



THE STATE
of **ALASKA**
GOVERNOR MIKE DUNLEAVY

Department of Health

Certificate of Need Program

3601 C Street, Suite 978
Anchorage, Alaska 99503
Main: 907-538-2452

May 18, 2023

Ms. Cassy Freeman, Office Manager
McKinley Surgery Center, LLC
3745 Geist Road
Fairbanks, Alaska 99709

Via email: cfreeman@mckinleyortho.com

RE: Request for Determination – McKinley Surgery Center, LLC dated January 16, 2023

Ms. Freeman,

Thank you for your original request for determination (RFD) whether a certificate of need (CON) is necessary for McKinley Surgery Center, LLC's (MSC) proposed ambulatory surgical center, received by the department on January 16, 2023, in response to the department's inquiry relating to establishment of ambulatory surgical services at 3745 Geist Road, Fairbanks, Alaska.

The above referenced RFD was submitted after an Inquiry Letter was sent to McKinley Orthopedics, Sports Medicine and Spine (MKO), from the department, dated December 12, 2022, asking for information pertaining to MSC's proposed ambulatory surgical facility. Subsequently, the CON Program was contacted by Mr. Stanley James, owner, in part, of McKinley Surgery Center (MSC) and McKinley Imaging, LLC (MKI), and who identified himself as the contact regarding the Inquiry.

Mr. James informed the department MSC would submit an RFD for the project as a means of a response to the Inquiry Letter.

On January 16, 2023, MSC submitted its RFD for its proposed ambulatory surgical center to be located at 3745 Geist Road, Fairbanks, Alaska.

On February 6, 2023, after review of the initial RFD submission, the department issued its first Request for Additional Information. MSC responded to this request on February 10, 2023. Upon review of the submission, the department found the response to its request incomplete.

On March 6, 2023, the department sent its second Request for Additional Information. MSC responded to this request on March 13, 2023. Upon review of the submission, the department found the response to its request incomplete.

On April 11, 2023, the department issued its third Request (fourth request, overall) for Additional Information. On April 17, 2023, MSC responded with the requested information. After review of MSC's response, the department found the response to its request complete. A review of the project, and all the accompanying information and documentation pertaining to the Inquiry and subsequent RFD, was conducted.

PROJECT OVERVIEW:

MSC proposes to operate an ambulatory surgery center, in a self-contained mobile unit, fixed and attached to an existing structure located at 3745 Geist Road, Fairbanks, Alaska. The mobile operating suite contains one operating room, pre- and post-anesthesia care area, pre-operation area, nurses' station, clean room, soiled room, bathroom and janitor closet.

It is currently attached to MKO via a covered corridor. Per MSC:

"This surgical facility is pre constructed and is equipped with a patient screening/reception area, surgical scrub room, fully functional surgical suite, decontamination and clean room that is needed for every step of the surgical process. The surgical unit patient stations contain a full medical gas system with large storage tanks, manifolds, zone valves, alarm systems and hospital grade outlets. The facility is also completely self-supporting with electrical systems, water systems, medical gas and full vacuum systems, and highest capacity HEPA filtered HVAC system. All the systems have backup capabilities. This unit was previously used as a stand-alone unit in the continental United States and comes as a complete OR unit meeting all CMS standards."

MSC proposes to provide the following orthopedic, same-day, surgical procedures:

ORTHOPEDIC PROCEDURES
Arthroscopy
Arthrodesis
Closed/Open Reduction Internal Fixation
Hardware Removal
Foot and Ankle deformity correction
Arthroplasty
Manipulation of Joint
Excisional Biopsy Bone or Soft Tissue
Bursectomy/Synovectomy
Tendon/Ligament Repair
Nerve Decompression and Repair
Irrigation and Debridement/Wound Care
Epidural Steroid Injection
Arthrocentesis
Microdiscectomy/Discectomy
Decompression/Laminectomy

Cervical and Lumbar Fusion

MSC proposes to initiate services upon approval to proceed from the department, inclusive of the CON Program's consent, and fulfilling all state licensure and certification requirements necessary to perform proposed services.

MCS submitted a budget, along with a certified cost estimate and accompanying narrative, for the project. *(See Addendum A, attached.)*

MCS estimates a total project cost of \$1,435,966.89.

In conclusion, MSC's proposed project is subject to CON requirements. The total estimated costs of the proposed project are \$1,435,966.89. This expenditure amount is below the \$1.5 million statutory threshold under AS 18.07.031. Accordingly, a CON is not required for this project as it is proposed.

Since this determination is restricted to the specific project proposal, if the project experiences a change in scope, costs, or circumstances, then this office must be notified immediately because this determination is void and a CON may be required.

If you are dissatisfied with this determination, you may request reconsideration under 7 AAC 07.033. A request for reconsideration must be postmarked no later than 30 days after publication of the public notice.

