variety of musculoskeletal conditions which may include the ankle, elbow, finger/toe, hip, knee, shoulder, pelvis and pelvic ring fracture, dislocation, diastatis or subluxation, and the spine.

Ankle

No evidence was identified within the evidence-based peer-reviewed literature concerning ankle manipulation under anesthesia for the treatment of any condition.

Elbow

There is little data within the evidence-based, peer reviewed literature concerning the safety and effectiveness of using manipulation under anesthesia of the elbow. Although some studies suggest that it may be useful in the early-post operative recovery of patients with joint contractures, there is a lack of substantial evidence that validates this use.

Araghi and colleagues (2010) have used a technique of elbow examination (manipulation) under anesthesia in select patients. The study comprised 51 consecutive patients who underwent an examination under anesthesia.
Forty-four patients with a minimum of 12 months follow-up revealed a mean pre-examination arc of 33 degrees, which improved to 73 degrees at the final assessment. Three patients had no appreciable change (less than 10 degrees) in the total arc, and 1 patient lost motion. Four patients underwent a second examination under anesthesia at a mean of 119 days after the first examination. The average pre-examination arc of 40 degrees increased to 78 degrees at the final assessment (mean improvement of 38 degrees). The only complication was worsening of ulnar paresthesias in 3 patients; with 2 resolving spontaneously, and 1 requiring anterior ulnar nerve transposition. The authors concluded that because this was not a controlled series, additional studies should be conducted to better identify those not likely to benefit from this procedure. In addition, this study is limited by its small sample size and lack of a control group.

A retrospective review by Tan et al. (2006) looked at 52 patients who underwent open surgical treatment for post-traumatic elbow contracture at an average of 14 months from the time of injury. Indication for operative release was functional loss of elbow arc of motion that failed non-operative therapy and a splinting program. Follow-up was 18.7 months. Of the 52 patients, 14 required closed manipulation under anesthesia, in the early postoperative period. Five patients required a second contracture release at an average of 12 months after the index release. Four patients failed because of painful motion and elbow instability. The authors concluded that recurrence of post-traumatic stiffness in the postoperative period is common but is responsive to manipulation under anesthesia and repeat releases. The relatively small number of patients and lack of randomization and a control group are weaknesses of this study.

Antuna et al. (2002) reported in a study for ulnohumeral arthroplasty for primary degenerative arthritis of the elbow that 2 patients underwent elbow manipulation under anesthesia to improve the range of motion after the ulnohumeral arthroplasty. The indication for this procedure was loss of preoperative motion or of motion attained at surgery. Both patients underwent manipulation twice, and ulnar nerve symptoms developed after the second manipulation. The arc of motion increased 40° in one patient and 45° in the other. However, because of the ulnar symptoms they no longer recommend manipulation of the elbow in the early postoperative period if the nerve has not been decompressed or translocated. They felt that patients with postoperative stiffness after ulnohumeral arthroplasty might be better treated by progressive stretching with static splints.

Chao et al. (2002) reported in a study on surgical approaches for nonneurogenic elbow heterotopic ossification with ulnar neuropathy that forceful and repetitive manipulation may add further damage to an already stiffened elbow and should be avoided after immobilization or surgery.

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

Gaur (2003) reported on eight children (ten elbows) who were found to have severe heterotopic ossification of the elbow, leading to an inability to reach the mouth for feeding and the head and the perineum for self-care. Excision of the heterotopic ossification was undertaken if the patient had this limitation of function and if movement was restricted to a total arc of motion of <50° Four of the patients underwent a manipulation under anesthesia in the post-operative period. The nine elbows available for follow-up had an improved arc of motion (an average increase of 57° This study is limited by small numbers and lack of any control group or randomization.

Finger
There is little data within the evidence-based, peer reviewed literature concerning the safety and effectiveness of using manipulation under anesthesia of the finger.

A case report of 3 patients by Guly and Azam (1982) reviews the use of manipulation for a locked finger. All 3 patients were treated with manipulation under anesthesia using a local anesthetic injected into the finger joint. Two patients had a locked middle finger and 1 patient had a locked index finger. In each case, the patient was successfully treated with gentle manipulation. This study is limited by small sample size and lack of randomization.

Hip
No studies that provide substantial evidence regarding the use of manipulation under anesthesia of the hip joint were identified.

Knee
The use of knee joint manipulation following total knee arthroplasty appears to be effective as a means of improving flexion of the joint. It also appears that this procedure may lead to a decrease in pain scores as reported within the literature.

Fitzsimmons et al. (2010) conducted a systematic review to compare manipulation under anesthesia (MUA) with arthroscopy and open arthrolysis for knee stiffness following total knee arthroplasty. The review evaluated 14,421 studies of which 23 were deemed relevant. MUA alone resulted in a mean gain in knee motion of 30 to 47 degrees. Range of motion in the arthroscopy group increased between 18.5 to 60 degrees. The open arthrolysis group had less gain in range of motion with gains between 19 and 31 degrees. The authors concluded that both MUA and arthroscopy provide similar gains in range of motion for patients with knee stiffness following total knee arthroplasty. Open athrolysis had less favorable results.

Pariente et al. (2006) conducted a retrospective review on 333 patients who were unable to achieve adequate range of motion after total knee arthroplasty. The study was conducted to compare the efficacy of a modified manipulation technique, which uses epidural anesthesia continued for postoperative analgesia, hospital stay of one to three days, continuous passive motion (CPM) for two to three days, and daily physical therapy (PT) to standard manipulation under anesthesia. Manipulation using a standard technique was performed on 273 patients (334 knees) and manipulation using a modified technique was performed on 60 patients (65 knees). Average follow-up time was 18.4 months. With the modified technique, ROM improved from 71 degrees to 102 degrees, and knee society pain, function, and total clinical scores improved as well. Successful results were observed in 48 (74%) knees with 4 additional knees having a successful result after a subsequent manipulation. The authors concluded that manipulation under epidural anesthesia represents a viable option for treatment of persistent stiffness after total knee arthroplasty.

Keating et al. (2007) studied 90 patients (113 knees) who underwent manipulation for postoperative flexion of < or =90 degrees at a mean of ten weeks after surgery. Flexion was measured with a goniometer prior to total knee arthroplasty, at the conclusion of the operative procedure, before manipulation, immediately after manipulation, at six months, and at one, three, and five years postoperatively. Of the 90 patients, 81 (90%) achieved improvement of ultimate knee flexion following manipulation. The average flexion was 102 degrees prior to total knee

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

arthroplasty, 111 degrees following skin closure, and 70 degrees before manipulation. There was no significant difference in the mean improvement in flexion when patients who had manipulation within twelve weeks postoperatively were compared with those who had manipulation more than twelve weeks postoperatively. The authors concluded that manipulation generally increases ultimate flexion following total knee arthroplasty and patients with severe preoperative pain are more likely to require manipulation.

Namba and Inacio (2007) reviewed 195 patients who had undergone manipulation under anesthesia; 102 within 90 days of total knee arthroplasty and 93 more than 90 days after total knee arthroplasty. Average pain (10-point scale), satisfaction (10-point scale), flexion (degrees), and extension (degrees) were recorded before and after MUA. Flexion was significantly improved after MUA for both groups: early MUA from 68.4 degrees (+/-17.2 degrees) to 101.4 degrees (+/-16.15 degrees); and late MUA from 81.0 degrees (+/-13.3 degrees) to 98.0 degrees (+/-18.0 degrees). Pain decreased significantly with early MUA from 4.92 (+/-2.25) to 3.34 (+/-2.67) and with late MUA from 4.51 (+/-2.62) to 3.44 (+/-2.78). Extension improved only in the early MUA group from 7.15 (+/-10.1) to 2.50 (+/-4.98). Satisfaction scores were not improved. The authors concluded that both early and late manipulation can improve TKA pain and flexion.

Multiple Joints
Evidence supporting the need for multiple, repeat sessions of MUA for these conditions was not found in the published medical literature.

Pelvis
There is little data within the evidence-based literature to assess the safety and efficacy of pelvic ring manipulation under anesthesia; however, the use of manipulation under anesthesia of the pelvis and/or pelvic ring as a result of fracture(s) or dislocation is an integral part of the restoration of the pelvic ring whether used as part of a closed or open-reduction surgical technique (Hayes, 2008).

No literature was found to support manipulation under anesthesia of the pelvis for diastasis or subluxation.

Shoulder
The use of shoulder manipulation under anesthesia to reduce pain and improve range of motion appears to be effective in patients with adhesive capsulitis (frozen shoulder) when conservative non-surgical treatment has failed.

A blinded, randomized trial with a 1 year follow-up, by Kivimaki et al. (2007) evaluated 125 patients with a frozen shoulder to determine the effect of manipulation under anesthesia. Patients were randomly assigned to either a manipulation group (65 patients) or a control group (60 patients). Both the intervention group and the control group were instructed in specific therapeutic exercises by physiotherapists. Clinical data was gathered at baseline and at 6 weeks and 3, 6, and 12 months after randomization. The 2 groups did not differ at any time of the follow-up in terms of shoulder pain or working ability. Small differences in the range of movement were detected in favor of the manipulation group. Perceived shoulder pain decreased during follow-up equally in the 2 groups, and at 1 year after randomization, only slight pain remained. The authors concluded that manipulation under anesthesia does not add effectiveness to an exercise program carried out by the patient after instruction.

Ng et al. (2009) conducted a prospective trial of 50 patients to examine the efficacy of manipulation under anaesthesia (MUA) followed by early physiotherapy in treating frozen shoulder syndrome. Disabilities of the Arm, Shoulder and Hand (DASH) score and visual analogue score (VAS) for pain and range of movement were measured preoperatively and at 6 weeks post-procedure. The mean DASH score decreased from 48.07 to 15.84 and the mean VAS reduced from 6.07 to 1.88. Flexion improved from 104.18 to 157.56; abduction from 70.48 to 150.00; and external rotation from 13.88 to 45.62. The authors concluded that MUA combined

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

with early physiotherapy alleviates pain and facilitates recovery of function in patients with frozen shoulder syndrome.

In a prospective trial conducted between 2001 and 2003 by Loew et al. (2005), 30 patients with primary frozen shoulder manipulated under general anesthesia were evaluated for post manipulative intra-articular lesions. Patients with secondary stiffness caused by rotator cuff tears and glenohumeral arthritis were excluded. Arthroscopy was used after manipulation to document any intra-articular lesions. All patients noted an improvement in range of motion. Flexion improved on average from 70 degrees (+/- 33 degrees) to 180 degrees (+/- 15 degrees), abduction from 50 degrees (+/- 20 degrees) to 170 degrees (+/- 25 degrees), and external rotation from -5 degrees (+/- 10 degrees) to +40 degrees (+/- 20 degrees). Localized synovitis was detected in 22 of the patients in the area of the rotator interval, whereas disseminated synovitis was observed in 8 patients. After manipulation, the capsule was seen to be ruptured superiorly in 11 patients, the anterior capsule was ruptured up to the infraglenoid pole in 24 patients, and 16 patients each had a capsular lesion located posteriorly. In 18 patients no additional joint damage was found and in 4 patients, iatrogenic superior labrum anterior-posterior lesions were observed. The authors concluded that even though manipulation under anesthesia is effective in terms of joint mobilization, the method can cause iatrogenic intra-articular damage.

Flannery et al. (2007) evaluated 180 consecutive patients to determine what influence timing of manipulation under anesthesia (MUA) had on long-term outcomes for adhesive capsulitis of the shoulder. Of the 180 patients, 145 were available for follow-up after a mean period of 62 months (range of 12 to 125). All patients underwent MUA with intra-articular steroid injection. Improvement was noted in range of motion and function utilizing the Oxford Shoulder Score (OSS) and Visual Analogue Score (VAS) following manipulation. Eighty-three percent of the patients had MUA performed less than 9 months from onset of symptoms (early MUA). The remainder had MUA performed 9 to 40 months (late MUA) from onset of symptoms. The authors found that both groups had better mobility and Oxford Shoulder Score as well as less pain; however the early intervention group had the most improvement.

In a study by Farrell et al. (2005), manipulation under anesthesia was performed in 25 patients (26 shoulders) for whom non-operative treatment for idiopathic frozen shoulder had failed. All of the patients had physical therapy for a mean of 6.2 months. Long-term follow-up was obtained in 18 patients (19 shoulders) by questionnaire and averaged 15 years (range, 8.1 to 20.6 years). There were significant improvements in forward elevation from a mean of 104 degrees before manipulation to 168 degrees and in external rotation from 23 degrees to 67 degrees. There were 16 shoulders with no pain or slight pain and 3 with occasional moderate or severe pain. Of the 19 shoulders, 18 required no further surgery. The mean Simple Shoulder Test score was 9.5 out of 12 and the mean American Shoulder and Elbow Surgeons score was 80 out of 100. The authors conclude that treatment of idiopathic frozen shoulder by manipulation under anesthesia leads to sustained improvement in shoulder motion and function at a mean of 15 years after the procedure.

Spine

There are several studies in evidence based peer-reviewed literature which recommend that additional studies are needed to support the safety and effectiveness of spinal manipulation under anesthesia.

In a prospective study of 68 chronic low-back pain patients, Kohlbeck et al. (2005) compared changes in pain and disability for chronic low-back pain patients receiving treatment with medication-assisted manipulation (MAM) to patients receiving spinal manipulation only. All patients received an initial 4- to 6-week trial of spinal manipulation therapy (SMT), after which 42 patients received supplemental intervention with MAM and the remaining 26 patients continued with SMT. Low back pain and disability measures favored the MAM group over the SMT-only group at 3 months. The authors concluded that medication-assisted manipulation appears to offer some patients increased improvement in low back pain and disability; however the study is limited

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

by lack of randomization, small sample size and significant baseline differences between groups for the primary outcome variable (pain/disability scale).

In a prospective controlled study by Palmieri and Smoyak (2002), 87 patients who received either spinal manipulation under anesthesia (SMUA) or traditional chiropractic treatment for low back pain were evaluated. The participants were assigned to one of two groups: 38 to an intervention group who received MUA and 49 patients to a nonintervention group who received traditional chiropractic treatment. Patients were followed for 4 weeks. Self-reported outcomes, including back pain severity and functional status, were used to evaluate changes. The MUA group had an average decrease of 50% in the Numeric Pain Scale scores while the nonintervention group had a 26% decrease. The MUA group had an average decrease of 51% in the Roland-Morris Questionnaire scores while the nonintervention group had a 38% decrease. The authors concluded that while there was greater improvement in the intervention group, additional studies are needed to evaluate the safety and effectiveness of MUA.

