



THE STATE
of **ALASKA**
GOVERNOR MIKE DUNLEAVY

Department of Health

Certificate of Need Program

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April 11, 2023

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

RE: Request for Determination – McKinley Surgery Center, LLC dated January 16, 2023
3rd Request for Additional Information

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, and whose address is 3745 Geist Road in Fairbanks, Alaska.

OVERVIEW AND TIMELINE OF ACTIVITY TO DATE:

Overview:

This RFD was submitted after an Inquiry Letter was sent to McKinley Orthopedics, Sports Medicine and Spine (MKO), from the department, dated December 12, 2022 (attached), asking for information pertaining to MSC's proposed facility. Subsequently, the CON Program, was contacted by Mr. Stanley James, stating he had an ownership stake in (MSC) and McKinley Imaging, LLC (MKI), and he would be the contact for this Inquiry. After some discussion regarding the Inquiry Letter, Mr. James stated that he and his partners would submit an RFD for the project, as a means of a response to the Inquiry Letter, on behalf of MSC.

On January 16, 2023, MSC submitted its RFD for its proposed ambulatory surgical center.

On February 6, 2023, the department issued its first Request for Additional Information, as it pertained to MSC's RFD. MSC responded to this request on February 10, 2023. The department found the response to its request incomplete, and on March 6, 2023, sent its second Request for Additional Information. MSC responded to this request on March 13, 2023. This letter will serve as the department's third Request for Additional Information.

Please see the timeline of activity to date.

Timeline and Activity:

January 16, 2023-Receipt of RFD from MSC

The RFD provided the proposed project start date was projected to be September 9, 2022, and the proposed project end date to be on or about February 15, 2023. Included was a description of the proposed activity, stating it was a “new ambulatory surgery center, providing outpatient services for same day surgical care”.

The original cost breakdown submitted included the following:

TOTAL PROJECT COST: **\$1,060,771.11**

Facility Administrative:	5,372.19
Facility/Construction:	879,850.00
Operating Room Equipment:	54,851.00
Sterilizer Equipment:	36,012.00
Arthroscopy Equipment/Instruments Lease:	34,042.92
Anesthesia/Crash Cart Equipment:	50,643.00

February 6, 2023 -1st Request for Additional Information and
February 16, 2023 - MSC Response

The department, in a letter dated February 6, 2023, requested additional information to process MSC’s RFD. In its response, dated February 16, 2023, MSC provided the following response(s) to the department’s questions #1-3:

1. A clear concise description of the proposed ambulatory surgery center, to include:
 - a. How many operating rooms are proposed

MSC response: One operating room

- b. Proximity to existing services that McKinley current provides

MSC response: New surgery unit attached to the McKinley Orthopedic clinic, connected via a temporary corridor/hallway

- c. A comprehensive definition of the space in which you propose to provide ambulatory surgery services, i.e., fixed, or mobile
(*Note: While it appears, the space is a mobile unit; there was not sufficient information provided to draw a definitive conclusion.*)

MSC response: Mobile Ambulatory Surgery Center on wheels that is connected through a temporary corridor to existing clinic, that is 930 square feet

- d. What specific same day surgical care services are proposed

MSC response: A listing of 15 orthopedic same day surgeries and procedures

2. Certified cost estimates for all components of the project; to include:
 - a. Facility and Construction Costs
 - b. Operating Room Equipment
 - c. Sterilizer Equipment
 - d. Arthroscopy Equipment
 - e. Anesthesia Equipment
 - f. Other equipment
 - g. All property and instrument(s) lease and service agreements, as applicable

MSC response:

REVISED TOTAL PROJECT COST: **\$ 569,961.25**

Facility Administrative:	5,372.19
Facility/Construction:	351,375.54
Operating Room Equipment:	62,201.00
Sterilizer Equipment:	36,012.00
Arthroscopy Equipment/Instruments Lease:	64,007.52
Anesthesia/Crash Cart Equipment:	50,993.00

3. Updated timeline for the project; specifically, when do you propose to initiate provision of ambulatory surgery services?

MSC response: March 2023, pending CON determination and State Site Visit for Licensure

March 6, 2023 – 2nd Request for Additional Information and
March 13, 2023 - MSC Response

After review of your response to the departments 1st Request for Additional Information, the department then issued a 2nd Request for Additional Information, dated March 6, 2023. In its 2nd Request for Additional Information, the department stated it had found discrepancies in the calculation of the proposed project cost, and provided its calculation of cost, as follows:

<i>Submitted expenses</i>	<i>Vendor</i>	<i>Total Cost</i>
Anesthesia and Crash Cart	ST Surg, LLC	\$ 30,275
Arthroscopy Cost	Stryker	\$132,115
Facility and Construction	Valley Imaging	\$ 15,000
Facility and Construction	Rigid Electric, LLC	\$ 14,850
Facility Agreement	GE Healthcare, HCFS	\$964,577
Operating Room Equipment	ST Surg, LLC	\$ 57,745
Sterilizer	ST Surg, LLC	\$ 36,012

Total Cost	\$1,250,574
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MSC did not respond directly to the department's new, calculated project cost, instead provided three new, additional costs it identified.

MSC response: McKinley Surgery Center would like to add the following cost below for Anesthesia equipment.

- Alaris Medley Infusion Pump: Please see attached invoice: \$2,095.00
- Baxter Infusion OR Pump: Please see attached invoice: \$2,995.00
- Total Cost for Anesthesia/Crash Cart Equipment = \$56,083.00

Anesthesia equipment will be the last additional cost for equipment McKinley Surgery Center will be adding to the proposed project to the best of our knowledge.

