

Outpatient Procedure Center



390 Mitch Road Wilmington, DE 19804

Proposal:

Single specialty pain management free standing surgery center

Presented By:

Ganesh Balu, MD

M. Judy Zumbo, RN, BSN, JD

Madison Truemper, BS, OBS Administrator

History

- In 2018, Regional Medical Associates (RMA), a specialty pain management practice, established Outpatient Procedure Center a State recognized Office-Based Surgery center (OBS) in Wilmington
- Received accreditation from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).
- 1 large OR with staff and equipment to provide basic interventional pain procedures.

Why upgrade to an FSSC now?

- Since 2018, we have improved the facility for both efficiency and safety, this includes:
 - **Air Purification:**
 - Positive pressure ventilation, HEPA filters, REME HVAC purification system light
 - **Environmental:**
 - Scrubable ceiling and walls, Cove base flooring, Halosil fogger, LED battery backup lighting
 - **Equipment:**
 - Mobile laminar air flow, Biplanar mobile fluoroscope
- Advances in interventional pain management facilitated a number of upgrades to the physical plant which have resulted in the facility more closely resembling an FSSC than an OBS.
- At this time, any additional costs to become licensed can be financed without incurring any additional debt.

Who benefits from a single specialty FSSC, that is a part of a wellness-based treatment center?

- Patients
 - Removal of barriers associated with costs and time related to uncoordinated care among multiple providers at multiple locations.
 - Decreased stress by receiving services in a familiar, easily accessible location with recognizable staff.
 - Exposure to other patients and families with similar concerns and limitations, facilitating discussion and a feeling of acceptance.
- Physicians
 - More accessibility to the patients due to less travel time.
 - Increased access to specialty equipment and supplies.
 - Ability to utilize staff trained in IPM.
- Staff
 - Less time in procedure coordination which facilitates increased time in care coordination.
 - No negotiating with other centers who, at times, have restrictions on time or other barriers.
 - Trained staff providing unique procedures at a frequency to maintain highest skill level when supporting physician.

Why have a Delaware FSSC license?

A license represents to our patients, community, and payor sources that we:

- Embrace the higher standards (over OBS) of a FSSC;
- Meet the safety and efficiency requirements of a surgery center; and
- Provide quality services that welcome the oversight of Public Health/OHFLC.



Why Single Specialty?

- The advancements in interventional pain procedures, improved technology and exclusive equipment have demanded a unique operating room that is not readily available at existing multispecialty FSSCs.
- Successful pain management treatment incorporates complementary, behavioral health and wellness-based approaches to treat chronic pain.
- Pain management has become an increasingly recognized as an integral part of health care. This has resulted in an increased demand and improvement in service efficiency, which is most easily obtained by a full functioning pain center that includes a broad range of services.



Why single specialty? Cont.

Drug addiction, opioid tolerance, overdoses and death have resulted in a nation-wide crisis that has necessitate an ever-advancing medical specialty focused on the treatment of pain.

Acknowledgement of the crisis by the government (federal, state and local) has resulted in recognition that there is a unique disease threatening our survival.

National recognition of these issues, their impact on people's lives, the cost of medical intervention if untreated and increasing fear to prescribe opioid pain medication demands both a societal and medical solution.

Single specialty pain management with its multi-model approach is in a unique position to be one of those solutions. For it to be most effective, it must be capable of embracing and implementing IPM in a cost effective, efficient and consumer friendly manner. This proposal is a step in that process.

Why?

- It is time
 - to provide infrastructure for best pain management practices to be offered to Delaware residents.
 - to provide Delaware residents with choices as to providers and locations.
 - to support Delaware's efforts to address the opioid crisis ([Delaware's Opioid Crisis – My Healthy Community](#))
 - for specialty pain management providers to step up to meet the needs of our community and improve people's lives.

How Can We Help?

We believe that a FSSC dedicated to multimodal pain management with wellness based service support directly contributes to the health of Delaware citizens in both measurable and immeasurable ways.

Including:

- Ability to provide advanced IPM procedures
- Ability to control cost
- Ability to avoid the limitations of using multi-specialty centers (Access to space, time, equipment, supplies, staff etc.)
- Ability to increase the successful pain management treatment with our dedicated:
 - Behavioral health
 - Wellness Services (Massage, Nutrition, Yoga, Guided Meditation)
 - Alternative medicine (Acupuncture, AcuDetox, Cupping, CBD products)
- Ability to provide increased access to the physician

Application Summarized on the Following Slides

Criterion and Seven Guiding Principles:

1. Relationship of the proposal to the HRMP
2. The need fo the population for the proposed project
3. The availability of less costly and/or more effective alternatives to the proposal, including alternatives involving the use of resources located outside the state
4. The relationship of the proposal to the existing health care delivery system
5. The immediate and long-term viability of the proposal in terms of the applicant's access to financial, management, and other necessary resources
6. The anticipated effect of the proposal on the costs of and charges for health care
7. The anticipated effect of the proposal on the quality of healthcare

Criterion I: Relationship of the proposal to the HRMP

1. Access, cost, and quality of care issues:
 - o Convenient access to integrated pain management and IPM in one location
 - o Various services under one roof, with the same team avoids patients having to make multiple trips to different locations and providers

2. Care of the medically indigent:
 - o Will participate with state-mandated charity care requirements and offer services on sliding scale for poor, indigent, and uninsured
 - o Participates in Voluntary Initiative Program (VIP)

3. Managed, coordinated approach to service healthcare needs:
 - o Consolidating services, including surgery for pain management, opiate dependence/addiction, and behavioral health services into a one location eliminates silos and allows full, seamless integration and coordination of services, and enables the best patient outcomes.

4. Availability of out-of-state resources: Not applicable

4. Discourage incentives for overutilization:
 - o Will only be used by one practice.
 - o IPM is the one of the alternatives and only utilized if conservative treatments offered at the facility fail.

Criterion I: Continued

6. Projects enhancing meaningful markets are to be encouraged:

The proposed facility's market impact will be positive for patients, healthcare & society.

- o Patients will benefit from the convenience and cost control this project offers. The upgrade of the OBS will result in the offering of a full-service multi-modal approach to pain treatment, services, alternative medicine treatment options, and new upcoming IPM procedures.
- o The healthcare industry will be expanded through the creation of this new type of facility. It will challenge similar providers to look for opportunities for cost containment as well as ways to be current with the advancements in IPM.
- o The success of this project will affect the growing epidemic of opiate addiction in Delaware by providing more opportunities for pain treatments. It will diminish the potential for the use of prescription medications, street drugs, and alcohol.

7. Projects improving the health status of Delawareans are essential.

Proposed project will improve the health status of Delawareans by offering advanced IPM procedures in an easily accessible FSSC. The project will allow for a higher volume of patients to be treated.

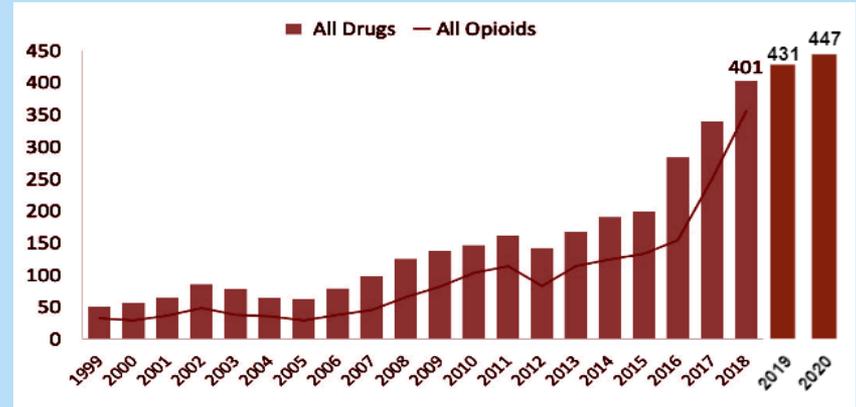
Criterion II: Need of the population for the proposed project

New Castle

- 2020 population of 65 years and older is 78,240 with projected to increase to 91,707 in 2025.
- Age range of 65+ years accounted for 26% of the patients identified as appropriate to have spine surgical procedures in the outpatient ambulatory setting.

OPIOIDS

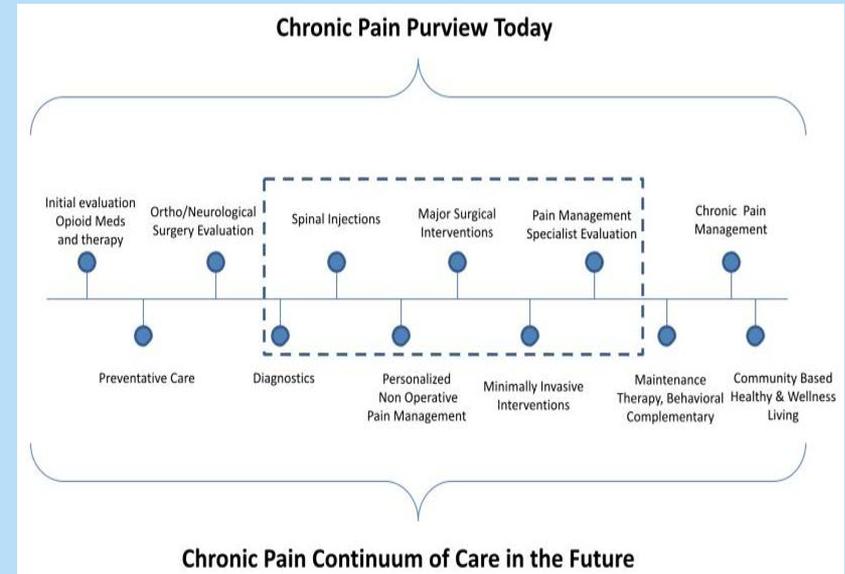
- National Institute on Drug Abuse (NIDA), In Delaware
 - 2018 = 88% of the 401 drug overdose deaths involved opioids, a total of 355 fatalities. Delaware providers wrote 60.6 opioid prescriptions for every 100 persons compared to the average U.S. rate of 51.4 prescriptions
 - 2019 = 431 overdose deaths
 - 2020 = 447 overdose deaths were reported.