This study is flawed due to the methods used to select subjects, lack of assessor blinding, failure to isolate the effects of the active intervention, and interpretation of outcomes. Subjects were selected largely based upon 2 criteria: meeting NAMUAP eligibility requirements and having insurance coverage for MUA. This led to significant baseline heterogeneities between intervention and control groups. Sample size (N=87; MUA group = 38; SMT group = 49) did not reach anticipated number of participants. The attempt to measure the difference in treatment effect between MUA and SMT was confounded by the addition of a specific exercise protocol for the MUA group vs. an undefined "home exercise" program for the SMT group. Follow-up period was limited. Problems with obtaining timely follow-up data were reported. The use of a percentile difference in outcome scores between groups does not take into account if each outcome of interest exhibited a clinically meaningful difference between each group. In fact, there were no statistical or clinically meaningful differences between groups. There was a difference of 1.52 points on the NRS at initial follow-up and 1.32 points difference at final follow-up (the minimal clinically important change has been widely reported as 2 points). The difference at initial follow-up for the RMDQ was 2.2 points and at final follow-up was 1 point (as noted in the study, a 4 point difference is necessary for it to be clinically meaningful).

Cremata et al. (2005) reported the results of manipulation under anesthesia (MUA) for 4 patients with chronic spinal, sacroiliac, and/or pelvic and low back pain. Patients with chronic pain who had not adequately responded to conservative medical and/or a reasonable trial (4 months minimum) of chiropractic adjustments, and had no contraindications to anesthesia or adjustments, were selected. The 4 patients went through 3 consecutive days of MUA followed by an 8-week protocol of the same procedures plus physiotherapy in-office without anesthesia. Data included pre- and post-MUA passive ranges of motion, changes in the visual analog scale, neurologic and orthopedic examination findings. The patients had follow-up varying from 9 to 18 months and showed improvement in passive ranges of motion, decreases in the visual analog scale rating, and diminishment of subsequent visit frequency. The authors concluded that manipulation under anesthesia was an effective approach to restoring articular and myofascial movements in patients who did not adequately respond to either medical in-office conservative chiropractic adjustments and/or adjunctive techniques. Weaknesses of this study include small sample size and lack of randomization. Additional studies are needed to evaluate the safety and effectiveness of spinal MUA.

A descriptive case series reported on the outcomes of 177 subjects, who met a set of inclusion criteria, which included prior failed response to conventional manipulation (2-6 weeks trial) (West, 1999). All subjects underwent three serial MUAs. Post-MUA results included increased range of motion and clinically meaningful pain reduction. Both these outcomes showed continued improvement at 6-months follow-up. Unfortunately, the study design was incompatible with the objective of establishing a causal relationship i.e., the efficacy of MUA for a selected population. Additionally, an attempt to measure the strength of association of MUA with the outcomes was confounded by the inclusion of a broad range of other interventions rendered within the

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

framework of this study. Interventions reportedly included: passive modalities, different types of exercise, as well as traditional spinal manipulative therapy.

Temporomandibular Joint (TMJ)
Available evidence for manipulation under anesthesia for temporomandibular joint syndrome is limited to small, uncontrolled studies with limited follow-up.

Foster et al. (2000) studied 55 patients receiving manipulation under general anesthesia of the temporomandibular joint to determine the success rate of MUA effectiveness in an effort to reduce the number of patients being referred for invasive surgery. Of the 55 patients participating in this study, 15 improved, 15 did not, 6 showed partial improvement and 19 were not treated. The median pre-treatment opening was 20mm (range 13-27). Among those who improved after manipulation, the median opening after treatment was 38mm (range 35-56). The authors concluded that MUA may help some patients; however, some of those who improved experienced a return of TMJ clicking but not of joint or muscle tenderness.

Toe
No evidence was identified within the evidence-based peer-reviewed literature concerning manipulation under anesthesia of the toe.

Wrist
Available evidence for manipulation under anesthesia for wrist is limited to small, uncontrolled studies with limited follow-up or case studies.

Hanson et al. (1988) reported on 10 patients having thickening and contracture of the wrist joint capsule. Four of the 10 patients required manipulation under anesthesia which resulted in some improvement in range of motion. The authors note that while manipulation under anesthesia may be promising, careful technique and judicious patient selection are of paramount importance. Small sample size, lack of randomization, and no indication of follow-up are limitations of this study.

Professional Societies
The International Chiropractors Association (ICA), in its 2000 publication *Recommended Clinical Protocols And Guidelines For The Practice Of Chiropractic*, ICA states that within the armamentarium of chiropractic techniques, efficient methods exist that address the pain profiles of even the most sensitive patient. Furthermore, the chiropractic adjustment relies on the body's own inherent constructive survival mechanisms to innately accomplish adjusted correction. In light of the above considerations, the International Chiropractors Association holds that anesthesia is inappropriate and unnecessary to the deliverance of a chiropractic adjustment.

The International MUA Academy of Physicians lists the following general indications for manipulation under anesthesia (IMUAA, 2006):

- Fibro adhesion buildup
- Chronic disc problems
- Herniated disc without fragmentation
- Chronic myofascitis
- Intractable pain from neuromusculoskeletal conditions
- Torticollis
- Chronic re-injury
- Failed back surgery

According to the American College of Occupational and Environmental Medicine (ACOEM) practice guidelines regarding physical methods of treatment for low back disorders (Hegmann, 2007;update: Hegmann, et al., 2008), due to insufficient evidence manipulation under anesthesia

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

(MUA) and medication-assisted spinal manipulation (MASM) for acute, subacute or chronic low back pain is not recommended.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Manipulation is a procedure and therefore not subject to FDA regulation.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for manipulation under anesthesia. Local Coverage Determinations (LCDs) for Manipulation Under Anesthesia (MUA), exist and compliance with these policies is required where applicable. (Accessed January 11, 2012)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT® Code	Description
21073	Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)
22505	Manipulation of spine requiring anesthesia, any region
23700	Manipulation under anesthesia, shoulder joint, including application of fixation apparatus (dislocation excluded)
24300	Manipulation, elbow, under anesthesia
25259	Manipulation, wrist, under anesthesia
26340	Manipulation, finger joint, under anesthesia, each joint
27194	Closed treatment of pelvic ring fracture, dislocation, diastasis or subluxation; with manipulation, requiring more than local anesthesia
27275	Manipulation, hip joint, requiring general anesthesia
27570	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices)
27860	Manipulation of ankle under general anesthesia (includes application of traction or other fixation apparatus)

CPT® is a registered trademark of the American Medical Association.

ICD-9 Code (Proven)	Description
718.51	Ankylosis of joint of shoulder region
718.52	Ankylosis of upper arm joint
718.56	Ankylosis of lower leg joint
726.0	Adhesive capsulitis of shoulder
726.10	Unspecified disorders of bursae and tendons in shoulder region
726.11	Calcifying tendinitis of shoulder
733.19	Pathologic fracture of other specified site
805.6	Closed fracture of sacrum and coccyx without mention of spinal cord injury
806.61	Closed fracture of sacrum and coccyx with complete cauda equina lesion
806.62	Closed fracture of sacrum and coccyx with other cauda equina injury

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

806.79	Open fracture of sacrum and coccyx with other spinal cord injury
808.0	Closed fracture of acetabulum
808.2	Closed fracture of pubis
808.41	Closed fracture of ilium
808.42	Closed fracture of ischium
808.43	Multiple closed pelvic fractures with disruption of pelvic circle
808.44	Multiple closed pelvic fractures without disruption of pelvic circle
808.49	Closed fracture of other specified part of pelvis
808.53	Multiple open pelvic fractures with disruption of pelvic circle
808.54	Multiple open pelvic fractures without disruption of pelvic circle
839.41	Closed dislocation, coccyx
839.42	Closed dislocation, sacrum

ICD-10 Codes (Preview Draft)
In preparation for the transition from ICD-9 to ICD-10 medical coding on October 1, 2014`, a sample listing of the ICD-10 CM and/or ICD-10 PCS codes associated with this policy has been provided below for your reference. This list of codes may not be all inclusive and will be updated to reflect any applicable revisions to the ICD-10 code set and/or clinical guidelines outlined in this policy. *The effective date for ICD-10 code set implementation is subject to change.

ICD-10 Diagnosis Code (Effective 10/01/14)	Description
M24.611	Ankylosis, right shoulder
M24.612	Ankylosis, left shoulder
M24.619	Ankylosis, unspecified shoulder
M24.621	Ankylosis, right elbow
M24.622	Ankylosis, left elbow
M24.629	Ankylosis, unspecified elbow
M24.661	Ankylosis, right knee
M24.662	Ankylosis, left knee
M24.669	Ankylosis, unspecified knee
M66.211	Spontaneous rupture of extensor tendons, right shoulder
M66.212	Spontaneous rupture of extensor tendons, left shoulder
M66.219	Spontaneous rupture of extensor tendons, unspecified shoulder
M66.811	Spontaneous rupture of other tendons, right shoulder
M66.812	Spontaneous rupture of other tendons, left shoulder
M66.819	Spontaneous rupture of other tendons, unspecified shoulder
M75.00	Adhesive capsulitis of unspecified shoulder
M75.01	Adhesive capsulitis of right shoulder
M75.02	Adhesive capsulitis of left shoulder
M75.100	Unspecified rotator cuff tear or rupture of unspecified shoulder, not specified as traumatic
M75.101	Unspecified rotator cuff tear or rupture of right shoulder, not specified as traumatic
M75.102	Unspecified rotator cuff tear or rupture of left shoulder, not specified as traumatic
M75.30	Calcific tendinitis of unspecified shoulder
M75.31	Calcific tendinitis of right shoulder
M75.32	Calcific tendinitis of left shoulder
M75.50	Bursitis of unspecified shoulder
M75.51	Bursitis of right shoulder
M75.52	Bursitis of left shoulder
M80.011A	Age-related osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

M80.012A	Age-related osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.019A	Age-related osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.041A	Age-related osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.042A	Age-related osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.049A	Age-related osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.811A	Other osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.812A	Other osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.819A	Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.841A	Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.842A	Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.849A	Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M84.411A	Pathological fracture, right shoulder, initial encounter for fracture
M84.412A	Pathological fracture, left shoulder, initial encounter for fracture
M84.419A	Pathological fracture, unspecified shoulder, initial encounter for fracture
M84.441A	Pathological fracture, right hand, initial encounter for fracture
M84.442A	Pathological fracture, left hand, initial encounter for fracture
M84.443A	Pathological fracture, unspecified hand, initial encounter for fracture
M84.444A	Pathological fracture, right finger(s), initial encounter for fracture
M84.445A	Pathological fracture, left finger(s), initial encounter for fracture
M84.446A	Pathological fracture, unspecified finger(s), initial encounter for fracture
M84.454A	Pathological fracture, pelvis, initial encounter for fracture
M84.474A	Pathological fracture, right foot, initial encounter for fracture
M84.475A	Pathological fracture, left foot, initial encounter for fracture
M84.476A	Pathological fracture, unspecified foot, initial encounter for fracture
M84.477A	Pathological fracture, right toe(s), initial encounter for fracture
M84.478A	Pathological fracture, left toe(s), initial encounter for fracture
M84.479A	Pathological fracture, unspecified toe(s), initial encounter for fracture
M84.48XA	Pathological fracture, other site, initial encounter for fracture
M84.511A	Pathological fracture in neoplastic disease, right shoulder, initial encounter for fracture
M84.512A	Pathological fracture in neoplastic disease, left shoulder, initial encounter for fracture
M84.519A	Pathological fracture in neoplastic disease, unspecified shoulder, initial encounter for fracture
M84.541A	Pathological fracture in neoplastic disease, right hand, initial encounter for fracture
M84.542A	Pathological fracture in neoplastic disease, left hand, initial encounter for fracture
M84.549A	Pathological fracture in neoplastic disease, unspecified hand, initial encounter for fracture
M84.550A	Pathological fracture in neoplastic disease, pelvis, initial encounter

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

	for fracture
M84.574A	Pathological fracture in neoplastic disease, right foot, initial encounter for fracture
M84.575A	Pathological fracture in neoplastic disease, left foot, initial encounter for fracture
M84.576A	Pathological fracture in neoplastic disease, unspecified foot, initial encounter for fracture
M84.611A	Pathological fracture in other disease, right shoulder, initial encounter for fracture
M84.612A	Pathological fracture in other disease, left shoulder, initial encounter for fracture
M84.619A	Pathological fracture in other disease, unspecified shoulder, initial encounter for fracture
M84.641A	Pathological fracture in other disease, right hand, initial encounter for fracture
M84.642A	Pathological fracture in other disease, left hand, initial encounter for fracture
M84.649A	Pathological fracture in other disease, unspecified hand, initial encounter for fracture
M84.650A	Pathological fracture in other disease, pelvis, initial encounter for fracture
M84.674A	Pathological fracture in other disease, right foot, initial encounter for fracture
M84.675A	Pathological fracture in other disease, left foot, initial encounter for fracture
M84.676A	Pathological fracture in other disease, unspecified foot, initial encounter for fracture
M84.68XA	Pathological fracture in other disease, other site, initial encounter for fracture
M99.14	Subluxation complex (vertebral) of sacral region
S32.10XA	Unspecified fracture of sacrum, initial encounter for closed fracture
S32.10XB	Unspecified fracture of sacrum, initial encounter for open fracture
S32.110A	Nondisplaced Zone I fracture of sacrum, initial encounter for closed fracture
S32.111A	Minimally displaced Zone I fracture of sacrum, initial encounter for closed fracture
S32.112A	Severely displaced Zone I fracture of sacrum, initial encounter for closed fracture
S32.119A	Unspecified Zone I fracture of sacrum, initial encounter for closed fracture
S32.120A	Nondisplaced Zone II fracture of sacrum, initial encounter for closed fracture
S32.121A	Minimally displaced Zone II fracture of sacrum, initial encounter for closed fracture
S32.122A	Severely displaced Zone II fracture of sacrum, initial encounter for closed fracture
S32.129A	Unspecified Zone II fracture of sacrum, initial encounter for closed fracture
S32.130A	Nondisplaced Zone III fracture of sacrum, initial encounter for closed fracture
S32.131A	Minimally displaced Zone III fracture of sacrum, initial encounter for closed fracture
S32.132A	Severely displaced Zone III fracture of sacrum, initial encounter for closed fracture
S32.139A	Unspecified Zone III fracture of sacrum, initial encounter for closed

