

**OFFICE BASED SURGERY  
ACCREDITATION EVALUATION REPORT**

Pain Specialists, PA  
150 Main Drive, Suite 144  
Wilmington, DE 19804

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## **OVERVIEW**

### **INTRODUCTION**

**Northeast Management Consulting, Inc. (“NEM”)** has been retained by the medical practice of Pain Specialists, PA (the “Practice”) in order to help it assess its readiness for obtaining certification as an office-based surgery medical practice (hereafter the “OBS”) as required by the State of Delaware. The Practice has a location in Delaware where it currently provides general pain management medical procedures under local anesthetic at 150 Main Drive, Suite 144, Wilmington, DE 19804 (the “Wilmington Office” or “Facility”).

### **STEPS PERFORMED**

The following evaluative steps were taken during the Accreditation Evaluation Study:

- I. NEM performed a walk-through of the Practice’s Wilmington Office
- II. A review of the current surgical and diagnostic procedures currently being performed at the Wilmington Office was made with Practice personnel.
- III. An evaluation of the current policies and procedures, staffing, supplies, equipment and physician plant at the Wilmington Office was made.
- IV. Based upon the type of procedures and status of the physician location, a determination of the appropriate accreditation agency to utilize for certification was made.
- V. This Accreditation Evaluation Study Report has been prepared documenting any potential shortcomings regarding certification and recommendation of either moving forward with certification of the Wilmington Office or relocating to another location.

Details of the above steps, conclusions and recommendations are detailed below.

Please note that this evaluation is limited to the readiness for accreditation of the location as an OBS. The actual accreditation process, if the Practice elects to move forward with accreditation with an accreditation agency approved by the State of Delaware, will be performed under a separate agreement. In addition, for a variety of factors, there is no guarantee that the Practice will obtain accreditation based on this evaluation.

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**BACKGROUND**

**Office Based Surgery Facility or Office Based Surgery Medical Practice** - Although the precise definition varies from state-to-state, an OBS Facility or Practice is generally a customized medical office where surgical or diagnostic procedures are performed that are invasive or involve subcutaneous penetration, excluding minor surgical procedures. Most jurisdictions classify procedures as “surgical” or “invasive” by reference to the type and level of sedation or anesthesia used. Accordingly, an OBS medical practice can be located in any structure or suite of rooms established by one or more physicians for the private practice of medicine, but is typically limited to one surgical operating or procedure room.

Twenty-six state health departments, including Delaware, have jurisdiction on office-based surgery meeting various thresholds. The most common specialties performing office-based surgery are pain management, plastic surgery and GI. The requirement is typically based on the levels of anesthesia used and/or complexity of procedure performed.

In Delaware an OBS medical practice is exempt from licensure requirements that apply to other surgical centers, such as hospitals or ambulatory surgical centers (ASCs). Unlike these larger institutional surgical facilities, OBS practices do not have to satisfy the more stringent physical plant, safety and sanitary requirements imposed on the licensed facilities.

However, Delaware State law requires a practice performing office-based surgery to register with the Office of Health Facilities Licensing and Certification (OHFLC). In addition, Delaware also requires certification of the office-based medical practice location where the surgery takes place by one of the following accrediting agencies which have been approved by the State of Delaware:

- The Joint Commission (TJC)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Healthcare Facilities Accreditation Program (HFAP)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAASF)
- Delaware Board of Dentistry and Dental Hygiene Anesthesia Advisory Committee

An Office Based Surgery Medical Practice is an integrated part of a medical practice. All billing is done through the EIN of the medical practice and, accordingly, the ownership of the OBS is the same as that of the medical practice.

An OBS practice cannot bill a separate facility fee for procedures performed although the professional fee that is billed and reimbursed for the office-based surgery procedure is often at a significantly higher level that would otherwise be paid by a payor.

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## **DETAILS OF STEPS PERFORMED**

**I. NEM performed a walk-through of the Practice’s Wilmington office –**

NEM personnel performed a site visit and walk through of the Practice’s Wilmington office on October 15, 2018. The Practice had three staff members provide NEM with a detailed explanation of the functions of each of the rooms and areas of the facility. The facility is a combined “office visit and procedure room” location with office visits along with various non-procedure functions occurring on one side of the office and medical procedures being evaluated being performed on the other side. The general condition of the office as well its adherence to the requirements of the various accreditation agencies was evaluated.

**II. A review of the current surgical and diagnostic procedures currently being performed at the Wilmington Office was made with Practice personnel.**

NEM discussed the general practices employed by the Practice during the performance of pain management procedures. The Practice performs a majority of the procedures on Monday and Friday with a nominal number of procedures during the other days of the week. The Practice has patients with a mix of Payors but with a significant portion of workers’ compensation and personal injury patients.

