

Excel Surgery Center, LLC

DoN #ESC-22101909-AS

Background

Q1. The Application states that chronic pain affects at least 75% of the population (pg.2). Please provide a reference for this information.

Answer:

In response to your question listed above, we submit the following for your review:

First, it should be noted that there has been a great deal of confusion about the statistics related to the pain as a medical problem.

This confusion is related to lack of ONE strict criteria in defining and classifying pain as a symptom or disease, in addition to different factors such as age, area of pain, timing as explained below:

1- The International Society for the study of pain defined pain in 1979 as follows: "Pain is defined as an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage".

This definition by itself had left the door open for so many different interpretations and definitions since pain at the end is " personal experience" which may differ from person-to-person.

2- There has been many ways to classify pain. Some experts consider duration of the symptoms, others rely on the severity of the symptoms and some may consider the nature of the symptoms.

If we consider "duration of the symptoms" then pain can be classified to:

*Acute pain: any pain symptoms lasting up 3 to 4 weeks

*Chronic pain: any pain symptoms lasting more than 3 months. However, some experts state that in order to consider a pain chronic, the symptoms must last 4 to 6 months.

Any pain lasting between 3 to 4 months is classified as sub-acute pain or pre- chronic pain.

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3- Many experts consider the pain to be chronic if the symptoms are felt on daily basis. However, we have good number of people who may experience pain symptoms frequently or few days a week or probably few days a month.

4-Many experts and societies take in consideration mostly (The musculoskeletal system pain) when they talk about chronic pain.

However, pain caused by other medical problems such as diabetes mellitus and vascular diseases should be considered since they are treated in the pain clinics.

5- Most medical societies and research centers including CDC has been reporting that chronic pain can affect (1 in 5 Americans), making the prevalence of chronic pain about 20% of the population. It is also stated in many places that 50 million Americans are affected by chronic pain!

We believe that such statements have not been updated for at least 15 to 20 years as based on pain prevalence of 20%, then the American population should be 250 million Americans!

The U.S. Census Bureau projected the US population to be 335 million Americans as of January 1, 2023!!

An article published in PubMed in Demography. 2021 April 01; 58(2): 711–738. doi:10.1215/00703370-8977691, "Pain Trends Among American Adults, 2002–2018: Patterns, Disparities, and Correlates" by Anna Zajacova, Hanna Grol-Prokopczyk, and Zachary Zimmer.

It clearly shows in table 1 that in 2018, %53.8 of the American adults aged 25-84, had suffered of any pain.

Using a chronic pain module introduced in the 2019 edition of National Health Interview Survey, 50.2 million adults (20.5%) reported pain on most days or every day!

Prevalence of chronic pain among adults in the United States by Yong, R. Jason^a; Mullins, Peter M.^b; Bhattacharyya, Neil^c

JAMA network in 2018 published an article about Chronic Pain Prevalence in 2018 (JAMA. 2018;320(16):1632. doi:10.1001/jama.2018.16009), showing that chronic pain prevalence ranges between 11 to 40%

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Lastly, John Elflein, a well -respected research expert for topics concerning health, diseases, and medical professionals in the United States and worldwide, published a study in December 2020 titled: **Prevalence of chronic pain among U.S. adults in 2019, by age.**

The study concluded that around % 31 of adults aged 65 years and older suffered from chronic pain, compared to % 26 of adults aged 45 to 64 years, compared to %14.6 of adults aged 30-44 years.

In conclusion, there is no final agreement on the prevalence of the chronic pain among experts. However, if we add the group of patients suffering from chronic pain on daily basis (%20), the group of patients suffering from chronic pain frequently or few days of the week/ month (%40) and the group of patients with pain symptoms from diabetes mellitus and vascular disease (%5-10), it can be safely accepted to state that up to 65-75% of the American populations suffer from pain of all kind.

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Q2. Which hospitals does Dr. Rustum have admitting privileges?

Answer:

Please be advised that Dr. Rustum has privileges at the following hospitals:

Lawrence General Hospital/ Lawrence, MA

Steward Holy Family Hospital/ Methuen, MA

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Patient Panel

Q3. The Exhibit titled MVPMA Pts distribution per town copy includes the Category 'Other'. Please define this category.