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

	fracture
S32.14XA	Type 1 fracture of sacrum, initial encounter for closed fracture
S32.15XA	Type 2 fracture of sacrum, initial encounter for closed fracture
S32.16XA	Type 3 fracture of sacrum, initial encounter for closed fracture
S32.17XA	Type 4 fracture of sacrum, initial encounter for closed fracture
S32.19XA	Other fracture of sacrum, initial encounter for closed fracture
S32.2XXA	Fracture of coccyx, initial encounter for closed fracture
S32.2XXB	Fracture of coccyx, initial encounter for open fracture
S32.301A	Unspecified fracture of right ilium, initial encounter for closed fracture
S32.302A	Unspecified fracture of left ilium, initial encounter for closed fracture
S32.309A	Unspecified fracture of unspecified ilium, initial encounter for closed fracture
S32.311A	Displaced avulsion fracture of right ilium, initial encounter for closed fracture
S32.312A	Displaced avulsion fracture of left ilium, initial encounter for closed fracture
S32.313A	Displaced avulsion fracture of unspecified ilium, initial encounter for closed fracture
S32.314A	Nondisplaced avulsion fracture of right ilium, initial encounter for closed fracture
S32.315A	Nondisplaced avulsion fracture of left ilium, initial encounter for closed fracture
S32.316A	Nondisplaced avulsion fracture of unspecified ilium, initial encounter for closed fracture
S32.391A	Other fracture of right ilium, initial encounter for closed fracture
S32.392A	Other fracture of left ilium, initial encounter for closed fracture
S32.399A	Other fracture of unspecified ilium, initial encounter for closed fracture
S32.401A	Unspecified fracture of right acetabulum, initial encounter for closed fracture
S32.402A	Unspecified fracture of left acetabulum, initial encounter for closed fracture
S32.409A	Unspecified fracture of unspecified acetabulum, initial encounter for closed fracture
S32.411A	Displaced fracture of anterior wall of right acetabulum, initial encounter for closed fracture
S32.412A	Displaced fracture of anterior wall of left acetabulum, initial encounter for closed fracture
S32.413A	Displaced fracture of anterior wall of unspecified acetabulum, initial encounter for closed fracture
S32.414A	Nondisplaced fracture of anterior wall of right acetabulum, initial encounter for closed fracture
S32.415A	Nondisplaced fracture of anterior wall of left acetabulum, initial encounter for closed fracture
S32.416A	Nondisplaced fracture of anterior wall of unspecified acetabulum, initial encounter for closed fracture
S32.421A	Displaced fracture of posterior wall of right acetabulum, initial encounter for closed fracture
S32.422A	Displaced fracture of posterior wall of left acetabulum, initial encounter for closed fracture
S32.423A	Displaced fracture of posterior wall of unspecified acetabulum, initial encounter for closed fracture
S32.424A	Nondisplaced fracture of posterior wall of right acetabulum, initial encounter for closed fracture

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

S32.425A	Nondisplaced fracture of posterior wall of left acetabulum, initial encounter for closed fracture
S32.426A	Nondisplaced fracture of posterior wall of unspecified acetabulum, initial encounter for closed fracture
S32.431A	Displaced fracture of anterior column [iliopubic] of right acetabulum, initial encounter for closed fracture
S32.432A	Displaced fracture of anterior column [iliopubic] of left acetabulum, initial encounter for closed fracture
S32.433A	Displaced fracture of anterior column [iliopubic] of unspecified acetabulum, initial encounter for closed fracture
S32.434A	Nondisplaced fracture of anterior column [iliopubic] of right acetabulum, initial encounter for closed fracture
S32.435A	Nondisplaced fracture of anterior column [iliopubic] of left acetabulum, initial encounter for closed fracture
S32.436A	Nondisplaced fracture of anterior column [iliopubic] of unspecified acetabulum, initial encounter for closed fracture
S32.441A	Displaced fracture of posterior column [ilioischial] of right acetabulum, initial encounter for closed fracture
S32.442A	Displaced fracture of posterior column [ilioischial] of left acetabulum, initial encounter for closed fracture
S32.443A	Displaced fracture of posterior column [ilioischial] of unspecified acetabulum, initial encounter for closed fracture
S32.444A	Nondisplaced fracture of posterior column [ilioischial] of right acetabulum, initial encounter for closed fracture
S32.445A	Nondisplaced fracture of posterior column [ilioischial] of left acetabulum, initial encounter for closed fracture
S32.446A	Nondisplaced fracture of posterior column [ilioischial] of unspecified acetabulum, initial encounter for closed fracture
S32.451A	Displaced transverse fracture of right acetabulum, initial encounter for closed fracture
S32.452A	Displaced transverse fracture of left acetabulum, initial encounter for closed fracture
S32.453A	Displaced transverse fracture of unspecified acetabulum, initial encounter for closed fracture
S32.454A	Nondisplaced transverse fracture of right acetabulum, initial encounter for closed fracture
S32.455A	Nondisplaced transverse fracture of left acetabulum, initial encounter for closed fracture
S32.456A	Nondisplaced transverse fracture of unspecified acetabulum, initial encounter for closed fracture
S32.461A	Displaced associated transverse-posterior fracture of right acetabulum, initial encounter for closed fracture
S32.462A	Displaced associated transverse-posterior fracture of left acetabulum, initial encounter for closed fracture
S32.463A	Displaced associated transverse-posterior fracture of unspecified acetabulum, initial encounter for closed fracture
S32.464A	Nondisplaced associated transverse-posterior fracture of right acetabulum, initial encounter for closed fracture
S32.465A	Nondisplaced associated transverse-posterior fracture of left acetabulum, initial encounter for closed fracture
S32.466A	Nondisplaced associated transverse-posterior fracture of unspecified acetabulum, initial encounter for closed fracture
S32.471A	Displaced fracture of medial wall of right acetabulum, initial encounter for closed fracture
S32.472A	Displaced fracture of medial wall of left acetabulum, initial encounter

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

	for closed fracture
S32.473A	Displaced fracture of medial wall of unspecified acetabulum, initial encounter for closed fracture
S32.474A	Nondisplaced fracture of medial wall of right acetabulum, initial encounter for closed fracture
S32.475A	Nondisplaced fracture of medial wall of left acetabulum, initial encounter for closed fracture
S32.476A	Nondisplaced fracture of medial wall of unspecified acetabulum, initial encounter for closed fracture
S32.481A	Displaced dome fracture of right acetabulum, initial encounter for closed fracture
S32.482A	Displaced dome fracture of left acetabulum, initial encounter for closed fracture
S32.483A	Displaced dome fracture of unspecified acetabulum, initial encounter for closed fracture
S32.484A	Nondisplaced dome fracture of right acetabulum, initial encounter for closed fracture
S32.485A	Nondisplaced dome fracture of left acetabulum, initial encounter for closed fracture
S32.486A	Nondisplaced dome fracture of unspecified acetabulum, initial encounter for closed fracture
S32.491A	Other specified fracture of right acetabulum, initial encounter for closed fracture
S32.492A	Other specified fracture of left acetabulum, initial encounter for closed fracture
S32.499A	Other specified fracture of unspecified acetabulum, initial encounter for closed fracture
S32.501A	Unspecified fracture of right pubis, initial encounter for closed fracture
S32.502A	Unspecified fracture of left pubis, initial encounter for closed fracture
S32.509A	Unspecified fracture of unspecified pubis, initial encounter for closed fracture
S32.511A	Fracture of superior rim of right pubis, initial encounter for closed fracture
S32.512A	Fracture of superior rim of left pubis, initial encounter for closed fracture
S32.519A	Fracture of superior rim of unspecified pubis, initial encounter for closed fracture
S32.591A	Other specified fracture of right pubis, initial encounter for closed fracture
S32.592A	Other specified fracture of left pubis, initial encounter for closed fracture
S32.599A	Other specified fracture of unspecified pubis, initial encounter for closed fracture
S32.601A	Unspecified fracture of right ischium, initial encounter for closed fracture
S32.602A	Unspecified fracture of left ischium, initial encounter for closed fracture
S32.609A	Unspecified fracture of unspecified ischium, initial encounter for closed fracture
S32.611A	Displaced avulsion fracture of right ischium, initial encounter for closed fracture
S32.612A	Displaced avulsion fracture of left ischium, initial encounter for closed fracture
S32.613A	Displaced avulsion fracture of unspecified ischium, initial encounter

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

	for closed fracture
S32.614A	Nondisplaced avulsion fracture of right ischium, initial encounter for closed fracture
S32.615A	Nondisplaced avulsion fracture of left ischium, initial encounter for closed fracture
S32.616A	Nondisplaced avulsion fracture of unspecified ischium, initial encounter for closed fracture
S32.691A	Other specified fracture of right ischium, initial encounter for closed fracture
S32.692A	Other specified fracture of left ischium, initial encounter for closed fracture
S32.699A	Other specified fracture of unspecified ischium, initial encounter for closed fracture
S32.810A	Multiple fractures of pelvis with stable disruption of pelvic ring, initial encounter for closed fracture
S32.810B	Multiple fractures of pelvis with stable disruption of pelvic ring, initial encounter for open fracture
S32.811A	Multiple fractures of pelvis with unstable disruption of pelvic ring, initial encounter for closed fracture
S32.811B	Multiple fractures of pelvis with unstable disruption of pelvic ring, initial encounter for open fracture
S32.82XA	Multiple fractures of pelvis without disruption of pelvic ring, initial encounter for closed fracture
S32.82XB	Multiple fractures of pelvis without disruption of pelvic ring, initial encounter for open fracture
S32.89XA	Fracture of other parts of pelvis, initial encounter for closed fracture
S32.9XXA	Fracture of unspecified parts of lumbosacral spine and pelvis, initial encounter for closed fracture
S33.2XXA	Dislocation of sacroiliac and sacrococcygeal joint, initial encounter
S34.131A	Complete lesion of sacral spinal cord, initial encounter
S34.132A	Incomplete lesion of sacral spinal cord, initial encounter
S34.3XXA	Injury of cauda equina, initial encounter

REFERENCES

Antuna SA, Morrey BF, Adams RA, et al. Ulnohumeral arthroplasty for primary degenerative arthritis of the elbow: Long-term outcome and complications. Journal of Bone and Joint Surgery - Series A. 84(12) (pp 2168-2173), 2002.

Araghi A, Celli A, Adams R, Morrey B. The outcome of examination (manipulation) under anesthesia on the stiff elbow after surgical contracture release. J Shoulder Elbow Surg. 2010; 19(2):202-208.

Chao EK, Chen AC, Lee MS, et al. Surgical approaches for nonneurogenic elbow heterotopic ossification with ulnar neuropathy. Journal of Trauma-Injury Infection & Critical Care. 53(5):928-33, 2002 Nov.

Cremata E, Collins S, Clauson W, et al. Manipulation under anesthesia: A report of four cases. Journal of Manipulative and Physiological Therapeutics. 28(7)(pp 526-533), 2005.

ECRI Institute. Hotline Report. Manipulation Under Anesthesia for Low Back Pain. September 12, 2007.

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

ECRI Institute. Hotline Report. Manipulation Under Anesthesia of Nonspinal Body Joints. October 2010.

Fitzsimmons SE, Vazquez EA, Bronson MJ. How to treat the stiff total knee arthroplasty?: a systematic review. Clin Orthop Relat Res. 2010 Apr;468(4):1096-106. Epub 2010 Jan 20.

Flannery O, Mullett H, Colville J. Adhesive shoulder capsulitis: does the timing of manipulation influence outcome?. Acta Orthopaedica Belgica. 73(1):21-5, 2007 Feb.

Foster ME, Gray RJ, Davies SJ, et al. Therapeutic manipulation of the temporomandibular joint. Br J Oral Maxillofac Surg. 2000;38(6):641-644.

Gaur A, Sinclair M, Caruso E, et al. Heterotopic Ossification Around the Elbow Following Burns in Children: Results After Excision. J Bone Joint Surg Am. 2003;85:1538-1543.

Guly HR, Azam MA. Locked Finger Treated by Manipulation. Br ES of Bone and Joint Surgery. 1982;64B(1):73-75.

Hanson EC, Wood VE, Thiel AE, et al. Adhesive capsulitis of the wrist. Diagnosis and treatment. Clin Orthop Relat Res. 1988 Sep;(234):51-5.

Hayes Inc. Custom Health Technology Assessment. Closed treatment of Pelvic Ring Fracture, Dislocation, Diastasis or subluxation, with manipulation, requiring more than local. Lansdale, PA: Hayes Inc.; May 2008a.

Hayes Inc. Search and Summary. Spinal Manipulation Under Anesthesia for the Treatment of Pain. Lansdale, PA: Hayes Inc.; September 2007. Last updated December 14, 2009.

Keating EM. Ritter MA. Harty LD. et al. Manipulation after total knee arthroplasty. Journal of Bone & Joint Surgery - American Volume. 89(2):282-6, 2007 Feb.

Kivimaki J, Pohjolainen T, Malmivaara A, et al. Manipulation under anesthesia with home exercises versus home exercises alone in the treatment of frozen shoulder: A randomized, controlled trial with 125 patients. Journal of Shoulder and Elbow Surgery. 16(6)(pp 722-726), 2007.

Kohlbeck FJ, Haldeman S, Hurwitz EL, et al. Supplemental care with medication-assisted manipulation versus spinal manipulation therapy alone for patients with chronic low back pain. J Manipulative Physiol Ther. 2005 May;28(4):245-52.

Loew M, Heichel TO, Lehner B. Intraarticular lesions in primary frozen shoulder after manipulation under general anesthesia. Journal of Shoulder & Elbow Surgery. 14(1):16-21, 2005 Jan-Feb.