**III. An evaluation of the current policies and procedures, staffing, supplies, equipment and physician plant at the Wilmington Office was made.**

NEM reviewed and discussed the policies and procedures, staffing, supplies, equipment and physician plant of the Practice at the Wilmington location with Practice staff. Again, all items were reviewed from the perspective of evaluating the appropriate accreditation agency for the Practice and the activities being performed at the Wilmington location.

**IV. Based upon the type of procedures and status of the physician location, a determination of the appropriate accreditation agency to utilize for certification was made.**

The ultimate certification of a medical practice location as an OBS involves a spectrum of requirements that are determined by each of the accreditation agencies listed above. Each

agency has different requirements and, although some overlap, most accreditation agencies requirements focus on varying types of facilities. Accordingly, since any one of the listed agencies is acceptable to the State of Delaware, it is important to select the accreditation agency that is most appropriate for the type of facility seeking to obtain the certification which, in this case, is an Office Based Surgery Medical Practice or OBS.

## **RESULTS OF STUDY AND RECOMMENDATIONS**

### **APPROPRIATE ACCREDITATION AGENCY RECOMMENDATION**

Based upon the type, frequency, and volume of pain management procedures being performed at the Wilmington Location, NEM has determined that the appropriate accreditation agency guidelines to utilize are the *American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)*. This Association is typically oriented towards OBS facilities and appears to be the appropriate one for the Delaware location. This Association provides accreditation for OBS facilities both with and without Medicare certification. We recommend that, if accreditation is applied for, certification without Medicare certification is requested.

### **POLICIES AND PROCEDURES RECOMMENDATIONS**

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) has detailed requirements for written facility policy and procedures that fall under the below subjects:

- HIPPA Manual
- OSHA Manual
- Annual Training Manual
- Infection Control Plan
- Quality Improvement Plan
- Patient Satisfaction Surveys
- Patient Safety Plan
- Disaster Manual
- Patient Rights and Responsibilities brochure
- Affirmation of CLIA testing logs as required

Based on our visit the Wilmington Location, the practice does not have sufficient internal policies and procedures in place nor does it have any at all in a written format at this office. A number of the above policies and procedures manual are substantial and need to be adapted to the specific location. In addition, the appropriate respective staff must be trained in each of the requisite manuals, procedures and policies.

If the Practice elects to apply for accreditation we recommend that an entire set of these policies and procedures be written and revised to reflect all items necessary for an OBS under the AAAASF current requirements at Wilmington Location.

### **PHYSICAL PLANT RECOMMENDATIONS**

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) also has detailed requirements regarding the physical structure, appearance, and location of specific items within an OBS. Based upon those requirements we recommend the following:

#### **General Physical Attributes**

After touring the Wilmington Location's physical plant and equipment and discussions with staff it is apparent that at least some modifications and upgrades are necessary in order to obtain accreditation.

The below is a list of the major items we observed during our visit. There are a number of other less significant suggestions we would advise be implemented. Please note that these recommendations only apply to the OBS side of the Practice's Wilmington Location, not the general patient visit side of the facility.

- Each of the patient holding rooms should be updated and the lighting enhanced.
- The procedure room should be repainted and all non-medical information, should be removed from the walls of the procedure room.
- Additional shelving and supply cabinets need to be added in certain locations.
- There should be signage outside of each room indicating its purpose and use.

#### **Relocation and Upgrade of Existing Items**

In a number of instances, the Facility has requisite equipment (smoke/heat detectors, fire extinguishers, etc) but not in sufficient quantity nor in working order. The following are the minimum additions that should implemented:

- All equipment in the procedure room relocated off the floor onto either cabinets or shelving on the walls or attached to the walls directly.
- Additional smoke/heat detectors need to be added throughout the suite.
- All emergency lighting needs to be charged and tested.
- Glucose machine needs to be specific for multi patient use.

### **Changes and Additions to Existing Facility**

There are a number of changes and additions that must be made to the existing physical structure of the Facility. The following are the most significant items:

- The procedure room floor must be sealed using a commercial poly sealant.
- A sink must be installed in the sterilization room.
- Locked cabinets need to be installed in a number of areas including the procedure room, supply room and new sterilization room.
- Although there is an area for patient privacy behind the reception desk it needs to be marked as such.

### **CLOSING**

We are, of course, available to help the Practice implement the above recommendations. **We have attached an ADDENDUM to this report providing you with the estimated costs of NEM helping the Practice obtain accreditation.** We would be happy to provide a full proposal for that implementation should you decide to implement the above changes and proceed with obtaining certification as an Office Based Surgery Medical Practice as required under Delaware State law.

The ultimate objective of this report is to provide information to help the Practice make an informed decision regarding whether or not to proceed and we trust that the above report and its observations and recommendations provide a secure basis for the Practice regarding that decision.

Please feel free to ask us to discuss anything enclosed in this proposal with you at any time.

Sincerely,

*Northeast Management Consulting, Inc.*