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December 24, 2008

Ms. Phyllis Powell
Certificate of Need Unit
Division of Licensing & Regulatory Services
11 State House Station
Augusta, Maine 04333-0011

Re: **Letter of Intent and Request for Confirmation of Non-Applicability or Waiver of Certificate of Need ("C.O.N.")**

Dear Ms. Powell:

This office represents Central Maine Orthopaedics, P.A. ("CMO"), a professional services corporation comprised of eight surgeon shareholders. The entity operates, and holds a license as, an ambulatory surgical facility ("ASF") in Auburn, Maine. On behalf of CMO, this letter serves both as a letter of intent pursuant to 22 M.R.S.A 337(1), and chapter 6 of the Maine Certificate of Need Procedures Manual, and as an inquiry regarding the applicability of the Certificate of Need Program to the proposed undertaking by CMO. Essentially, CMO seeks confirmation that the activity described below is not subject to C.O.N. review.

## Background

The activity that is the subject of this Letter of Intent involves CMO's plan to provide orthopaedic pain management services in its ambulatory surgical facility ("the Project"). Currently, many CMO patients are referred by CMO to other providers for pain management, either following surgery and/or in connection with the treatment of diagnosed orthopaedic conditions. Therefore, incorporating such services into the facility would be a natural extension of the services already provided.

At this stage, CMO anticipates that the pain management services would be rendered in one of the current operating rooms in the ASF, by either (i) the current fellowship-trained anesthesiologists contracted with CMO and already rendering anesthesiology services in the ASF or (ii) experienced physiatrists or other qualified providers who would be contracted with or employed by CMO in the future. The care would be viewed as corollary to the services rendered by the CMO surgeons, as a team approach to treatment. While the surgeons would not supervise the individual treatment by the providers, they would have access to the records of care, to assist with the surgeons' general management of patient care.

**Evaluation of the Certificate of Need Criteria**

For the reasons set forth below, the subject transaction should be deemed to fall outside of the purview of the C.O.N. statute, 22 M.R.S.A. §329,[1] and thus review and approval of the transaction by the State should not be required. Pertinent aspects of the planned project include the following:

- There will not be a transfer of ownership.

- There will not be an acquisition of major medical equipment in excess of $1.2 million dollars. 22 M.R.S.A. §329 (2-A). CMO would purchase a C-arm X-ray machine. This machine is small and mobile enough that it allows the conducting of an x-ray examination of a patient from several different positions, without the need to reposition the patient.[2] Note that use of the C-arm would not be limited to pain management procedures, but would be incorporated into other, current CMO services. The C-arm will likely be purchased and used in the facility regardless of the integration of pain management treatment. CMO has received estimates from different vendors for this piece of equipment of $45,000 to $53,000. Another machine that would likely be purchased is a Radiofrequency Machine, the cost of which would be approximately $35,000. No other major medical equipment is anticipated for purchase.

- The project will not require a capital expenditure of $2,400,000 or more. 22 M.R.S.A. §329(3). No capital expenditure is anticipated.

- The project will not entail the construction, development or other establishment of a new health care facility. 22 M.R.S.A. 329 §4-A. The currently existing facilities will remain intact.

- The project will not impact or involve changes in bed complement (22 M.R.S.A. 329 §5), nursing facilities (22 M.R.S.A. 329 §6), or major medical equipment for serving inpatients of a hospital.

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[1] The statute precludes a person or entity from entering into any commitment for financing a project that requires a certificate of need or from incurring any expenditure for the project without having sought and received a certificate of need. A C.O.N. is not required for an entity, unless the specific criteria of the statute are met.

[2] The term "C-arm" refers to the C-shaped member of the machine that contains an x-ray source and an image receptor mounted on opposing ends of the C-arm such that x-rays emitted by the source are incident on and detected by the image receptor.

The only remaining factor to be considered under the C.O.N. statute in connection with a non-applicability ruling, relates to "new health services". 22 M.R.S.A. §329(4). Because it does not seem that the undertaking by CMO is a "new health service", review should not be triggered.