Namba R.S. Inacio M. Early and Late Manipulation Improve Flexion After Total Knee Arthroplasty. Journal of Arthroplasty. 22(6 SUPPL.)(pp 58-61), 2007. Date of Publication: Sep 2007.

Ng CY, Amin AK, Narborough S, et al. Manipulation under anaesthesia and early physiotherapy facilitate recovery of patients with frozen shoulder syndrome. *Scott Med J* 2009; 54:29-31.

Palmieri NF. Smoyak S. Chronic low back pain: a study of the effects of manipulation under anesthesia. Journal of Manipulative & Physiological Therapeutics. 25(8):E8-E17, October 2002.

Pariente GM, Lombardi AV Jr, Berend KR, et al. Manipulation with prolonged epidural analgesia for treatment of TKA complicated by arthrofibrosis. Surgical Technology International. 15:221-4,

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

2006.

Reid R, Desimone R. Manipulation under anesthesia for pain. Spine-health.com. October 23, 2002. Available at: http://www.spine-health.com/treatment/chiropractic/manipulation-under-anesthesia-pain. Accessed December 7, 2011

Tan V, Daluiski A, Simic P, et al. Outcome of open release for post-traumatic elbow stiffness. Journal of Trauma - Injury, Infection and Critical Care. 61(3)(pp 673-678), 2006. Date of Publication: Sep 2006.

West DT, et al. Effective management of spinal pain in one hundred seventy-seven patients evaluated for manipulation under anesthesia. *JMPT* 1999; 22:299-308.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2012	• Added list of applicable ICD-10 codes (preview draft) in preparation for the transition from ICD-9 to ICD-10 medical coding on 10/01/14
05/01/2012	• Updated description of services to reflect most current clinical evidence, CMS information and references; no change to coverage rationale • Updated list of applicable (proven) ICD-9 diagnosis codes; added 808.44 and 808.53 • Archived previous policy version 2011T0515E

Proprietary Information of UnitedHealthcare. Copyright 2012 United HealthCare Services, Inc.

SUPPLEMENTAL - # 1
BCBST - MUA
OCTOBER 20
9:40am

Manipulation of Musculoskeletal System Under Anesthesia (General, Mild Sedation and Local)

DESCRIPTION

Manipulation under anesthesia (MUA) consists of passive movements and stretching of joints performed while the individual receives anesthesia (usually short acting anesthetics or moderate sedation).

Manipulation refers to a variety of manual adjustment techniques and is believed to ease pressure on nerves, break up fibrous scar tissue or restore normal musculoskeletal alignment to relieve pain and improve range of motion. Anesthesia or sedation is used to lessen pain, spasm and the conscious reflex muscle guarding; thereby reducing resistance and apprehension for the individual and enhance the therapeutic effects of the joint manipulation through a full range of motion. Manipulation procedures can be offered under general anesthesia, during mild sedation, or following the injection of anesthetic solutions (i.e. local anesthetic agent) into specific areas of the spine or joints. Typically, MUA is an alternative to conservative treatments that have lasted at least six to eight weeks without relieving pain or promoting a return to normal function.

Spinal manipulation under anesthesia has been used in the treatment of acute and chronic back and neck pain where there has been limited success of prior attempts to manipulate the spine. In MUA, a low velocity/high amplitude technique may be used in contrast to the high velocity/low amplitude technique that is used in the typical chiropractic/osteopathic adjustment.

MUA has also been used as a treatment for fibroarthrosis following total knee replacement, in refractory cases of adhesive capsulitis (frozen shoulder), in the setting of displaced fractures and complete joint dislocations, and for temporomandibular joint syndrome.

POLICY

- Manipulation under anesthesia is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below).**
- Manipulation under anesthesia for other joints including the wrist, elbow, hand, finger, ankle, and pelvis, in the absence of fracture or complete dislocation, is considered ***investigational.***
- Spinal manipulation under anesthesia, (e.g. general anesthesia, joint anesthesia, epidural anesthesia with corticosteroid injections) as a treatment for conditions including, but not limited to chronic spinal pain (e.g. cranial, cervical, thoracic, and lumbar) and chronic sacroiliac and pelvic pain, is considered ***investigational.***
- Spinal manipulation and manipulation of other joints under anesthesia involving serial treatment sessions (greater than 1 treatment) is considered ***investigational.***

See also:

- Intravenous Anesthetics for the Treatment of Chronic Pain
- Modified Condylotomy for Treatment of Temporomandibular Joint (TMJ) Disorders
- Orthognathic Surgery
- Temporomandibular Joint (TMJ) Arthroscopy

MEDICAL APPROPRIATENESS

- Manipulation under anesthesia is considered medically appropriate if ANY ONE of the following criteria are met:
  - Treatment of adhesive capsulitis that has failed at least 3 months of conservative interventions (e.g. physical therapy, patient directed exercise, NSAIDS, and/or steroid injections)

- Arthrofibrosis of the knee following total knee arthroplasty, knee surgery, or fracture
- Temporomandibular joint disorder
- Closed reduction of displaced fracture
- Complete joint dislocation

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

As with any treatment of pain, controlled clinical trials are considered particularly important to isolate the contribution of the intervention and to assess the extent of the expected placebo effect. A search of the published medical literature did not identify any controlled clinical trials. Several case series were identified, which included individuals with cervical, thoracic and lumbar back pain, treated according to varying protocols.

SOURCES

BlueCross BlueShield Association. Medical Policy Reference Manual. (4:2010). *Manipulation under anesthesia for the treatment of chronic and pelvic pain.* (8.01.40). Retrieved December 13, 2010 from BlueWeb. (7 articles and/or guidelines reviewed)

Cremata, E., Collins, S., Clauson, W., Solinger, A., & Roberts, E. (2005) Manipulation under anesthesia: A report of four cases. *Journal of Manipulative and Physiological Therapeutics*, 28 (7), 526-533. (Level 4 Evidence - Independent)

ECRI Institute. Health Technology Information Service. Evidence Reports. (2003, February). *Manipulation under anesthesia for low-back pain.* Retrieved December 10, 2010 from ECRI Institute. (66 articles and/or guidelines reviewed)

Kawchuk, G., Haugen, R., Fritz, J. (2009). A true blind for subjects who receive spinal manipulation therapy. *Archives of Physical Medicine and Rehabilitation*, 90 (2), 366-368. (Level 4 Evidence - Independent)

Manske, R., Prohaska, D. (2008). Diagnosis and management of adhesive capsulitis. *Current Reviews of Musculoskeletal Medicine*, 1 (3-4), 180-189. (Level 5 Evidence - Independent.)

Mohammed, R., Syed, S., & Ahmed, N. (2009). Manipulation under anesthesia for stiffness following knee arthroplasty. *Annals of the Royal College of Surgeons of England*, 91 (3), 220-223. (Level 4 Evidence - Independent)

ORIGINAL EFFECTIVE DATE: 8/1/2002

MOST RECENT REVIEW DATE: 5/14/2011

ID_BT

Policies included in the Medical Policy Manual are not intended to certify coverage availability. They are medical determinations about a particular technology, service, drug, etc. While a policy or technology may be medically necessary, it could be excluded in a member's benefit plan. Please check with the appropriate claims department to determine if the service in question is a covered service under a particular benefit plan. Use of the Medical Policy Manual is not intended to replace independent medical judgment for treatment of individuals. The content on this Web site is not intended to be a substitute for professional medical advice in any way. Always seek the advice of your physician or other qualified health care provider if you have questions regarding a medical condition or treatment.

This document has been classified as public information.

MEDICAL NECESSITY GUIDELINES

SUPPLEMENTAL- # 1
OCTOBER 20
CareAllies 9:40am

Subject: Manipulation Under Anesthesia
Number: 0276

Effective Date: 2/15/2005
Revision Date: 3/15/2006, 6/15/2007, 12/15/2007, 10/15/2008, 10/15/2009, 10/15/2010, 10/15/2011

INSTRUCTIONS FOR USE
This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA Health Management, Inc. *© Copyright 2011.*

Single treatment of manipulation under anesthesia* (MUA) is considered medically necessary for ANY of the following indications:

- adhesive capsulitis (i.e., frozen shoulder) when there is failure of conservative medical management, including medications with or without articular injections, home exercise programs and physical therapy (Common Procedural Terminology [CPT] code 23700)
- post-traumatic or postoperative arthrofibrosis of the knee (e.g., total knee replacement, anterior cruciate ligament repair) (CPT code 27570) when there is failure of conservative medical management, including exercise and physical therapy
- reduction of a displaced fracture (e.g., vertebral, long bones) (e.g., CPT code 22505, 25675)
- reduction of acute/traumatic dislocation (e.g., vertebral, perched cervical facet) (e.g., CPT code 22505)
- chronic contracture of upper or lower extremity joint (e.g., fixed contracture from a neuromuscular condition) when there is failure of conservative medical management including range of motion exercise programs and physical therapy

***MUA provided for these indications consists of a SINGLE treatment session. Repeat treatment sessions involving a previously treated bone or joint are subject to medical necessity review. Furthermore, serial treatment sessions (i.e, treatments of the same bone/joint provided subsequently over a period of time) are not in accordance with generally accepted standards of medical practice and are therefore not medically necessary.**

MUA for any other indication, including the treatment of acute or chronic pain conditions, involving one or more of the following joints, because it is considered experimental, investigational or unproven (This list may not be all inclusive):

- ankle (CPT code 27860)
- cervical, thoracic or lumbar spine (e.g., CPT code 22505)
- elbow (CPT code 24300)
- finger (e.g., CPT code 26340, 26675)
- hip (CPT code 27275)
- pelvis, sacroiliac (CPT code 27194)
- temporomandibular (CPT code 21073)
- thumb (CPT code 26340)

Willing Family Chiropractic
5959 Shallowford Road Ste 527
Chattanooga, Tn 37421

Dr. Evan G. Willing D.C.
Tin# 62-1641949

Phone: 423-499-0102
Fax: 423-499-9857

October 18, 2013

To Whom It May Concern,

I would like to introduce myself, my name is Dr. Evan G. Willing D.C.. Several years back I was introduced to a fellow Chiropractor who explained that he would like to bring me on board for an amazing procedures called Manipulation Under Anesthesia/ Adhesive Release Technique, and it would benefit my patients beyond belief. Manipulation Under Anesthesia/ Adhesive Release Technique is a process whereby the patient is put under sedation, allowing for better manipulation without the resistance. The benefits have shown to be amazing and patients have stated that it has changes their lives. They have had significant changes in Range of Motion, Adhesive release, better mobility allowing for patients to get back to their normal activities of daily living.

Many of my patients have been to pain management, orthopedic specialists, as well as surgeons for relief of their conditions. Manipulation Under Anesthesia/Adhesive Release Techniques provides patients with long term relief from disc her nations, frozen shoulder, adhesive disease, disc protrusions, disc bulges, pain in the extremities just to name a few. However, I feel the patients that received injections prior to the procedure were more responsive to the treatment .

With these techniques my patients return to their activities of daily living in a much shorter time, and in many cases have stopped taking their medications for pain. I feel the patients would be adversely affected if they were unable to do these techniques.

Thank You,

Dr. Evan G. Willing III D.C.

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am

Knoxville Oral & Maxillofacial Surgery, PC

Turner P. Emery, DDS, MD
Michael D. Wooten, DDS

Fellow
American Association of
Oral and Maxillofacial Surgeons

6207 Highland Place Way, Suite 207
Knoxville, Tennessee 37919
Phone (865) 584-6207
www.knoxoms.com

Diplomate
American Board of
Oral and Maxillofacial Surgery

September 1, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for Interventional Pain Management Procedures

Dear Ms. Hill,

The growing number of Medicaid patients and future Obama Care patients in our community is creating a need for an ambulatory surgery center to accept these patients.

The Smoky Mountain Ambulatory Surgery Center is planning on accepting all Medicaid and indigent patients in the East Tennessee region and will fulfill a need for our community.

I am writing in support of this surgery center and its application for a certificate of need to provide interventional pain management procedures.

Sincerely,

Turner Emery, MD, DDS

MICHEAL D WOOTEN DDS Fax:8659340080 Sep 3 2013 11:56 P.02

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

Rocky Top Medical Center
1105 Oak Cluster Drive
Sevierville, TN 37862
865-908-3636

September 2, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

Our community needs the above referenced ASTC to be approved for various interventional pain procedures that will meet my patient's needs. Particularly this ASTC because it will accept my indigent patients without a long waiting period, the few other centers that accept Medicaid may take as long as eight weeks, if at all .

Since this ASTC has Physicians on staff for evaluation and treatment, my patients may be seen and released back to me in a timely fashion.

Sincerely,

Steven W. Johnson, DO

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

Southern Medical Group

Weisgarber Location (Main)
6600 Nightingale Lane
Knoxville, TN 37909
(865) 632-5885

South Knoxville Location
7564 Mountain Grove Dr.
Knoxville, TN 37920
(865) 632-5885

10/01/2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

Our community needs the above referenced ASTC to be approved for various interventional pain procedures that will meet my patient's needs.

Patient Centered Care is one of the big reasons for a surgery center. Healthcare providers, from MD's, physician extenders and specialists, partnering with each other and the patient to establish the best possible care with the primary goal being great outcomes. I believe that having access to Smoky Mountain Ambulatory Surgery Center with providers, who are familiar with performing procedures, is an improvement in the quality of care. Increasing the services of Smoky Mountain Ambulatory Surgery Center to include interventional pain procedures, will allow a comprehensive approach to pain treatment not based on medications.

Sincerely,

Sunil M. John, MD

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

Lensgraf Clinic, P.C.
1346 Papermill Pointe Way
Knoxville, TN 37909

August 26, 2013

Melanie Hill, Executive Director
Health Services and Development
Frost Building, 3rd Floor
161 Rosa Parks Blvd
Nashville, TN 37243

I am writing to you as a medical professional seeking some advocates for our Interventional Pain Management Patients. I currently work at the Lensgraf Clinic in the area of Pain Management and Nurse Practitioner Oversight. We are seeking support for the upcoming meeting at the state level regarding our application for a Certificate of Need in the area of Ambulatory Surgery Center.