Answer:

In response to this question, please be advised that we treat patients from many towns seeking, however the number of patients per town is less than 10.

The number of patients for each town was added up and labeled (Others).

As an example, the number of patients who were treated at Merrimack Valley Pain Management Associates and live in Worcester area was 7 patients in 2021 and 8 patients in 2022.

These patients were added to others from other towns.

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Patient Panel

Q 4. MVPMA payer mix includes the category “Other”. Please define this category.

Answer:

In response to this question, the category titled (Other), refers to patients who may have military/ VA insurance, privately insured businesses, out of state insurances and self-pay

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Factor 1a: Patient Panel Need

Q 5. How did you determine that Methuen is the best location for the proposed ASC?

Answer:

In response to this question, please note that multiple factors were considered in choosing the location of the proposed ASC, not limited to the following:

1- Medical Commercial Space Availability

2- Proposed ASC building ease of access by the patients:

- Relatively new construction,
- Ample Parking spaces,
- Limited number of floors to no more than 3 which will make using the elevators service much easier to the patients
- The presence of designated handicapped parking spaces, automatic doors, wide elevators which fit wheelchairs and medical structures

3- Ease of access from the highways as the proposed ASC location is just off I-495, 213. It is also less than 5 minutes away from I-93.

4-The proposed ASC location is surrounded by multiple other medical practices which we share many patients with them, including but not limited to:

Urgent care clinic, Quest laboratory, LabCorp, Northeast physical therapy and rehabilitation, Radiology services, primary Care Offices, Internal Medicine Offices, Rheumatology Clinic, Cardiology Offices, Vascular Surgery clinic and more.

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It will be more convenient to our patient to keep his/her other medical treatments and needs within such medical community.

5-Lastly, the proposed ASC location is in the center of circle with 10 miles radius which covers the majority of our current patient's population at Merrimack Valley pain management Associates.

Please see attached maps:

Map #1 shows the proposed ASC project location and the surrounding medical facilities

MAP #2 shows the location of the proposed ASC project in relation to the major roadways

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Factor 1a: Patient Panel Need

Q 6. Given that this is a new facility, explain with data how you determined that two ORs were necessary to address Patient Panel need for outpatient surgical services.

Answer:

In response to this question, I did reach out to Department of public health inquiring about the minimum required operating rooms for the proposed ASC.

The regulations set by Centers for Medicare & Medicaid Services states that " All ASCs must have **at least one** dedicated operating room and the equipment needed to perform surgery safely and ensure quality patient care".

It is preferred to have minimum of 2 operating rooms so patients services may not be interrupted or affected in case of technical problems/issues in 1 room.

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Factor 1a: Patient Panel Need

Q7. The Application (Exhibit 7 Pain Procedures delay 2021) includes the number of pain procedures performed in calendar year 2021, by type of procedure.

- a. Provide city/town of origin for patients receiving these procedures. Please combine counts less than 11 into another category to protect patient privacy and confidentiality.
- b. Provide the payer mix for Procedures performed in 2021.
- c. Provide a list of ASCs and HOPDs where these procedures were performed.
- d. To better understand need for the proposed ASC's services, please complete the Table below. Feel free to modify the table as needed.

Answer:

a.

TOWN	# of Procedures
Methuen	68
Lawrence	51
Haverhill	31
Lowell	17
Salem, NH	14
Andover	12
Others	58

b. The payer mix for the performed procedures is as follows:

- Medicare/ Medicaid: %46
- Commercial insurances: 23 %
- Worker's Comp: %31

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c. As the hospitals were recovering from the pandemic and started to reopen in mid 2021, please be advised that the surgical procedures listed in 2021 were all done at:

North East Ambulatory Center
3 Woodland Rd
Stoneham, MA 02180

d.