Historically and currently, the treatment plan for numerous CMO patients has included pain management. A description of the array of pain management procedures used in orthopaedic facilities is included here at Enclosure #1. These are common if not integral components of the range of services offered nationally, to patients under the care of an orthopaedic surgeon or orthopaedic ambulatory surgical facility, whether to manage pain and obviate the need for surgical intervention, or to manage post-surgical pain. Numerous articles have been written on the subject. See, e.g., Herkowitz, M.D. et al, Pain Management, the Orthopaedic Surgeon's Perspective, The American Journal of Bone and Joint Surgery. 2007; 89:2532-2535. Accordingly, it is reasonable to conclude that integrating pain management services into the ASF should not be deemed a "new health service". At the same time, CMO acknowledges that in the past, when the CMO surgeons have recommended pain management, the subsequent treating providers were not CMO employees or contractors. Instead, the patients obtained care from, or were referred to, other health care providers. The services were not rendered at or by the ASF, or at any other facility on the CMO premises.

Regardless of whether the pain management treatment is viewed as a "new health service" for the purposes of §329, the C.O.N. review process should not be triggered, as the pain management services would not entail incremental operating costs in the third fiscal year of operations of five hundred nine thousand four hundred forty nine dollars ($509,449.000) or more[3]. 22 M.R.S.A. §328(17-A). The details regarding the anticipated operating costs are included here at Enclosure #2, and reflect projected third year incremental operating costs of less than $400,000.00.

In accordance with the above, and based upon the materials included here at the referenced Tabs, it is my hope that you will issue a determination that the proposed plan by CMO to provide pain management services at its ambulatory surgical facility is not subject to C.O.N. review. If it is determined that this Project is subject to review under Maine's Certificate of Need Program, an application will be submitted on or before March 20, 2009. I, and representatives of CMO, would be happy to meet with you, or provide any further information that might be helpful, to assist with your consideration of this matter.

[3] This is the amount confirmed by Steven Keating of the C.O.N. Unit as the current regulatory ceiling established by the Department for C.O.N. reviewed operating costs.

Sincerely,

Jennifer S. Riggle
Legal Counsel to CMO

JSR/j
Enclosures

**Enclosure #1 to Letter of Intent from Central Maine Orthopaedics, P.A.:**

**Description of Orthopaedic Pain Management Procedures.**

An array of options is available to orthopaedic surgeons for the treatment of pain -- including managing chronic pain, alleviating conditions without requiring surgical intervention, and addressing post-surgical pain. These options include the following, all of which would be utilized at CMO, as appropriate, depending upon particular patient needs.

Diagnostic Sympathetic Nerve Block

A local anesthetic is injected into the *stellate ganglia* in the neck when treating the upper extremity. The stellate ganglia are a group of interconnected nerve cell bodies. Injecting anesthetic into the low back is used to treat the lower extremity. The injected anesthetic should numb the affected limb. Pain relief and improved temperature of the extremity is a positive diagnostic test.

Spinal Cord Stimulator Trial

Placement of temporary wires for the trial is considered a minimally invasive procedure. An epidural needle is placed near the spinal cord. This is done with the help of a special X-ray called *fluoroscopy*. The electrode wires are then inserted through the needle. The wires are attached to an external stimulator. The procedure is performed under local anesthesia.

Sacroiliac Joint Injection and Facet Joint Injections

SI joint injections are done with the help of fluoroscopic guidance. The fluoroscope is an x-ray machine (already owned by CMO) that allows the doctor to actually see an x-ray image while doing the procedure. This allows the doctor to watch where the needle goes as it is inserted. This makes the injection much safer and much more accurate. Once the needle is in the right location, a small amount of radiographic dye is injected. This liquid dye shows up on the x-ray image, and the doctor can watch where it goes. The anesthetic medication and the cortisone go in the same place. The doctor wants to make sure the injection will put the medication where it can do the most good. Once the correct position is confirmed, the anesthetic and cortisone are injected, and the needle is removed. The procedure is performed under local anesthesia.

Epidural steroid injections

Epidural steroid injections (ESI) are commonly used to control back and leg pain from many different causes. These injections control pain by reducing inflammation and swelling. They do not cure any of the diseases they are commonly used for, but can control the symptoms for prolonged periods of time.

In some cases, the ESI may be used to control the symptoms to allow participation in a physical therapy program. Lidocaine or bupivicaine are the anesthetic agents usually used. Kenalog and/or decadron are the agents used for inflammation. The procedure is performed under local anesthesia.