You know the lack of available surgical referral sites for some of our indigent and elderly patients poses a great health risk. A local pain physician here in Knoxville has cited a more than 200% increased need in our community for better surgical options. As it stands now, there is no way the current number of facilities can care for all patients that need care.

With the implementation of the Affordable Care Act, otherwise known as Obama care, there will be many more Americans seeking local and affordable healthcare options. These options are limited to the number of providers (like us) that will be participating in the system and also the number of facilities that will accept our patients to care for them.

Our community really needs more Ambulatory Care locations. With in-patient costs soaring, the options of out-patient surgery is more cost-effective, has better outcomes and are preferred by patients and their doctors instead of going into a large hospital far from their homes and offices. I recently had out-patient surgery and using a One-Day Surgery Unit saved money and time in my case.

These locations serve as alternatives to meet the needs of our community and our patients. So this letter is being sent to you to ask for your support. This support is needed in the way of a positive vote for the Smoky Mountain Ambulatory Surgical Care Center to be allowed to perform the much needed Interventional Pain Procedures.

Thank-you in advance for your help in this endeavor and, as always, let's help improve the healthcare of our neighborhoods, our city, our state and our nation!

Professionally,

James W. Foster MD

James W. Foster, MD
Internal Medicine

SUPPLEMENTAL- #1
OCTOBER 20
9:40am

Emmanuel S. John, MA, MSW, LCSW-C
105 Osborne Road, Johnson City, TN 37601
423-202-3046/410-929-5525

Melanie Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson State Office Building, #850
500 Deaderick Street
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Requests for Interventional Pain Management Procedures

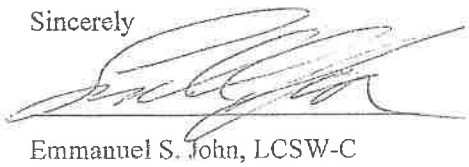
Dear Ms. Hill (et. al.)

Please allow me to introduce myself. My name is Emmanuel John: I am a licensed clinical social worker in both Maryland and Tennessee. I have worked and volunteered in the mental health field for more than 28 years. I have worked in all treatment modalities from intervention and prevention to extended inpatient. Originating from the Baltimore and DC area I have been fortunate to work directly with the National Institute of Health, as well as the National Institute of Drug Abuse, Johns Hopkins Hospital and the American Medical Association. I have worked in both the public and private sectors. I have conducted numerous professional ethics seminars for people in both the medical and mental health fields. I'm a published author with books selling around the world and often work as an expert witness in judicial proceedings.

As a provider who has recently relocated to Eastern Tennessee I have often been astounded by the distance my clients/patients have to travel to get their healthcare services. I conduct pre-surgical psychological evaluations and I often have chronic pain patients reporting travel times of as long as 2 1/2 hours. This amount of time spent sitting in a car is often difficult for most pain patients. (The current minimum travel time I hear is about 40 min.) Most of my patients can't sit for more than 15 minutes before their pain presents. Patients are reporting fewer and fewer choices for their healthcare needs as hospital and medical centers in the area reduce both services and staff. In my short time in the area I have already seen available services diminish substantially. In addition to lengthy travel distances the price of gas also creates financial hardships for my patients, almost all of whom are on fixed incomes. The solution is simple; we need more service providers!

During the decades I have worked in the health field I have held very strict standards for the organizations that I affiliate myself with. I have been working with the Lensgraf organization and its subsidiaries for nearly a year now. I have encountered nothing but caring providers enthusiastically seeking to solve or resolve their patient's struggles as effectively as possible. In addition, I have found the providers at these clinics to be hypervigilant in regards to preventing abuses of the health care system. These providers take painstaking measures to solve patient problems without resorting to surgical methods but sometimes that is not enough. It is also my experience that the Lensgraf organization manages it subsidiaries very well. Teaching their providers how to find real solutions by as minimally invasive means as possible. It is my impression that they will continue to seek to improve existing methods as well as research and implement cutting-edge techniques and technologies. You can be sure that they will be good stewards of both resources and personnel. We need more providers who are willing to put patients first.

Sincerely



Emmanuel S. John, LCSW-C

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

Advanced Medical Group P.C.

615 Leeper Parkway, Suite 101, Lenoir City, TN 37772

Melaine Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

I am writing in support of Smoky Mountain Ambulatory Surgery Center. It is very beneficial for my patients to have this clinic in our area. They have two Anesthesiologists on staff that can provide my patients with the type of pain management procedures that I cannot, and without long delays in getting appointments.

Please grant Smoky Mountain Ambulatory Surgery Center the CON so our patients can continue to have the treatments they need.

Sincerely,

Terry Bragg, D.C.

Terry Bragg, D.C.

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

ACCESS HEALTHCARE P.C.

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

To whom it may concern:

On several occasions I have referred patients to what is now Smoky Mountain Ambulatory Surgery Center through Lensgraf Clinic, and I feel it is vital for my patients to have a convenient and local source for pain management procedures as it is difficult to find an ASTC to accept patients in our area. It is my understanding there are two anesthesiologists practicing at this location, and their services are always professional. My patients have received quality and prompt care from the staff and providers at this facility. I feel confident in continuing to refer my patients and request for inclusion of interventional pain procedures as part of their services.

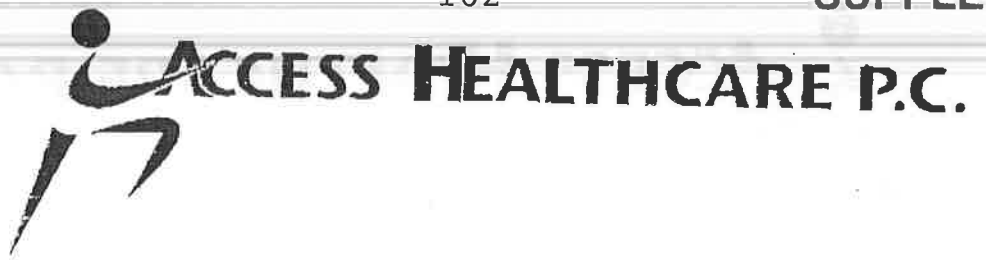
Sincerely,

Dr. David S. Newport

8874 Kingston Pike • Knoxville, TN 37923
(865) 690-4200 (Phone) • (865) 531-9018 (Fax)

2905 Tazwell Pike • Knoxville, TN 37918
(865) 686-1600 (Phone) • (865) 686-3380 (Fax)

SUPPLEMENTAL- # 1
OCTOBER 29
9:40am



Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

To whom it may concern:

On several occasions I have referred patients to what is now Smoky Mountain Ambulatory Surgery Center through Lensgraf Clinic, and I feel it is vital for my patients to have a convenient and local source for pain management procedures as it is difficult to find an ASTC to accept patients in our area. It is my understanding there are two anesthesiologists practicing at this location, and their services are always professional. My patients have received quality and prompt care from the staff and providers at this facility. I feel confident in continuing to refer my patients and request for inclusion of interventional pain procedures as part of their services.

Sincerely,

Dr. J. Scott Brown

8874 Kingston Pike • Knoxville, TN 37923
(865) 690-4200 (Phone) • (865) 531-9018 (Fax)

2905 Tazwell Pike • Knoxville, TN 37918
(865) 686-1600 (Phone) • (865) 686-3380 (Fax)

SUPPLEMENTAL- # 1
OCTOBER 20
9:40am

James H. Leslie, R.N., PhD
1346 Papermill Pointe Way
Knoxville, TN 37909

October 16, 2013

Melanie Hill
Executive Director
Tennessee Health Services & Development Services
Andrew Jackson State Office Bldg., Suite 850
500 Deaderick Street
Nashville, TN 37243

RE: Lensgraf Clinic/Smokey Mountain Ambulatory Surgical Center
Certificate of Need Application No. CN0811-112A

Dear Ms. Hill,

As Director of Clinical and Regulatory Compliance of the Lensgraf Clinic and Medical Center, I would like to offer my strong support to the above referenced certificate of need application. This entire proposed project has been thoroughly and thoughtfully designed to meet the specific needs of patients suffering from chronic pain conditions. I sincerely hope the Agency and Agency staff will give the application favorable consideration.

The need for this initiative is very clear. Chronic pain is a common and serious problem for many Tennesseans and growing daily. Appropriate pain management is not always readily available for this population. Many patients are finding themselves without access to care from well established providers like Lensgraf Clinic and Medical Center. The center has been well known for over 40 years as a highly respected provider of Evidence Based and Best Practice, Best Outcomes based clinical expertise.

SUPPLEMENTAL #1
OCTOBER 20
9:40am

I have enjoyed over 40 years of nursing practice, and proudly hold a Doctorate Degree in Nursing Science and Research. I have been employed by Lensgraf Clinic and Medical Center for quite some time and find that this establishment strictly follows the Tennessee Board of Medical Examiner guidelines for chronic pain management and the practice is steadily being known as a "Center of Excellence." The center utilizes a comprehensive approach to managing and treating chronic pain that includes cognitive behavioral therapy, physical therapy, interventional pain management procedures and careful medical management. The Center's commitment to the highest quality multi-disciplinary pain management for their patient's ensures this initiative will be an asset in the state's efforts to limit opioid abuse.

For all of these reasons, I am more than confident that this initiative is more than worthy of my very enthusiastic support. Please do not hesitate to let me know if I can do anything more in support of this excellent proposal.

Respectfully,

James H. Leslie, RN, PhD

James H. Leslie, R.N., PhD
Director, Clinical and Regulatory Compliance
Lensgraf Clinic and Medical Center
1346 Papermill Point Way
Knoxville, TN 37909

2013 AUG 8 PM 1 42

LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the *Knoxville New Sentinel* (Name of Newspaper) which is a newspaper of general circulation in Knox County (County), Tennessee, on or before August 10, 2013 (Month / day) (Year) for one day.

==========

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §68-11-1601, et seq., and the Rules of the Health Services and Development Agency, that Smoky Mountain Ambulatory Surgery Center, LLC ("Applicant"), 1338 Papermill Pointe Way, Knoxville, Tennessee 37909-1903, owned and managed by itself, intends to file an application for a Certificate of Need for the addition of interventional pain management services at its ASTC. The Applicant currently provides manipulation under anesthesia ("MUA") services. This new service will be provided in the same one procedure room which is currently licensed. There are no beds and no major medical equipment involved with this project. No other health services will be initiated or discontinued. It is proposed that Medicare, TennCare, commercially insured, and private-pay patients will be served by the ASTC, which will be licensed by the Tennessee Department of Health. The estimated project cost is anticipated to be approximately $200,000.00.

The anticipated date of filing the application is: August 15, 2013.

The contact person for this project is E. Graham Baker, Jr., (Contact Name) Attorney (Title)

who may be reached at: his office located at (Company Name) 2021 Richard Jones Rd. Suite 350 (Address)

Nashville (City) TN (State) 37215 (Zip Code) 615 /370-3380 (Area Code / Phone Number)

E Graham Baker Jr (Signature) August 08 2013 (Date) graham@grahambaker.net (E-mail Address)

==========

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Frost Building
161 Rosa L. Parks Blvd., 3rd Floor
Nashville, Tennessee 37243

==========

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

==========

* The project description must address the following factors:

1. General project description, including services to be provided or affected.
2. Location of facility: street address, and city/town.
3. Total number of beds affected, licensure proposed for such beds, and intended uses.

WEEKS & ANDERSON
An Association of Attorneys

2021 RICHARD JONES ROAD, SUITE 350
NASHVILLE, TENNESSEE 37215-2874
TELEPHONE 615/383-3332
FACSIMILE 615/383-3480

KENT M. WEEKS
ROBERT A. ANDERSON

F. B. MURPHY, JR.
E. GRAHAM BAKER, JR.

DIRECT TELEPHONE NUMBER: 615/370-3380

January 9, 2014

Melanie Hill, Executive Director
Health Services and Development Agency
Andrew Jackson Building
502 Deaderick Street, 9th Floor
Nashville, Tennessee 37243

Re: Certificate of Need Application (CN1308-032)
Smoky Mountain Ambulatory Surgery Center

Dear Melanie:

Please find attached letters of support for the reference project.

Respectfully,

E. Graham Baker, Jr.
/np

JOE ARMSTRONG
State Representative
15th Legislative District

PO BOX 6597
Knoxville, TN 37914

LEGISLATIVE OFFICE
35 Legislative Plaza
Nashville, TN 37243-0115
Phone: (615) 741-0768
Fax: (615) 253-0316
rep.joe.armstrong@capitol.tn.gov

House of Representatives
State of Tennessee

President
National Black Caucus of State Legislators

MEMBER of COMMITTEES

Finance, Ways and Means
Transportation
Sub of Finance, Ways and Means

December 30, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center - Knoxville
Tennessee Spine and Nerve Institute - Nashville
Request for Interventional Pain Management Procedures

Dear Ms. Hill:

As discussed in the meeting earlier this year, I am concerned with the procedures taken by your office in regard to the Smoky Mountain Ambulatory Surgery Center in Knoxville and the Tennessee Spine and Nerve Institute in Nashville.

The lack of accessible surgical referral sites for some of our indigent and elderly patients poses a great health risk. Locations such as the Smoky Mountain Ambulatory Surgery Centers serve as alternatives to meet the needs of our community and our patients.

Our communities need more Ambulatory Care locations serving patients with interventional pain management procedures. Having access to Smoky Mountain Ambulatory Surgery Center with providers, who are familiar with performing procedures, is an improvement in the quality of care. Increasing the services of Smoky Mountain Ambulatory Surgery Center to include interventional pain procedures, will allow a comprehensive approach to pain management not based on medications.

I strongly support the Smoky Mountain Ambulatory Surgery Centers and I ask that you please grant their request for inclusion of interventional pain procedures as part of their services.

Sincerely,

Joe Armstrong

State Representative Joe Armstrong

PREMIER ORTHOPAEDICS
& SPORTS MEDICINE, PLC
Skyline Care Center
3443 Dickerson Pike
Suite 190
Nashville, TN 37207
Telephone (615) 860-1580
Fax (615) 860-1541
www.premier-ortho.com

Steven G. McLaughlin, M.D.
L. Brett Babat, M.D.
Steve G. Salyers, M.D.
Daniel J. Burval, M.D.