Sincerely,

Alexandria Hicks

Alexandria Hicks, CON Program Coordinator

/attach
Addendum A

Addendum A

MCKINLEY SURGERY CENTER, LLC		LINE-ITEM BUDGET REPORT	DATE: 04/17/2023
1. Cost Category: Facility Administrative			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
McKinley Surgery Center, LLC License	State Of Alaska	\$250.00	State of Alaska License Fee
Ambulatory Surgery Center Application	State Of Alaska	\$650.00	Ambulatory Surgery Center Application Fee
McKinley Surgery Center Facility Logo Design	Glacial Media	\$150.00	McKinley Surgery Center Facility Logo Design
CLIA Laboratory Program	CMS	\$180.00	CLIA waiver for blood glucose and urine pregnancy testing
Drug Room License	State Of Alaska	\$250.00	Drug Room License
Ambulatory Surgical Center Package Joint Commission Manual MCN	Medical Consultants Network, Inc	\$1,999.99	Ambulatory Surgical Center Package Joint Commission Manual MCN
Background check for McKinley Surgery Center Employees	NABCS State of Alaska	\$970.75	Background check for McKinley Surgery Center employees
Nursing Training for Director of Nursing	National Institute of First Assisting	\$649.00	Nursing Training for Director of Nursing
Health Care Facilities Code NFPA	Life Safety Code Standards	\$272.45	Health Care Facilities Code NFPA
		TOTAL	\$5,372.19
2. Cost Category: Facility Cost			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
Calutech Mobile Solutions, INC	Anton Edwin Hosch JR	\$964,576.62	Calutech OR Unit
		TOTAL	\$964,576.62
3. Cost Category: Construction			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
Himoinsa Generator	Valley Imaging, LLC	\$15,000.00	Back up generator in case the power goes out
Installing Power to Surgical Trailer	Rigid Electric LLC	\$14,850.00	Installing the current carrying conductors from Golden Valley to surgical trailer
		TOTAL	\$29,850.00
4. Cost Category: Operating Room Equipment			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
Steris Operating Table 4085	ST Surgical LLC	\$27,500.00	Patient bed for operating room
Arm Boards 26" & 2" Padding X2	ST Surgical LLC	\$500.00	Patient arm boards that connect to the OR table
Amico i30x30 Surgical Light	ST Surgical LLC	\$17,475.00	Surgical lighting for operating room
Dual Wall Light Control	ST Surgical LLC	\$1,000.00	Light control system for OR lights
AMICO Surg Equipment Plate	ST Surgical LLC	\$500.00	Mounting plate for surgical lights
ICE LED Surgical Light Handle	ST Surgical LLC	\$100.00	Handle for moving surgical lights
Blair Hugger 775 & Rolling Cart X2	ST Surgical LLC	\$3,000.00	Warming system for patients pre and post surgery
Stryker SM 104 Transport Stretcher/5th Wheel X3	ST Surgical LLC	\$8,400.00	Patient Transport Stretcher
Mayo Stand X2 16 1/4 x21	ST Surgical LLC	\$1,356.00	Mayo Stand for surgical instruments
Back Table X2 24 x 72 x 34	ST Surgical LLC	\$2,370.00	Table for surgical instruments
		TOTAL	\$62,201.00
5. Cost Category: General Surgical Instruments			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
General OR Instruments	31 Medical	\$662.56	Instruments: Forceps, Elevator, Scissors, Codman, Needle Holder, Mallet Etc
Stryker TPS Set	Orthopedic Surgical Solutions, LLC	\$6,142.00	Power Drill, Driver and attachments for Orthopedic Cases
General OR Instruments	Henry Shein Medical	\$2,218.60	Instruments: Scissors, Freer Elevator, Forceps, Knife Holder, Retractors Etc
		\$9,023.16	
6. Cost Category: Sterilizer Equipment			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
Tuttnauer 3780 Sterilizer w/Printer	ST Surgical LLC	\$13,015.00	Sterilizer for operating room instruments
Steelco DS 500 CDL Washer C797 3 Level Wash Cart	ST Surgical LLC	\$21,497.00	Instrument Washer for operating room instruments
3M Attest Auto-Reader	ST Surgical LLC	\$1,500.00	Biological Readers Testing Monitor for sterilizer
		TOTAL	\$36,012.00
7. Cost Category: Styker Arthroscopy Rental and Service Agreement Equipment/Instruments			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
PKG VISIONPRO 26" DISPLAY COVER-standard X2	Styker Sales, LLC	Rental Agreement	Display system for arthroscopy cases
PKG.FIBEROPTIC CABLE 5MM X 10FT (3.05M)-standard X2	Styker Sales, LLC	Rental Agreement	Light cord for arthroscopy cases
Connected OR Cart 120 V-standard	Styker Sales, LLC	Rental Agreement	Cart for arthroscopy equipment
FLAT PANEL ROLL STAND KIT-standard	Styker Sales, LLC	Rental Agreement	Display system for arthroscopy OR cases
PKG. PUMP CANNULA 5,8MM W/2 ROTATING STOPCOCKS-standard X2	Styker Sales, LLC	Rental Agreement	Arthroscopy instruments
PKG. PENCIL OBTURATOR 5,8MM PUMP CANNULA-standard X2	Styker Sales, LLC	Rental Agreement	Arthroscopy instruments
ENDOSCOPE AND HARDWARE SET TRAY-standard X2	Styker Sales, LLC	Rental Agreement	Arthroscopy instruments
70MM IN/OUTFLOW CANNULA KIT-standard X2	Styker Sales, LLC	Rental Agreement	Arthroscopy instruments