Procedure	Performed		Delayed	
	ASC	HOPD	ASC	HOPD
SCS Implant	45			11
SCS Revision	32			14
SCS Trial	50			10
Pain Pump revision/change	22			7
Vertiflex	44			18
MILD Procedure	39			18
Kyphoplasty	19			5
Total	251		83	

Please be advised that:

- The treatment plan on most of the delayed patients was temporarily changed in order to schedule the procedures at the ASC in 2022, total of 38 pts.
- Patients elected not to seek the treatment in part secondary to insurance change or change of mind, 13 pts
- Patients started on opiates, 22 pts
- Lost contact/? went somewhere else: 10 pts

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Factor 1a: Patient Panel Need

Q8. The Application states there is an ongoing demand for pain surgical treatment that is related to improved life expectancy rates, quality of life, and the need to treat co-morbidities (pg.6). Provide data showing increasing demand for surgical pain treatments.

Answer:

In response to your question, we would like to submit the following focusing on to issues:

1-The importance of interventional pain management

2-The growing demand for physicians in the United States in general and interventional pain management physicians in particular.

The rule of interventional pain management:

Interventional pain medicine utilizes a multidisciplinary approach, in which a team of health care professionals works together, to provide a full range of treatments and services for patients suffering from chronic and/or acute pain.

The goals of interventional pain management are to relieve, reduce, or manage pain and improve a patient's overall quality of life through minimally invasive techniques specifically designed to diagnose and treat painful conditions. Interventional pain management also strives to help patients return to their everyday activities quickly and without heavy reliance on medications.

The evidence of interventional pain management improving quality of life is tremendous and being seen on daily basis.

An article published in *BMC health services research* on July 1, 2020 by *Johan Hambræus et al*

" Patient perspectives on interventional pain management: thematic analysis of a qualitative interview study" have shown that Health-related quality of life has been reported to improve significantly after interventional pain management.

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🌐 The growing demand for physicians in the United States in general and interventional pain management physicians in particular:

1- On July 1, 2020, The Association of American Medical Colleges had published an article on its website titled " We Need More Doctors".

The article's conclusion is that the pandemic has underscored what many of us have been saying for years: We do not have enough physicians to meet the needs of a growing, aging population now or in the future.

2- Henry Ford health system in Michigan had published an article on August 12, 2013" Few Doctors Have Adequate Training to Effectively Treat Chronic Pain".

The article calls for training more physicians in the field of pain management to meet the growing demands of the aging population in the United States.

3- Many research institutions such as Coherent Market Insight (CMI) had stated the need for more interventional pain physicians to meet the growing demands by the aging patients.

The CMI noted in its report published in January 2023 that:

" Rising prevalence of chronic pain is expected to increase the demand for interventional pain management techniques for its treatment, thereby fueling interventional pain management market growth in the near future. For instance, according to a study published by the National Centre for Biotechnology Information (NCBI) in 2015, around 19.6% of the individuals aged between 20 to 60 years were suffering from low back pain worldwide.

Increasing establishment of new national interventional pain management platform is expected to support growth of the global interventional pain management market over the forecast period.

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The chances of chronic pain in geriatric population are very high. Therefore, increasing geriatric population is expected to increase demand for interventional pain management and fuel global interventional pain management market growth over the forecast period".

4-An article published in the Journal of Pain Research January 11, 2022 titled " Pain Management providers in the era of COVID-19: Who is taking care of those who provide care?" by Gabriela Toutin Dias and Michael E Schatman Stated the following:

(Given the shortage of trained pain physicians and lengthy wait times prior to accessing treatment that were identified well prior to the onset of the COVID-19 crisis, this phenomenon spells potential disaster for many suffering from chronic pain).

5-Lastly, in reviewing the classified advertisements in many well-respected journals such as New England Journal of Medicine (NEJM), Journal of Pain Research, Journal of Pain, Journal of American Medical Association (JAMA), it is clear that there is mounting evidence that many clinics and medical centers around the nation are seeking hiring interventional pain physicians.

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Factor 1a: Patient Panel Need

Q 9. Given that the volume of procedures performed annually will increase from 251 (currently) to 1,200, where will the new volume originate? How much of the additional volume do you anticipate will come from existing patients and how much will come from new patients?