Paul A. Abbey, M.D.
Malcom E. Baxter, M.D.
Joseph D. Chenger, M.D.
Robert M. Dimick, M.D.
Brandon H. Downs, M.D.
James W. Eby, M.D.
James M. Fish, D.O.
Jason K. Haslam, M.D.
William J. Jekot, M.D.
Sean B. Kaminsky, M.D.
Melvin D. Law, Jr., M.D.
Jeffrey P. Lawrence, M.D.
Robert W. Lowe III, M.D.
William C. Mayfield, III, M.D.
Daniel J. McHugh, M.D.
Gregg A. Motz, M.D.
Vincent P. Novak, M.D.
Roger N. Passmore, M.D.
V. Douglas Pierce, Jr., M.D.
Michael L. Reid, M.D.
R. James Renfro, Jr., M.D.
Marc A. Tressler, D.O.
Joseph A. Wieck, M.D.

To whom it may concern,

I have been referring patients to Tennessee Spine and Nerve for the past three to four years. My patients and I have been more than impressed by the quality of care they deliver. Their response time is excellent, I have seen no safety issues at all, and I find their communication with me and, more importantly, with the patients I send, to be exemplary. I certainly support their effort to expand MUA of Middle TN to include interventional pain procedures.

Sincerely,

L. Brett Babat, MD

LEGISLATIVE OFFICE:
36 LEGISLATIVE PLAZA
NASHVILLE, TENNESSEE 37243-0167
(615) 741-4410 PHONE
(615) 253-0202 FAX
rep.gary.odom@capitol.tn.gov

House of Representatives

State of Tennessee

JAN 8 '14 AM 9:55

MEMBER OF COMMITTEES:
FINANCE WAYS & MEANS
FINANCE SUBCOMMITTEE
HEALTH

GARY ODOM
STATE REPRESENTATIVE
55TH LEGISLATIVE DISTRICT
DAVIDSON COUNTY

December 31, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center - Knoxville
Tennessee Spine and Nerve Institute - Nashville
Request for Interventional Pain Management Procedures

Dear Ms. Hill,

As I personally advised you during our meeting earlier this year, I am very concerned about the process that has been followed by your agency with regards to the Smoky Mountain Ambulatory Surgery Center in Knoxville and the Tennessee Spine and Nerve Institute in Nashville. Both of the surgery centers utilize multi-disciplinary physicians, including an anesthesiologist, internist, osteopath, and chiropractor, with support of an on-staff orthopedic surgeon and neurosurgeon, in providing the highest quality of care for their patients. It has long been my belief that these types of practices, which have the capability of providing a broad spectrum of care through a multi-disciplinary system of providers, are models for optimum patient care.

My concerns center on the fact that, when complaints were filed against both surgery centers by a lobbyist for the Tennessee Medical Association and an anesthesiologist in Knoxville, your agency unilaterally suspended their CONs on December 27, 2012, despite the fact that CONs had been appropriately issued to them. At the time of our meeting on March 19, 2013, your agency had received no complaints by patients filed against either center nor were there any allegations of malpractice or poor outcomes, except perhaps by competing interests, not patients. As you will recall, following our meeting, the CONs for both center were reinstated under the condition that there would be full hearings on both CONs sometime in the future. It is clear that the reinstatement following more than three months of the unilateral suspension accomplished two things.

First, the suspension resulted in both centers suffering significant financial damage during the three months they were basically out of business. Second, the reinstatement was a clear admission that you had no evidence of malpractice or even poor patient outcomes from either center. It is just as clear that this unprecedented process was initiated by competing interests, including the Tennessee Medical Association. In addition, I have seen copies of emails from a Nashville anesthesiologist, associated with a large group practice of anesthesiologists, urging his colleagues not to do business with a large medical supply company that provides equipment and supplies to the two surgery centers that have been subjected to this "witch hunt." These actions constitute clear evidence of anti-trust and/or anti-competitive activities. For this reason, I have initiated a request for investigation by the Federal Trade Commission into all of these events.

I have always supported the certificate of need process throughout my legislative service. I have done so in order to protect the larger interest of our citizens because in many cases a CON granted to a surgery center can do great financial damage to small hospitals, especially hospitals in our rural areas which are already struggling to survive. This damage is accomplished by a center siphoning off a revenue stream from the hospital that is used to help provide emergency and in-patient care. However, this matter is quite different. Once an existing CON for a surgery center, especially in an urban area, can be placed in jeopardy, not because of poor quality care but by competing interests who, in most cases, will not even accept Medicaid patients, I must rethink my position.

These two surgery centers, one of which is located in the district I represent, have suffered significant damage from the actions of your agency. They were literally closed down for several months after you suspended their CON. This resulted in current patients not being able to receive care and was financially devastating to each surgery center. Both surgery centers have been damaged as a result of unhappy competitors who appear to be more concerned about driving patients to their own offices by government edict than they are about actual patient care, especially the care available to our citizens covered by Medicaid. This is not the way our health care delivery system should function. I urge you to stop persecuting these two surgery centers and take whatever action is necessary to allow them to continue providing care for my constituents in Nashville and our citizens in the Knoxville area who wish to continue receiving their care from the provider of their choice. I look forward to your response.

Respectfully

Gary Odom
State Representative
55th District

Michelle Prater

From: Michelle Prater [michelleprater01@gmail.com]
Sent: Wednesday, January 08, 2014 10:05 AM
To: 'Michelle Prater'
Subject: ASTC CON SUPPORT

From: Rep. Joshua Evans [mailto:Joshua@EvansForHouse.com]
Sent: Friday, December 27, 2013 2:52 AM
To: Michelle Prater

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center- Knoxville

Dear Ms. Hill,

I would like to offer my strong support to Smoky Mountain Ambulatory Surgery Center Certificate of Need application. This entire proposed project has been thoroughly and thoughtfully designed to meet the specific needs of patients suffering from chronic pain conditions. I request HSDA give the application favorable consideration.

Chronic pain is a common and serious problem for many Tennesseans and growing daily. Appropriate pain management is not always readily available for this population. Many patients are finding themselves without access to care from well established providers.

Utilizing a comprehensive approach to managing and treating chronic pain that includes cognitive behavioral therapy, physical therapy, Manipulation Under Anesthesia, interventional pain management procedures and careful medical management, this ASTC is offering quality multi-disciplinary pain management for their patient's ensures this initiative will be an asset for Tennessee.

I am more than confident that this initiative is more than worthy of my very enthusiastic support.

Respectfully,

Joshua Evans
State Representative

Michelle Prater

From: Michelle Prater [michelleprater01@gmail.com]
Sent: Wednesday, January 08, 2014 10:02 AM
To: 'Michelle Prater'
Subject: CON ASTC

From: Staceycampfield4staterep@yahoo.com [mailto:Staceycampfield4staterep@yahoo.com]
Sent: Friday, January 03, 2014 10:44 PM
To: Michelle Prater

Dear Ms. Hill,

In follow up on our previous meeting, it is my understanding that the Smoky Mountain Ambulatory Surgery Center in Knoxville and the Tennessee Spine and Nerve Institute in Nashville are in the process of reapplying for their certificate of need.

Both of the surgery centers utilize multi-disciplinary physicians including an anesthesiologist, internist, osteopath and chiropractor with support of an on-staff orthopedic surgeon and neurosurgeon in providing the highest quality of care for their patients.

It has long been my belief that these types of practices, which have the capability of providing a broad spectrum of care through a multi-disciplinary system of providers, are models for optimum patient care.

While a CON was appropriately issued to each of these surgery centers, complaints were filed against both surgery centers by a lobbyist for the Tennessee Medical Association and an anesthesiologist in Knoxville. Following that, your agency unilaterally suspended the CON for both surgery centers on December 27, 2012. Yet when we last spoke regarding this matter, there were no complaints filed with your agency by patients, nor were there any allegations of malpractice or poor outcomes by patients of either center. If that has changed please let me know.

As you will recall, following our meeting, the CONs for both center were reinstated under the condition that there would be full hearings on both CONs sometime in the future. While the reinstatement was a step in the right direction, It is clear that this initial action, the following more than three months of suspension, followed by the reinstatement presents several issues.

First, the suspension resulted in both centers suffering significant financial damage during the three months they were basically out of business. This loss opens the state, and possibly yourself up to lawsuit. While I do not think this is the goal of the center it must be recognized as a possible detrimental outcome.

Second, the reinstatement looks to be a clear admission that the "evidence" of malpractice or even poor patient outcomes from either center was nonexistent to limited at best. Thus the position of removing the CON for public safety null and void.

Third, It is just as clear that this unprecedented process was flawed as it was initiated by competing interests. Clearly this should not become standard practice especially without some strong compelling interest or presentation of strong evidence of wrong doing.

This flawed example of over site of an existing CON surgery center, especially in an urban area is setting a dangerous precedence. One where a business can be placed in jeopardy, not because of poor quality care but by competing interests who clearly has a vested interest in their success or failure

These two surgery centers, one of which is located in the district I represent, have suffered significant damage from these actions not just in loss of income but in loss of customers, un used facilities, loss in advertising and credibility within their field among their competitors, suppliers, and customers.

Therefor, I ask that unless there is some new, strong, compelling interest to the contrary has recently come to light, that you....

First, take action as is necessary to allow these businesses to continue providing care for my constituents, be they in Nashville or in the Knoxville area.

Next, as this ordeal appears to have un needly cost these businesses substantial funds already (not just in lost income revenue, but also in lost time and expense to re apply for a CON) that you do all you can to alleviate and eliminate this cost and expense to them so as to not wrongly burden them further.

Finally, I ask that you look to setting up new criteria for restricting or repealing a CON where actual safety/substantial harm to patients is the main criteria.

Respectfully

Sen. Stacey Campfield

ABERCROMBIE RADIOLOGY

William R. McKissick, MD
John D. Simmons, MD
Margaret Uri, MD
J. Breese Johnson, Jr., MD
Gwen Uri, MD
Lynn Barrett, MD
Diane L. Edge, MD
Dale E. Nichols, MD
Andrew M. Evancho, MD
Lane P. Williams, MD
Wayne M. Eberenz, MD
Kenneth H. Pryor, MD
F. Gregory Curtin, MD
Samuel L. Maynard, MD
Daniel W. Walsh, MD
Donna K. Culhane, MD
Jason R. Cameron, M.D.
Daniel A. Baker, M.D.

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L Parks Blvd
Nashville, TN 37243

Dear Ms. Hill,

I write this letter in support of CON approval for expansion of services at Smoky Mountain Ambulatory Surgery Center to include interventional pain procedures. Our group has spent many years providing diagnostic imaging services for patients being treated at the Lensgraf Clinic. It is my understanding that the ambulatory surgery center now has board certified Anesthesiologists practicing at this location and that it accepts Medicaid, Medicare and Indigent patients. I believe that the expansion of services will provide an immediate benefit to the community and in particular those who have limited access to these services due to financial constraints.

I have also learned that the center, in conjunction with a local Neurosurgeon, has undertaken a therapeutic trial involving placing temporary spinal stimulator devices prior to inserting the very costly permanent devices intraoperatively. I feel that this represents a very imaginative, practical and potentially cost saving mode of practice.

Thank you for your attention in this matter. Please feel free to contact me at 865-804-3649 for any questions.

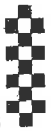
Sincerely,

F. Gregory Curtin, MD

Weisgarber Medical Center
1112 Weisgarber Road
Knoxville, Tennessee 37909
865/588-1397 • Fax: 865/558-0395

Centralized Scheduling 865/584-3444

St. Mary's Professional Building
930 Emerald Avenue, Suite 514
Knoxville, Tennessee 37917
865/637-0095 • Fax: 865/673-0339



Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

To whom it may concern:

On several occasions I have referred patients to what is now Smoky Mountain Ambulatory Surgery Center through Lensgraf Clinic, and I feel it is vital for my patients to have a convenient and local source for pain management procedures as it is difficult to find an ASTC to accept patients in our area. It is my understanding there are two anesthesiologists practicing at this location, and their services are always professional. My patients have received quality and prompt care from the staff and providers at this facility. I feel confident in continuing to refer my patients and request for inclusion of interventional pain procedures as part of their services.

Sincerely,

Dr. David S. Newport

8874 Kingston Pike • Knoxville, TN 37923
(865) 690-4200 (Phone) • (865) 531-9018 (Fax)

2905 Tazwell Pike • Knoxville, TN 37918
(865) 686-1600 (Phone) • (865) 686-3380 (Fax)

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

To whom it may concern:

On several occasions I have referred patients to what is now Smoky Mountain Ambulatory Surgery Center through Lensgraf Clinic, and I feel it is vital for my patients to have a convenient and local source for pain management procedures as it is difficult to find an ASTC to accept patients in our area. It is my understanding there are two anesthesiologists practicing at this location, and their services are always professional. My patients have received quality and prompt care from the staff and providers at this facility. I feel confident in continuing to refer my patients and request for inclusion of interventional pain procedures as part of their services.

Sincerely,

Dr. J. Scott Brown

8874 Kingston Pike • Knoxville, TN 37923
(865) 690-4200 (Phone) • (865) 531-9018 (Fax)

2905 Tazwell Pike • Knoxville, TN 37918
(865) 686-1600 (Phone) • (865) 686-3380 (Fax)

Rocky Top Medical Center
1105 Oak Cluster Drive
Sevierville, TN 37862
865-908-3636

September 2, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

Our community needs the above referenced ASTC to be approved for various interventional pain procedures that will meet my patient's needs. Particularly this ASTC because it will accept my indigent patients without a long waiting period, the few other centers that accept Medicaid may take as long as eight weeks, if at all .

Since this ASTC has Physicians on staff for evaluation and treatment, my patients may be seen and released back to me in a timely fashion.

Sincerely,

Steven W. Johnson, DO

W. Keith Porter, PA

Steven W. Johnson, DO

Lensgraf Clinic, P.C.
1346 Papermill Pointe Way
Knoxville, TN 37909

August 26, 2013

Melanie Hill, Executive Director
Health Services and Development
Frost Building, 3rd Floor
161 Rosa Parks Blvd
Nashville, TN 37243

I am writing to you as a medical professional seeking some advocates for our Interventional Pain Management Patients. I currently work at the Lensgraf Clinic in the area of Pain Management and Nurse Practitioner Oversight. We are seeking support for the upcoming meeting at the state level regarding our application for a Certificate of Need in the area of Ambulatory Surgery Center.