The department, in addition to its inquiry into overall project cost, sought clarification on the following topics:

1. As it pertains to the "Arthroscopy Cost", the rental agreement with Stryker states "you must maintain equipment in good, working condition". Service agreements and cost for maintenance of equipment need to be included for consideration when considering expenditures for purposes of CON. *Please provide any maintenance and service agreements for the proposed project's equipment.*

MSC response: See the attached Stryker arthroscopy service agreement and rental agreement for your review.

2. As it pertains to the "Facility Agreement", and associated documentation submitted to be considered for the purposes of determining cost, the following applies:

The Bill of Sale and Agreement (executed between Seller and Buyer) states cost of trailer is \$850,000, with the Buyer depositing an escrow amount of \$75,000 with the Seller. Further, once the trailer is delivered to the Buyer, and operational, the escrow deposit of \$75,000 is released back to Buyer, from the Seller.

The Buyer's agreement, with the Buyer's Lender, is a 60-month lease to own agreement, with the following terms: total cost: \$964,577, over 54 months at a cost of \$17,862.53 per month.¹

Please provide an updated Facility Agreement cost and supporting documentation, or justification to support the current, submitted cost.

MSC response: a. See the attached GE Healthcare lease agreement for justification of facility cost. (Lease Proposal)
b. See the attached Bill of Sale Agreement and Title for review. (Facility Agreement)

¹ Bill of Sale and Agreement and Equipment Schedule to Master Lease Agreement ref: Seller: Anton Edwin, Hoch, Jr., Buyer: McKinley Ortho, Buyer's Lender: GE Healthcare, Healthcare Financial Services.

3. Per the original request for additional information, dated February 6, 2023, #2 (f), which asked for the certified costs of all equipment for the proposed project, and the department's original Inquiry Letter, dated December 12, 2022:

"The CON Program is asking you to confirm and provide the following:

1. MKO is a health care facility subject to CON per AS 18.07.111;
2. MKO has added surgical capacity, and to what extent;
3. MKO has added independent diagnostic testing equipment, and to what extent; and
4. MKO has considered the CON requirements as it pertains to provision of existing or planned healthcare services at its Fairbanks location."

MSC response:

- MKO is not adding surgical capacity and is not subject to CON. McKinley Surgical is looking to become an independent ASC and is subject to CON per 18.07.111.
- Please note that MKO has not added surgical capacity. McKinley Surgery Center, LLC is a separate entity.
- Please note that MKO has not added independent diagnostic testing equipment.
- McKinley Imaging Center, LLC is a separate entity.
- Yes, MKO has considered the CON requirements.

NEW - 3rd Request for Additional Information necessary to process RFD

To provide a history and genesis of the submittal of the RFD, by MSC, an overview and timeline of activity relating to the a) MKO Inquiry Letter and, b) MSC's (subsequent) RFD CON filing with the department, has been provided, above. I hope the history and timeline prove a resource for MSC, moving forward.

While MKO was initially the addressee, or the identified entity in the Inquiry Letter, MSC has filed the current RFD. Henceforth, I will address my queries relating to the Inquiry Letter and MSC's RFD, to MSC. However, this does not rule out the possibility, or the necessity to refer to or request information from, other identified, and related entities, in this matter.

To render a decision on MSC's RFD, the department needs the following information, in the format requested. Please provide the following:

1. An updated, line-item budget; inclusive of **all costs** incurred to establish the ambulatory surgery service, in the following format:

Expenses	Vendor	Total Cost
TOTAL PROJECT COST:		\$

Each cost listed will need to be accompanied by a current, certified cost estimate, to the best of your ability. Additionally, the budget should include a narrative section, describing the purpose of the expense and other detail to illustrate the function and necessity of the expense as it relates to the proposed project.

To reiterate, this budget needs to be complete, concise, tallied, and supported with a descriptive narrative and the associated, certified cost estimates. When referencing sale, and lease and service agreements, these will need to reflect updated terms and conditions.

2. To the best of your ability and knowledge, please disclose the current and proposed services offered at 3745 Geist Road, Fairbanks, to include a) McKinley Orthopedics, Sports Medicine and Spine, b) McKinley Imaging, LLC, and c) McKinley Surgery Center, LLC. In your response, please provide the description of each health care service provided, and any equipment associated with that service. Please provide any existing, or planned, coordination of delivery of service, whether it is a verbal arrangement or obligation, contractual, or other agreement, among the entities listed above, at this location to coordinate services in provision of health care services.
3. The department is aware of the ownership stake of each LLC listed, in #2, above . Please provide any justification and explanation as to why the department should consider each entity (specifically McKinley Imaging, LLC and McKinley Surgery Center, LLC), for purposes of CON, separately, as it pertains to the current, MSC RFD review.
4. Per the GE Healthcare Lease Agreement provided, the following applies: “Proposal and terms expire on 7/13/2022, if not accepted, and signed.” The copy of the Lease Agreement is not signed. Further, the Lease Agreement notes that if it is not accepted, and signed, and the date of 7/13/2022 has passed with lease commencement no later than 9/11/22, all terms and conditions of the agreement expire.
 - A. Please provide all updated information, including dates and the certified costs associated with the GE Healthcare Lease Agreement or any other agreements that may exist as it relates to the mobile surgical unit.
 - B. Please provide a narrative description containing the details of the purchase of the mobile surgical unit and the relationship and fiduciary responsibility of all parties involved. This should include any lease, lease to own, or other scenario description(s) that impact the overall cost of the unit, as it relates to determining expenditures for purposes of CON.
5. Please provide an updated, and current narrative description of the proposed project, and valid dates for the establishment of services, i.e., when do you plan on offering surgical services? This description should include any details outlined in your answers #1-4 above, and be concise, and up to date as possible.

The department requires additional information to process your RFD. Please provide the requested information thirty days from the date of this letter.

Sincerely,



Alexandria Hicks, CON Program Coordinator

/ah

Attach