Trigger Point Pain Injections

Therapeutic injections are intended to to reduce, or eliminate pain symptoms for some period of time. Injections rarely eliminate pain permanently. Some injections may last weeks to months.

The medications that are normally injected during a therapeutic pain injection include an anesthetic and cortisone. An anesthetic medication (such as novocaine, lidocaine or bupivicaine) is the same numbing medication that is used in minor surgery, such as stitching a wound. The medication causes temporary numbness lasting 1 hour to 6 hours, depending on which type of anesthetic is used.

Radiofrequency Rhizotomy

Radiofrequency (RF) rhizotomy or neurotomy is a therapeutic procedure designed to decrease and/or eliminate pain symptoms arising from degenerative facet joints within the spine. The procedure involves destroying the nerves that innervate the facet joints with highly localized heat generated with radiofrequency. By destroying these nerves, the communication link that signals pain from the spine to the brain can be broken.

**Enclosure #2 to Letter of Intent from Central Maine Orthopaedics, P.A.:**

**Description of Operating Costs for Orthopaedic Pain Management Procedures.**

Annual operating costs, in each of the first three years of services, would be less than $400,000.00 per year.

CMO has projected utilization of approximately 200 pain management cases per month; thus 2,400 cases annually.

It is anticipated that CMO would hire one new physician, at an annual salary of between $200,000.00 to $250,000.00. This figure is based upon the national salary data contained in the 2008 Sullivan/Cotter National Survey regarding Physical Medicine Physicians.

The estimated operating costs per case, excluding physician salaries, is sixty two dollars ($62.00), yielding an annual cost per case of approximately $148,000.00, (increasing by $62.00 for each case over 200). These costs include:

- **Staff**: New Staff, or additional hours for current Staff, would be required as follows:

| Title | # hours per week | $ Dept Totals |
|---|---|---|
| Registered Nurse | 10 | 15,516.21 |
| Medical Assistant | 20 | 14,348.71 |
| | | 29,864.92 |
| | | |

- **Supplies**: The costs for supplies, utilities and other items required for undertaking the pain management procedures (other than the equipment, such as the C-arm previously referenced) is reflected below:

| Supplies | |
|---|---|
| RADIOPAQUE DYE | 10.00 |
| BAG PATIENT DRAWSTRING 20x22 WHT | 0.47 |
| BANDAGE ADHSV FLEX 1"x3" | 0.10 |
| BLADE, CLIPPER ASSEMBLY | 3.14 |
| CAP BOUF BLUE LG, 24" | 0.27 |
| DRAPE C-ARM/FLURO USE | 7.45 |
| ELECTRODE EKG MONITOR ADLT | 0.49 |

| | |
|---|---|
| GLOVE SURG LTX PF STR SZ8.5 | 1.66 |
| ID BAND ADULT WHITE | 0.12 |
| LIDOCAINE MDV 1%, 20ML | 0.02 |
| LIDOCAINE MDV 2% 20ML | 0.00 |
| LIDOCAINE TTB 0.5% 50ML | 0.00 |
| MARCAINE HCL, SDV 0.5% 10ML | 0.19 |
| MARCAINE MPF 0.25% SDV 30ML | 0.00 |
| MARCAINE MPF 0.5% SDV 30ML | 0.00 |
| MARKER SKIN | 0.72 |
| NEEDLE SPINAL STR 18GX3 1/2" | 4.32 |
| NEEDLE, 18G X 1 1/2, ECLIPSE HYPO, SAFETY | 0.16 |
| NEEDLE, 22G X 1 1/2, ECLIPSE HYPO, SAFETY | 0.17 |
| NEEDLE, 25G X 1 1/2, ECLIPSE HYPO, SAFETY | 0.17 |
| PAD, ALCHL PREP STR MED | 0.05 |
| PILLOWCASE DISP WHT | 0.23 |
| SPONGE, GAUZE, 4x4, STERILE | 0.93 |
| SYRINGE LL 10CC | 0.07 |
| SYRINGE/NDL 3CC 21GX1 1/2" | 0.05 |
| SYRINGE/NDL 5CC 21GX1 1/2" | 0.11 |
| THERMOMETER SKIN STRIP MULTIPK | 0.91 |
| TOWEL OR STR BLU 4/PK | 2.45 |
| | **35.55** |

- **Annual Depreciation:** The estimated annual depreciation for the C-Arm machine is $10,000.00.