You know the lack of available surgical referral sites for some of our indigent and elderly patients poses a great health risk. A local pain physician here in Knoxville has cited a more than 200% increased need in our community for better surgical options. As it stands now, there is no way the current number of facilities can care for all patients that need care.

With the implementation of the Affordable Care Act, otherwise known as Obama care, there will be many more Americans seeking local and affordable healthcare options. These options are limited to the number of providers (like us) that will be participating in the system and also the number of facilities that will accept our patients to care for them.

Our community really needs more Ambulatory Care locations. With in-patient costs soaring, the options of out-patient surgery is more cost-effective, has better outcomes and are preferred by patients and their doctors instead of going into a large hospital far from their homes and offices. I recently had out-patient surgery and using a One-Day Surgery Unit saved money and time in my case.

These locations serve as alternatives to meet the needs of our community and our patients. So this letter is being sent to you to ask for your support. This support is needed in the way of a positive vote for the Smoky Mountain Ambulatory Surgical Care Center to be allowed to perform the much needed Interventional Pain Procedures.

Thank-you in advance for your help in this endeavor and, as always, let's help improve the healthcare of our neighborhoods, our city, our state and our nation!

Professionally,

James W Foster MD

James W. Foster, MD
Internal Medicine

Southern Medical Group

Weisgarber Location (Main)
6600 Nightingale Lane
Knoxville, TN 37909
(865) 632-5885

South Knoxville Location
7564 Mountain Grove Dr.
Knoxville, TN 37920
(865) 632-5885

10/01/2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

Our community needs the above referenced ASTC to be approved for various interventional pain procedures that will meet my patient's needs.

Patient Centered Care is one of the big reasons for a surgery center. Healthcare providers, from MD's, physician extenders and specialists, partnering with each other and the patient to establish the best possible care with the primary goal being great outcomes. I believe that having access to Smoky Mountain Ambulatory Surgery Center with providers, who are familiar with performing procedures, is an improvement in the quality of care. Increasing the services of Smoky Mountain Ambulatory Surgery Center to include interventional pain procedures, will allow a comprehensive approach to pain treatment not based on medications.

Sincerely,

Sunil M. John, MD

Advanced Medical Group P.C.

615 Leeper Parkway, Suite 101, Lenoir City, TN 37772

Melaine Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for interventional pain management procedures

Dear Ms. Hill,

I am writing in support of Smoky Mountain Ambulatory Surgery Center. It is very beneficial for my patients to have this clinic in our area. They have two Anesthesiologists on staff that can provide my patients with the type of pain management procedures that I cannot, and without long delays in getting appointments.

Please grant Smoky Mountain Ambulatory Surgery Center the CON so our patients can continue to have the treatments they need.

Sincerely,

Terry Bragg, D.C.

Terry Bragg, D.C.

Emmanuel S. John, MA, MSW, LCSW-C
105 Osborne Road, Johnson City, TN 37601
423-202-3046/410-929-5525

Melanie Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson State Office Building, #850
500 Deaderick Street
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Requests for Interventional Pain Management Procedures

Dear Ms. Hill (et. al.)

Please allow me to introduce myself. My name is Emmanuel John: I am a licensed clinical social worker in both Maryland and Tennessee. I have worked and volunteered in the mental health field for more than 28 years. I have worked in all treatment modalities from intervention and prevention to extended inpatient. Originating from the Baltimore and DC area I have been fortunate to work directly with the National Institute of Health, as well as the National Institute of Drug Abuse, Johns Hopkins Hospital and the American Medical Association. I have worked in both the public and private sectors. I have conducted numerous professional ethics seminars for people in both the medical and mental health fields. I'm a published author with books selling around the world and often work as an expert witness in judicial proceedings.

As a provider who has recently relocated to Eastern Tennessee I have often been astounded by the distance my clients/patients have to travel to get their healthcare services. I conduct pre-surgical psychological evaluations and I often have chronic pain patients reporting travel times of as long as 2 1/2 hours. This amount of time spent sitting in a car is often difficult for most pain patients. (The current minimum travel time I hear is about 40 min.) Most of my patients can't sit for more than 15 minutes before their pain presents. Patients are reporting fewer and fewer choices for their healthcare needs as hospital and medical centers in the area reduce both services and staff. In my short time in the area I have already seen available services diminish substantially. In addition to lengthy travel distances the price of gas also creates financial hardships for my patients, almost all of whom are on fixed incomes. The solution is simple; we need more service providers!

During the decades I have worked in the health field I have held very strict standards for the organizations that I affiliate myself with. I have been working with the Lensgraf organization and its subsidiaries for nearly a year now. I have encountered nothing but caring providers enthusiastically seeking to solve or resolve their patient's struggles as effectively as possible. In addition, I have found the providers at these clinics to be hypervigilant in regards to preventing abuses of the health care system. These providers take painstaking measures to solve patient problems without resorting to surgical methods but sometimes that is not enough. It is also my experience that the Lensgraf organization manages it subsidiaries very well. Teaching their providers how to find real solutions by as minimally invasive means as possible. It is my impression that they will continue to seek to improve existing methods as well as research and implement cutting-edge techniques and technologies. You can be sure that they will be good stewards of both resources and personnel. We need more providers who are willing to put patients first.

Sincerely

Emmanuel S. John, LCSW-C

Willing Family Chiropractic
5959 Shallowford Road Ste 527
Chattanooga, Tn 37421

Dr. Evan G. Willing D.C.
Tin# 62-1641949

Phone: 423-499-0102
Fax: 423-499-9857

October 18, 2013

To Whom It May Concern,

I would like to introduce myself, my name is Dr. Evan G. Willing D.C.. Several years back I was introduced to a fellow Chiropractor who explained that he would like to bring me on board for an amazing procedures called Manipulation Under Anesthesia/ Adhesive Release Technique, and it would benefit my patients beyond belief. Manipulation Under Anesthesia/ Adhesive Release Technique is a process whereby the patient is put under sedation, allowing for better manipulation without the resistance. The benefits have shown to be amazing and patients have stated that it has changes their lives. They have had significant changes in Range of Motion, Adhesive release, better mobility allowing for patients to get back to their normal activities of daily living.

Many of my patients have been to pain management, orthopedic specialists, as well as surgeons for relief of their conditions. Manipulation Under Anesthesia/Adhesive Release Techniques provides patients with long term relief from disc her nations, frozen shoulder, adhesive disease, disc protrusions, disc bulges, pain in the extremities just to name a few. However, I feel the patients that received injections prior to the procedure were more responsive to the treatment .

With these techniques my patients return to their activities of daily living in a much shorter time, and in many cases have stopped taking their medications for pain. I feel the patients would be adversely affected if they were unable to do these techniques.

Thank You,

Dr. Evan G. Willing III D.C.

Knoxville Oral & Maxillofacial Surgery, PC

Fellow
American Association of
Oral and Maxillofacial Surgeons

Turner P. Emery, DDS, MD
Michael D. Wooten, DDS

6207 Highland Place Way, Suite 207
Knoxville, Tennessee 37919
Phone (865) 584-6207
www.knoxoms.com

Diplomate
American Board of
Oral and Maxillofacial Surgery

September 1, 2013

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd
Nashville, TN 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center
Request for Interventional Pain Management Procedures

Dear Ms. Hill,

The growing number of Medicaid patients and future Obama Care patients in our community is creating a need for an ambulatory surgery center to accept these patients.

The Smoky Mountain Ambulatory Surgery Center is planning on accepting all Medicaid and indigent patients in the East Tennessee region and will fulfill a need for our community.

I am writing in support of this surgery center and its application for a certificate of need to provide interventional pain management procedures.

Sincerely,

Turner Emery, MD, DDS

Sep 3 2013 11:56 P.02

ABERCROMBIE RADIOLOGY

William R. McKissick, MD
John D. Simmons, MD
Margaret Uri, MD
J. Breese Johnson, Jr., MD
Gwen Uri, MD
Lynn Barrett, MD
Diane L. Edge, MD
Dale E. Nichols, MD
Andrew M. Evancho, MD
Lane P. Williams, MD
Wayne M. Eberenz, MD
Kenneth H. Pryor, MD
F. Gregory Curtin, MD
Samuel L. Maynard, MD
Daniel W. Walsh, MD
Donna K. Culhane, MD
Jason R. Cameron, M.D.
Daniel A. Baker, M.D.

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L Parks Blvd
Nashville, TN 37243

Dear Ms. Hill,

I write this letter in support of CON approval for expansion of services at Smoky Mountain Ambulatory Surgery Center to include interventional pain procedures. Our group has spent many years providing diagnostic imaging services for patients being treated at the Lensgraf Clinic. It is my understanding that the ambulatory surgery center now has board certified Anesthesiologists practicing at this location and that it accepts Medicaid, Medicare and indigent patients. I believe that the expansion of services will provide an immediate benefit to the community and in particular those who have limited access to these services due to financial constraints.

I have also learned that the center, in conjunction with a local Neurosurgeon, has undertaken a therapeutic trial involving placing temporary spinal stimulator devices prior to inserting the very costly permanent devices intraoperatively. I feel that this represents a very imaginative, practical and potentially cost saving mode of practice.

Thank you for your attention in this matter. Please feel free to contact me at 865-804-3649 for any questions.

Sincerely,

F. Gregory Curtin, MD

Weisgarber Medical Center
1112 Weisgarber Road
Knoxville, Tennessee 37909
865/588-1397 • Fax: 865/558-0395

Centralized Scheduling 865/584-3444

St. Mary's Professional Building
930 Emerald Avenue, Suite 514
Knoxville, Tennessee 37917
865/637-0095 • Fax: 865/673-0339

CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
OFFICE OF HEALTH STATISTICS
615-741-1954

DATE: December 30, 2013

APPLICANT: Smokey Mountain Ambulatory Surgery Center, LLC
1338 Papermill Pointe Way
Knoxville, Tennessee 37909-1903

CON#: CN1308-032

CONTACT PERSON: E. Graham Baker, Jr. Esquire
2021 Richard Jones Road, Suite 350
Nashville, Tennessee 37215

COST: $53,000

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:
The applicant, Smokey Mountain Ambulatory Surgery Center, LLC located at 1338 Papermill Pointe Way in Knoxville, Tennessee, owned and managed by itself, is filing this Certificate of Need application to add interventional pain management services at its ambulatory surgical treatment center (ASTC). The applicant's ASTC was granted a Certificate of Need (CON) by the Health Services and Development Agency (HSDA) on 2/25/2009 (CN0811-112A) and was, as the HSDA website indicates, for the "establishment of a specialty ASTC providing only manipulation under anesthesia (MUA) services. The applicant will provide only MUA services and no actual surgical procedures will be performed in an existing office building." The project was implemented on 4/1/2011, according to HSDA documentation.

This CON was limited to the provision of MUA services. Additional comments relating to the licensure history of the applicant is contained in the Contribution to Orderly Development Section of this report.

The proposed new service will be located in the existing office building and will utilize the one procedure room which is currently licensed. There are no beds and no major medical equipment involved with this project, and no other health services will be initiated or discontinued.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

NEED:
The applicant's primary clinical service area for purposes of this CON application is Knox County. The Tennessee Department of Health, Division of Policy, Planning and Assessment-Office of Health Statistics latest population projections for Knox County in 2013 are 448,093 and will be 453,629 in

recent data available to the applicant at the time this application was prepared. The Office of Health Statistics utilized the Joint Annual Report of Ambulatory Treatment Centers 2012 Final. There were no differences in the data provided by the applicant and that provided by the Office of Health Statistics. There was no licensed single specialty ASTC devoted to interventional pain management services in Knox County.

Knox County ASTC's Performing Pain Management Services From Joint Annual Report 2012 Final

Facility	ORs	Procedure Rooms	2012 Procedures	2012 Patients*
Fort Sanders West Outpatient Surgery Center	4	0	7,791	3,406
Knoxville Orthopaedic Surgery Center	4	1	2,976	9,005
Parkwest Surgery Center	5	1	1,039	1,039
Physicians Surgery Center of Knoxville	5	0	1,071	2,884
St. Mary's Ambulatory Surgery Center	6	0	1,742	1,742
TOTAL	**24**	**2**	**22,461**	**10,234**

Source: *Joint Annual Report of Ambulatory Surgical Treatment Centers 2012 Final,* Tennessee Department of Health, Division of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics. *Unduplicated Patients.

One ASTC, located in Knox County, that reported performing interventional pain management services during the 2011 JAR reporting period, University Ambulatory Surgical Center, was closed, as noted in the Health Care Facilities website, and did not report providing any services during the 2012 JAR reporting period.

TENNCARE/MEDICARE ACCESS:
The applicant is a Medicare and Medicaid/TennCare provider. The Medicare provider number is 1526056 and the Medicaid/TennCare provider number is 103G42884.

The applicant on page 2 of Supplemental #1 states they have a contract with United Health, and have applied for a contract with BlueCare. Additionally, they note on page 3 of Supplemental #1 AmeriGroup has requested that they join them as an out-of-network provider. However, on page 7 of the CON application the applicant states it has contracts with AmeriChoice, BlueCare and TennCare Select. The current and planned Medicaid/TennCare contractual relationships by Smokey Mountain Ambulatory Surgery Center, LLC appear comprehensive in scope but the progress towards completion of these contractual relationships was not finalized at the time this CON was submitted.

The applicant initially provided an estimate of its payor mix based upon the number of patients receiving interventional pain management services in year one (1) of the project, as stated on page 9 of the application. The applicant projected its Medicare patients would represent 71% of its caseload, 21.5% would be commercial insurance and 7.5% would be Medicaid/TennCare patients. Based upon the applicant's calculations, Medicare revenue would be $4,600,800 followed by $486,000 in Medicaid/TennCare revenue and $1,393,200 in revenue from commercial insurance (see page 32 of the initial CON application).

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:
The Department of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and the projections are correct based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located in the application on page 23. The total estimated project cost is $53,000 according to the applicant.

The Office of Health Statistics reviewed and verified the Project Costs Chart and the comments made by the applicant on page 9 of the CON application which asserts that there

are no other costs, other than administrative for this project. The applicant also states that the equipment is already in place.