Drug Overdose deaths in DE NIDA

Criterion II: Need of the population for the proposed project - Continued

- DHHS “Pain Management Best Practices Inter-Agency Task Force Report”
 - Identified “current inconsistencies and fragmentation of pain care” as having a ***negative*** impact on best practices and patient outcomes.
 - Proposes an individualized multimodal, multidisciplinary pain management model to ensure maximum therapeutic benefit. In this model, interventional procedures are one of the five treatment approaches utilized.



Criterion II: Need of the population for the proposed project - Continued

The Pain Patient

- Limited or no success from other professionals,
- Can be irritable, fatalistic, demanding, and difficult to engage in treatment
- Physical limitations
- Co-occurring mental illness and/or substance use

To minimize potential for barriers by establishing a one-stop treatment center/office-based surgery site. Resulting in:

- Convenience,
- Minimal case coordination,
- Diminished delay in scheduling and
- Removal the impact of utilizing an off-site FSSC for interventional procedures (i.e., resources & supplies, unfamiliar staff, and insurance restrictions).

- Unforeseeable complication of COVID-19
 - Elective procedures shut down
 - IPM not prioritized which resulted in rise in patients self medicating

RESULT = INCREASING DEMAND FOR IPM AT OBS

Criterion II: Need of the population for the proposed project - Continued

- To ensure the future advancements and research in IPM do not outgrow the Pain Center, it is necessary to upgrade the OBS to FSSC
 - Failure to do so will limit procedures available on-site, impact resources, and inflate the cost to both the Center and the patient.
 - Proactively addressing the issue with minimize any services interruption and maintain the benefits that were created by opening the OBS

Delaware's focus on addiction and the associated problems with overdose and addiction recognizes pivotal part of IPM, wellness-based services and effective case management.

- The state of Delaware [[HelpsHereDE.com](https://www.helpshereDE.com)] is educating the public and providers concerning the safe prescription of opiates and availability of various non-opioid pain management treatment options like:
 - Acupuncture, Chiropractic, Cognitive Behavioral Therapy, Healthy Lifestyle for Pain Management, Interventional Treatments, Massage Therapy, Medical Marijuana, Physical Therapy, and Yoga Therapy.

Delaware has not historically recognized pain centers as a FSSC. Approximately 15 years ago it was excluded from licensing and received certification by Medicare as an ambulatory surgery center. The advancement of procedures during that time reflect the need as well as the demand for services. By supporting single specialty pain centers that include an OR, behavioral health services, wellness-based treatment and alternative medicine, we will be advancing the treatment of pain.

Criterion II: Need of the population for the proposed project - Continued

Calculation of Need for Freestanding Surgery Centers in New Castle County		
Formula	All ORs	GI Excluded
Step 1: Patients needing FSSC services using National Health Statistics (116.25 per 1,000 in 2006)	$(567,764 \times 116.25) / 1000 = 66,003$	$(567,764 \times 116.25) / 1000 = 66,003$
Step 2: Number of surgical visits per room per year = $A \times B \times C = 2000$ A: Assumed Number of Surgeries Per Hour: 1 B: Assumed Number of Hours Per Day: 8 C: Assumed Number of Work Days Per Year: 250	$1 \times 8 \times 250 = 2000$	$1 \times 8 \times 250 = 2000$
Step 3: Utilization (70%)	$2,000 \times 70\% = 1,400$	$2,000 \times 70\% = 1,400$
Step 4: Patients Needing FSSC / Surgical Visits	$66,003 / 1400 = 47 \text{ ORs}$	$66,003 / 1400 = 47 \text{ ORs}$
Step 5: FSSCs Available in the Newcastle County (see appendix 3)	55 available ORs	$55 - 8 \text{ GI} = 47 \text{ ORs}$
Step 6: Surplus or Deficit of ORs	$55 - 47 = 8 \text{ surplus ORs}$	$47 - 47 = 0 \text{ surplus ORs}$

*2020 New Castle County population is: 567,764

For the adjusted calculations Gastroenterology FSSCs were excluded due to the fact that the operating rooms do not meet the sterility requirements needed for IPM procedures.