SDC4K BASE + SDP Kit-standard	Styker Sales, LLC	Rental Agreement	Power Console for Video
PKG CAMERA AUTOCLAVABLE TRAY-standard x2	Styker Sales, LLC	Rental Agreement	Arthroscopy camera tray
PKG 30FT DVI CABLE-standard	Styker Sales, LLC	Rental Agreement	Video connection
PKG VISIONPRO 26" LED DISPLAY-CPO x2	Styker Sales, LLC	Rental Agreement	LED Display System
PKG PRECISION LED LIGHT SOURCE-CPO	Styker Sales, LLC	Rental Agreement	LED Display System
HD 4MM X 30Å ARTHROSCOPE SPEEDLOCK A/C-CPO x2	Styker Sales, LLC	Rental Agreement	Arthroscopy Instruments
PKG PRECISION AC 3-CHIP CAMERA CONTROL UNIT (CCU)-CPO	Styker Sales, LLC	Rental Agreement	Power source for camera
PKG PRECISION AC 3-CHIP AUTOCLAVABLE CAMERA C-MOUNT-CPO x2	Styker Sales, LLC	Rental Agreement	Camera attachment
PKG PRECISION AC COUPLER C-MOUNT-CPO x2	Styker Sales, LLC	Rental Agreement	Camera attachment
PKG CROSSFIRE 2 CONSOLE X2	Styker Sales, LLC	Rental Agreement	Power for motorized instrumentation
PACKAGING FORMULA SHAVER (HAND CONTROL) x2	Styker Sales, LLC	Rental Agreement	Arthroscopy Instruments
PKG CROSSFLOW CONSOLE x2	Styker Sales, LLC	Rental Agreement	Arthroscopy Pump
ADAPTABLE BEACH CHAIR SYSTEM	Styker Sales, LLC	Rental Agreement	Shoulder arthroscopy chair patient positioner equipment
ADAPTABLE ARM POSITIONER (POSITIONER ARM TRAY CONNECTOR)	Styker Sales, LLC	Rental Agreement	Patient positioner equipment for arthroscopy cases
ADAPTABLE ARM POSITIONER LATERAL DECUBITUS ATTACHMENT	Styker Sales, LLC	Rental Agreement	Patient positioner equipment for arthroscopy cases
STYKER EQUIPMENT SERVICE PLAN	Styker Sales, LLC		Routine maintenance agreement for all arthroscopy equipment
TOTAL		\$261,418.92	
8. X-Ray Unit			
X-Ray Unit		\$11,430.00	This is a mobile imaging unit used for fluoroscopic imaging during surgery
TOTAL		\$11,430.00	
9. Cost Category: Anesthesia/Crash Cart Equipment			
EXPENSES	VENDOR	TOTAL COST	NARRATIVE
GE Ohmeda Datex Aespire S/5 7900 Ventilator	ST Surgical LLC	\$18,900.00	Intubated patient airway management
Axia Anesthesia Monitor 1500/Gas Bench	ST Surgical LLC	\$11,000.00	Intubated patient monitoring
Axia Patient Monitor 1200 T X2	ST Surgical LLC	\$7,390.00	Standard patient monitoring
Rolling Stand for Axia Monitor X2	ST Surgical LLC	\$700.00	Attach Axia patient monitor for transport and holding
Anesthesia Cart/Lock/5 Drawer	ST Surgical LLC	\$1,995.00	Anesthesia equipment and material
Crash Cart/6 Drawer	ST Surgical LLC	\$1,818.00	Emergency equipment availability and storage
Emergency Accessory Kit/Crash Cart	ST Surgical LLC	\$1,190.00	Emergency equipment availability and storage
Lifepak 20e Defibrillator/FDA Approved	ST Surgical LLC	\$6,600.00	Emergency life saving equipment
ABS Medical Refrigerator	ST Surgical LLC	\$1,400.00	Medication storage for required refrigerated drugs
Alaris Medley Infusion Pump	Wilburn Medical USA	\$2,095.00	Medication infusion device for IV drugs
Baxter Infusion OR Pump	Dia Medical	\$2,995.00	Medication infusion device for IV drugs
TOTAL		\$56,083.00	
EXPENSES SUMMARY			
1. Facility Administrative		\$5,372.19	
2. Facility		\$964,576.62	
3. Construction		\$29,850.00	
4. Operating Room Equipment		\$62,201.00	
5. General Surgical Instruments		\$9,023.16	
6. Sterilizer Equipment		\$36,012.00	
7. Arthroscopy Equipment/Instruments		\$261,418.92	
8. X-Ray Unit		\$11,430.00	
9. Anesthesia/Crash Cart Equipment		\$56,083.00	
TOTAL PROJECT COST		\$1,435,966.89	