Answer:

First, please be advised that the average procedures performed yearly before 2021 was about 500-550 procedures, requiring sedation and anesthesia care in ASC settings.

The number of procedures in 2021 had dropped due to reasons related to the performing physician.

It is estimated that the number of procedures performed annually will double from its usual base of 500 procedures per year within 1 to 2 years for the following reasons:

1-We have been receiving increased number of referrals from primary care physicians, spine surgeons and other private entities specialized in coordinating treatment of patients involved in motor vehicle accidents, Workmen's Compensation without going through known medical insurances.

2-We are currently seeking hiring an MD with interventional pain management expertise in addition to 1 nurse practitioner or physician assistant in order to meet the growing demand by the new patients.

3- We have been receiving increased number of referrals from other pain physicians who are considering retirement to take over their patients care.

Practices names will be provided upon request.

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Factor 1a: Patient Panel Need

Q 10. The application states Dr. Rustum is the only interventional pain physician in the area (pg.5). Additionally, in assessing need for the Proposed Project, the Applicant relied on Patient Panel composition, historical and projected demand, as well as available resources in the area (pg.6). To better understand Patient Panel access to the services Dr. Rustum provides, please describe which areas were assessed when evaluating Patient Panel need.

Answer:

Please be advised that Dr. Rustum is not the only interventional pain physician in the area, however the statement on page 5 was clear in indicating that Dr. Rustum is the only interventional pain physician in the area with specific qualifications and interests to treat certain challenging conditions that are not currently treated by other interventional pain physicians in the area.

Dr. Rustum has extensive experience in dealing with amputees. I coordinate the treatment of such challenging conditions with vascular surgeons, physical therapy treatment, podiatry specialists in addition to the clinics specialized in providing prosthesis.

Dr. Rustum is the only interventional pain physician in the area with extensive experience in performing spinal cord stimulator implant procedure for different types of pain.

As a matter of fact, I have patients referred to me from other colleagues who used to perform this procedure. However, and for reasons related to the physicians, they elected to refer their patients to someone with more experience.

Finally, I would kindly invite you to visit the following link "<https://www.vertosmed.com/find-physician/>"

It clearly shows that Dr. Rustum is the only physician in the Merrimack Valley area who performs The MILD procedure.

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Otherwise, patients will travel more than 11 miles to seek such treatment at the nearest pain management center.

This novel treatment is minimally invasive surgery which takes place in ASC setting or hospital for the purpose of treating lower back pain secondary to spinal stenosis.

Such procedure has been saving a growing number of patients the need for the traditional back surgery.

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Factor 1a: Patient Panel Need

Q 11. The application states that the proposed ASC will help to fight the opioid crisis by offering patients a faster, true and effective treatment which will eliminate the need for narcotics (pg.6).

- a. What perioperative processes will be in place to reduce medication use and ensure safe, appropriate medication use, thereby minimizing risks for opioid misuse and harm.
- b. Do you currently use medication contracts with your patients, and will the proposed ASC?

Answer:

a. As you may know, many patients who may benefit from interventional pain therapies are currently being treated with opiates by other physicians such as primary care physician, orthopedic surgeon and even some pain physicians who may not incorporate certain effective and novel interventional pain therapies and their treatment panel.

We believe that these patients can be screened and evaluated for the possible benefit from non-opioid interventional pain therapies.

In order to do so, we propose weaning patients off narcotics before or after performing the new interventional pain treatment in very diligent way so they avoid any possible narcotic withdrawal symptoms.

We also offer constant education to the patients about narcotics side effects for long-term use.

More importantly, the physician is always on call for his patients needs and questions 24/7. It also should be noted that in certain circumstances and due to delay in performing certain procedures as a result of waiting for insurance approval or waiting for scheduling at the hospital, the patients in most cases are being maintained on some sort of narcotics to help manage the pain while waiting to have the procedure done.

It is obvious that such delay could be adding more troubles or complicating the ongoing narcotics crisis.

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We believe that approving the proposed ASC project will definitely make scheduling certain surgical pain procedures faster and more convenient to our patients.

b. Yes, we do currently use narcotic contract for all our patients on opioids.