Criterion III: Availability of less costly or more effective alternatives to the proposal

Alternatives

- No specialty surgery center dedicated to pain
- Currently complex IPM requires use of off-site FSSCs or the hospital. Which increase cost and creates travel and coordination expenses
- Continuing to provide IPM in an OBS while less costly for some services will be unable to provide advanced IPM services.

Utilizing an offsite FSSC:

- Increases administrative costs to the applicant due to the manpower associated with scheduling, prior authorizations, relevant paperwork, and care coordination that is needed before IPM services can be provided.
 - Increases physician travel time which decreases the time available to provide care for patients
 - Increases costs to the patient related to travel, loss of time, copays, co-insurance, deductibles, and unknown costs related to anesthesia services when provided by non-participating anesthesia providers
 - At the proposed pain center lack of these burdens give way to enhanced efficiency, additional availability of provider and team member's time dedicated to offering high-quality IPM services.
-

Criterion IV: The relationship to the existing health care system

- No diversion of services from other pain practices. No foreseeable burden created
 - Project promotes quality assurance and cost-effectiveness to the healthcare system by providing specialty IPM/surgical services under higher safety standards an FSSC requires with minimal additional costs.
 - No foreseeable negative impact on patient volumes and revenues to the existing local IPM providers
 - Applicant is privileged at Christiana Care Hospital's FSSC. However, access is limited by the availability of the OR time and restrictions on types of IPM procedures permitted in the hospital
 - The impact on existing hospital systems is minimal
 - Rare need for hospital emergency transfer and evaluation
 - Referring spine surgeons and neurosurgeons provide appropriate continuity care when patients require additional surgical treatment
-

Criterion V: The immediate and long-term viability of the proposal in terms of the applicant's access to financial, management, and other necessary resources.

No Identifiable financial risks for present or for the foreseeable future		
Financial	Immediate: Costs of renovations have been budgeted for and the capital exists.	Long-term: Marginal additional costs for added maintenance will be absorbed with increased IPM volume and revenues.
Size of the facility will not create a need to increase management		
Management	Immediate: Current management team does not need to be adjusted or increased to upgrade from the current OBS to FSSC.	Long term: There will be no additional services that require a larger management team.
Size of the facility will not create a need to increase resources		
Resources	Immediate: No additional resources shall be required because there is only one physician and one OR (as in the current OBS).	Long term: We are not adding additional providers and hence no added resources identified.

- **Resources:** The applicant currently operates a functioning OBS. Appropriately inspected and certified equipment is available on-site. Example: Fluoroscopic X-ray machine.
- **Manpower:** The applicant has been operating a fully staffed OBS with a team that consists of an anesthesia provider, a licensed nurse/nurse manager, a surgical technologist, and a medical assistant to support IPM procedures.
- **Management Personnel:** The applicant has been operating a successful OBS with a full-time office management coordinator and two full-time billing personnel. No additional manpower is required.

Criterion VI: The anticipated effect of the proposal on the costs of and charges of healthcare

- Any foreseeable increase in healthcare costs will be related to the new and additional IPM procedures performed at the pain center. Will be absorbed through budgeting, billing, and collections from the payor sources. For patients seeking care at the pain center, there will be no increased costs related to co-pays, deductibles, or non-covered charges.
- Derivation of the figures in the narrative.
 - The FSSC will be seeking OHFLC licensure following successful approval of CPR. The full financial impact after a successful year of operations would be evidenced by an increase in IPM procedures with a relative increase in operating costs and revenue.
 - The cost of operations is expected to increase with additional IPM procedures related to supply costs, additional manpower costs, and added infrastructure costs related to the cleaning and maintenance of the facility and equipment.
- Impact on the costs and charges of existing health services being provided within the healthcare system
 - The proposed project will have no added impact on the costs and charges of existing health services provided within the healthcare system.

Criterion VII: Effect of the proposal on the quality of healthcare

- All the upgrades related to OBS to FSSC will provide additional safety for the patients seeking care at the proposed pain center which will positively impact the quality of health care provided.
- Is the Applicant accredited by the Joint Commission on the Accreditation of Healthcare Organizations or some other accrediting organization? Yes
 - AAAASF - American Association for Accreditation of Ambulatory Surgery Facilities

Foster competition through the cost-effective measures that will provide like services at a lower cost as well as:

- Embrace the higher standards (over OBS) of a FSSC
 - Meet the safety and efficiency requirements of a surgery center
 - Provide quality services that welcome the oversight of Public Health/OHFLC
-

Thank You!

Thank you for your time and consideration

Questions?