Historical Data Chart: The Historical Data Chart can be found on page 27 of the CON application. The Historical Data Chart found on page 27R of Supplemental# 1, states the applicant, Smokey Mountain Ambulatory Surgery Center, LLC had gross revenue of $593,405 in 2011, $4,713,421 in 2012 and $1,099,224 in 2013 YTD. The net operating income (loss) during 2011 was ($16,480), was $307,738 during 2012 and was ($28,023) during 2013 YTD. These data elements are based upon January thru December fiscal year. The JAR fiscal year begins July 1 and ends June 30 of each respective year. Therefore, the data provided by the applicant is not comparable to the data reported in the respective JARs for the years in question.

Projected Data Chart: The Projected Data Chart is located on page 28R in the first Supplemental. This chart represents only interventional pain management services. The applicant projects 2,700 patients in year 1 and 3,100 patients in year 2 with a gross operating income of $6,480,000 and $7,440,000 in each year respectfully. The projected net operating income will be $512,400 and $597,040 in each year, respectively.

The review of the Projected Data Chart for the entire facility found on an unnumbered page following page 28R in the first Supplemental, states the total number of patients for the facility in year 1 will be 2,800 and in year 2 will be 3,215. These numbers reveal that Smokey Mountain Ambulatory Surgery Center, LLC will optimally perform MUA procedures on only 100 patients in year 1 and only 115 patients in year 2 of the project. Therefore, the facility would only generate by its estimates $172,740 in MUA net operating income in year 1 and $153,695 in year 2 of the project. The revenue from MUA patients would only represent approximately 25.2% of its total net revenue in year 1 and approximately 20.5% in year 2 of the project. The provision of interventional pain management services represents between 74.8% of total net revenue and 79.5% total net revenue in each respective year.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:
The applicant has a formal contractual relationship with STATCARE Medical Group, which is a division of Summit Medical Group, PLLC. This contract assures Smokey Mountain Ambulatory Surgery Center, LLC will have access to Fort Sanders Regional Medical Center, Parkwest Medical Center, St. Mary's Medical Center, St. Mary's North Medical Center and Laughlin Memorial Hospital as stated by the applicant.

The applicant states medical and chiropractic doctors, as appropriate, will be on site when interventional pain management procedures are performed.

The applicant states the approval of this project should not have any material adverse impact on any health care providers in the state. If the CON application for the addition of interventional pain management services by MUA of Middle Tennessee, LLC (CN1308-031) is approved there would be no other facilities dedicated to the provision of MUA and interventional pain management services except the one in Nashville.

The anesthesiologist and/or CRNA will bill for services separately as will the physicians. No additional staff will be added to those provided by the applicant as a result of the original CN0811-112A.

The applicant plans on working with area training programs to allow students to rotate through the facility to complete clinical training requirements.

The applicant will seek licensure from the Tennessee Department of Health, Board for Licensing Healthcare Facilities as a multi-specialty or specialty ASTC providing only MUA and interventional pain management services. The Department of Health, Division of Health Licensure and Regulation-Office of Health Care Facilities conducted an initial program and life safety survey on

2/10/2011 followed by an initial program certification survey. No deficiencies were cited by the Department of Health. The license as an ASTC limited to MUA services was granted on 2/22/2011 and expires on 2/22/2014.

The applicant was told by various insurers that MUA services would not be reimbursed unless interventional pain management services were attempted in the effort to resolve the patient's pain symptoms. The insurance providers did not view interventional pain management services as truly "incident to" MUA services. This led to a number of efforts to resolve this issue with the final result that HSDA informed the facility that it must apply for a CON to provide interventional pain management services. The applicant complied with the ruling by HSDA and this application is the culmination of that process.

The applicant in its efforts to establish and maintain a viable ASTC did not enhance the orderly development of health care because its assumptions regarding the reimbursement for MUA services were not valid and were the result of not accurately determining the actual reimbursement levels and any limitations by Medicare, Medicaid/TennCare and commercial insurers regarding the provision of MUA services prior to the time it filed the original CON application.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

AMBULATORY SURGICAL TREATMENT CENTERS

Determination of Need

1. **Need.** The minimum numbers of 884 Cases per Operating Room and 1,867 Cases per Procedure Room are to be considered as baseline numbers for purposes of determining Need. An applicant should demonstrate the ability to perform a minimum of 884 Cases per Operating Room and/or 1,867 Cases per Procedure Room per year, except that an applicant may provide information on its projected case types and its assumptions of estimated average time and clean up and preparation time per Case if this information differs significantly from the above-stated assumptions. It is recognized that an ASTC may provide a variety of services/Cases and that as a result the estimated average time and clean up and preparation time for such services/Cases may not meet the minimum numbers set forth herein. It is also recognized that an applicant applying for an ASTC Operating Room(s) may apply for a Procedure Room, although the anticipated utilization of that Procedure Room may not meet the base guidelines contained here. Specific reasoning and explanation for the inclusion in a CON application of such a Procedure Room must be provided. An applicant that desires to limit its Cases to specific type or types should apply for a Specialty ASTC.

   The applicant is seeking CON approval as a multi-specialty ASTC (or specialty ASTC) providing interventional pain management services in addition to its MUA services previously approved as CN0811-112A. In year one, the applicant projects 2,700 and 3,100 pain management procedures in year one and in year two respectively.

2. **Need and Economic Efficiencies.** An applicant must estimate the projected surgical hours to be utilized per year for two years based on the types of surgeries to be performed, including the preparation time between surgeries. Detailed support for estimates must be provided.

   The applicant estimated the projected cases for years one and two of the project based on the specific criteria contained herein. The applicant noted the pain management procedures would take less than 15 minutes including clean-up time.

3. **Need; Economic Efficiencies; Access.** To determine current utilization and need, an applicant should take into account both the availability and utilization of either: all existing outpatient Operating Rooms and Procedure Rooms in a Service Area, including physician office based surgery rooms (when those data are officially reported and available) OR, all existing comparable outpatient Operating Rooms and Procedure Rooms based on the type of Cases to be performed. Additionally, applications should provide similar information on the availability of nearby out-of-state existing outpatient Operating Rooms and Procedure Rooms, if that data are available, and provide the source of that data. Unstaffed dedicated outpatient Operating Rooms and unstaffed dedicated outpatient Procedure Rooms are considered available for ambulatory surgery and are to be included in the inventory and in the measure of capacity.

The Tennessee Department of Health, Division of Policy, Planning and Assessment-Office of Health Statistics verified the applicant's utilization data came from the Joint Annual Report of Ambulatory Surgical Treatment Centers 2012 Provisional which was the most recent data available to the applicant at the time this application was prepared. The Office of Health Statistics utilized the Joint Annual Report of Ambulatory Treatment Centers 2012 Final. There were no differences in the data provided by the applicant and that provided by the Office of Health Statistics. There was no licensed single specialty ASTC devoted to interventional pain management services in Knox County.

Knox County ASTC's Performing Pain Management Services
From Joint Annual Report 2012 Final

Facility	ORs	Procedure Rooms	2012 Procedures	2012 Patients*
Fort Sanders West Outpatient Surgery Center	4	0	7,791	3,406
Knoxville Orthopaedic Surgery Center	4	1	2,976	9,005
Parkwest Surgery Center	5	1	1,039	1,039
Physicians Surgery Center of Knoxville	5	0	1,071	2,884
St. Mary's Ambulatory Surgery Center	6	0	1,742	1,742
TOTAL	**24**	**2**	**22,461**	**10,234**

Source: *Joint Annual Report of Ambulatory Surgical Treatment Centers 2012 Final,* Tennessee Department of Health, Division of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics. *Unduplicated Patients.

4. **Need and Economic Efficiencies.** An applicant must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed, if those services are known and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above.

The applicant is not adding or replacing the one procedure room that currently exists per the original CON (CN0811-112A) but merely will utilize the same procedure room as currently authorized for MUA services for additional interventional pain management services. The applicant states on page 34 of the CON application that this project will not have a material impact on other ASTC providers because no other facility will provide both interventional pain management services and MUA services within Knox County.

5. Need and Economic Efficiencies. An application for a Specialty ASTC should present its projections for the total number of cases based on its own calculations for the projected length of time per type of case, and shall provide any local, regional, or national data in support of its methodology. An applicant for a Specialty ASTC should provide its own definitions of the surgeries and/or procedures that will be performed and whether the Surgical Cases will be performed in an Operating Room or a Procedure Room. An applicant for a Specialty ASTC must document the potential impact that the proposed new

ASTC would have upon the existing service providers and their referral patterns. A CON proposal to establish a Specialty ASTC or to expand existing services of a Specialty ASTC shall not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above. An applicant that is granted a CON for a Specialty ASTC shall have the specialty or limitation placed on the CON.

Note to Agency Members: The Department of Health, Division of Policy, Planning and Assessment cannot at the present time determine the number of cases since this data is not reported in the Joint Annual Report of Ambulatory Surgical Treatment Centers.

Other Standards and Criteria

6. Access to ASTCs. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility.

The Tennessee Department of Health, Division of Policy, Planning and Assessment-Office of Health Statistics reviewed the Joint Annual Report of Ambulatory Surgical Treatment Centers 2012 Final reveals Smokey Mountain Ambulatory Surgery Center, LLC served 379 patients and only 134 resided in Knox County. The percentage of patients from Knox County was approximately 35.4% in the 2012 JAR reporting period. This may indicate that the applicant's service area which is Knox County does not represent the actual service area at that point in time.

7. Access to ASTCs. An applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available.

The applicant notes the facility is located near to interstates and other surface transportation routes. The applicant responded to this item by stating the majority of patients will reside within 60 minutes average driving time of the facility.

8. Access to ASTCs. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project the origin of potential patients by percentage and county of residence and, if such data are readily available, by zip code, and must note where they are currently being served. Demographics of the Service Area should be included, including the anticipated provision of services to out-of-state patients, as well as the identity of other service providers both in and out of state and the source of out-of-state data. Applicants shall document all other provider alternatives available in the Service Area. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

The applicant expects 100% of its patients will come from Knox County, as noted in Item 6 of the Specific Criteria. The Tennessee Department of Health, Division of Policy, Planning and Assessment-Office of Health Statistics reviewed the Joint Annual Report of Ambulatory Surgical Treatment Centers 2012 Final reveals Smokey Mountain Ambulatory Surgery Center, LLC served 379 patients and only 134 resided in Knox County. The percentage of patients from Knox County was approximately 35.4% in the 2012 JAR reporting period. This may indicate that the applicant's service area which is Knox County did not represent the actual service area at that point in time.

9. Access and Economic Efficiencies. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters

following completion of the project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

The applicant provided data in the original CON application addressing projected patient utilization for the first eight quarters and described its methodology in the first Supplemental in response to question 9 from HSDA staff.

10. Patient Safety and Quality of Care; Health Care Workforce.
a. An applicant should be or agree to become accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization.

The applicant's reports its facility was recently surveyed by the Joint Commission and was certified as an ASTC meeting its accreditation standards. The survey took place on 8/31/2011-9/01/2011 and The Joint Commission granted the facility Accreditation with an effective date of 9/18/2011. The Joint Commission also recommended the organization for Medicare certification on that date. The applicant resolved deficiencies regarding Surgical Services (sub section 416.42) and Patient Admission, Assessment and Discharge (sub section 416.52).

b. An applicant should estimate the number of physicians by specialty that are expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel. An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.

The list of the 8 physicians using this facility can be found in the first Supplemental in response to question 10 by the HSDA staff. The applicant also stated that the facility has an anesthesiologist agreement in place at this time.

11. Access to ASTCs. In light of Rule 0720-11.01, this lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration.

Not applicable.

b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program;

Not applicable.

c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

The applicant is a Medicare and Medicaid/TennCare provider. The Medicare provider number is 1526056 and the Medicaid/TennCare provider number is 103G42884.

The applicant on page 2 of Supplemental #1 states they have a contract with United Health, and have applied for a contract with BlueCare. Additionally, they note on page 3 of Supplemental #1 AmeriGroup has requested that they join them as an out-of-network provider. However, on page 7 of the CON application the applicant states it has contracts

with AmeriChoice, BlueCare and TennCare Select. The current and planned Medicaid/TennCare contractual relationships by Smokey Mountain Ambulatory Surgery Center, LLC appear comprehensive in scope but the progress towards completion of these contractual relationships was not finalized at the time this CON was submitted.

d. Who is proposing to use the ASTC for patients that typically require longer preparation and scanning times? The applicant shall provide in its application information supporting the additional time required per Case and the impact on the need standard.

According to the applicant, the provision of interventional pain management services would be well within the available capacity of MUA of Middle Tennessee, LLC because the interventional pain management procedures only take up 15 minutes time including clean-up.

TIMOTHY HILL
STATE REPRESENTATIVE
3rd LEGISLATIVE DISTRICT

23 LEGISLATIVE PLAZA
NASHVILLE, TN 37243-0131
(615) 741-2251
E:MAIL
rep.timothy.hill@capitol.tn.gov
Toll Free to Nashville:
1-800-449-8366 Ext. 44202

House of Representatives
State of Tennessee

NASHVILLE

JAN 9 '14 AM 10:01

DISTRICT ADDRESS:
P O BOX 3071
BLOUNTVILLE, TN 37617
423-646-1589

COMMITTEES:
Calendar and Rules
Business and Utilities
Health

January 8, 2014

Melanie Hill, Executive Director
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37243

Re: CON Support
Smoky Mountain Ambulatory Surgery Center - Knoxville
Tennessee Spine and Nerve Institute - Nashville
Request for Interventional Pain Management Procedures

Dear Mrs. Hill,

I appreciate the CON review process, as we have discussed before. It has come to my attention that Smoky Mountain Ambulatory surgery center in Knoxville and Tennessee Spine and Nerve institute in Nashville are under the review process, based on the conversation we had during last legislative session. I have personally visited both locations and have found the staff to be professional and have a desire to be in compliance with the law. My hope is that they will be reapproved in this CON process, to allow them to serve what I perceive to be an underserved population. As always, I appreciate your work and look forward to the CON board determination.

Thank you,

Timothy Hill

State Representative Timothy Hill