We will continue to use narcotic contract and apply all the DEA regulations in this matter in our current practice and future proposed ASC.

Please be advised that the proposed ASC is a place to perform interventional/surgical procedures, NOT to evaluate patients needs for medications including narcotics.

Such evaluation and determination for need of medications including narcotics will take place at Merrimack Valley pain management Associates clinic/ office.

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Factor 1b: Public Health Value

Q 12. The DoN application question Fl.b.ii Public Health Value /Outcome-Oriented asks Applicants to Describe the impact of the Proposed Project and how the Applicant will assess such impact. (pg.9). Describe the measures that you will use to assess the impact of the Proposed Project.

Answer:

In order to assess the impact of the proposed ASC Project, the Applicant developed the following quality metrics and reporting schematic, as well as metric projections for quality indicators that will measure patient satisfaction and quality of care.

The measures are discussed below:

1. Patient Satisfaction: Satisfied patients with their care are more likely to seek additional treatment when needed. They are more likely serve as source of referring other patients to the proposed project.

The Applicant will review patient satisfaction levels with the ASC's surgical services.

1- Measure: The Outpatient & Ambulatory Surgery Community Assessment of Healthcare Providers and Systems (OAS-CAHPS) survey will be provided to all eligible patients.

The OAS-CAHPS survey focuses on the following key areas:

- Before a patient's procedure
- The ASC facility and staff
- Communications about the patient's procedure
- Patient recovery
- Overall experience
- Patient demographic information.

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Projections: The ASC is not yet operational, however the Applicant will aim to establish and achieve the top decile in "Overall Rating of Care" for reporting providers.

Monitoring: Any category receiving a less than "Good" or satisfactory rating will be evaluated, and policy changes instituted as appropriate. Metrics will be reviewed quarterly by clinical staff.

2. Clinical Quality -Surgical Site Infection Rates: This measure evaluates the number of patients with surgical site infections and aims to reduce or eliminate such occurrences.

Measure: The number of patients with surgical site infections.

Projections: The ASC plans to meet or exceed the national benchmark for surgical site infection rates, ultimately reaching a target of 0%.

Monitoring: Reviewed quarterly by clinical staff.

3. Clinical Quality -Pre-Operative Time-Out/ Marking the correct surgical site: This measure ensures pre-operative compliance with practices aimed at ensuring high quality outcomes among members of the care team and promoting communication.

Measure: The procedure team conducts a pre-operative time out. The operating physician must mark the correct surgical/ procedure site.

Projections: A pre-operative time-out as well as marking the correct procedure site will be completed 100% of the time on all surgical cases in the ASC.

Monitoring: Reviewed quarterly by clinical staff.

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Factor 1b: Public Health Value

Q 13. The Applicant states clinical staff will develop and implement a robust program for reviewing quality of care outcomes, identifying best practices and implementing performance improvement initiatives (pg.9). When will this program be implemented at the proposed ASC?

Answer:

Please be advised that at the current time, the medical staff at Merrimack Valley pain management Associates are implementing such a program as we strive to provide our patients with the best practices, treatment and outcomes.

We anticipate that the transitioning to implementing performance improvement initiatives should not be a problem, taking in consideration that few adjustments are expected to be made for the proposed project in a very short time, not to exceed 1 to 2 months from operating the proposed ASC.

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Factor 1b: Public Health Value

Q 14. The application states the Applicant will employ culturally competent staff and plans to develop a robust translation services program (pg.9).

a. Will the Applicant offer any cultural competency training for staff?

Answer:

As we strive to provide our patients with the best pain management care, we always look forward having multicultural, competent and well-trained staff in order to achieve our goals.

The proposed ASC will definitely offer all required training to new or existing staff members.

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Factor 1b: Public Health Value

Q 15. The Application states that the proposed ASC will provide online preregistration and cost transparency tools (pg.10). Given that technology may not be accessible to all patients (e.g., due to tech literacy, limited internet access), how is the Applicant working to ensure equitable access to these amenities (and/or alternative option for those experiencing barriers)?

a. Describe support services available to patients who may not be comfortable or able to use this technology, if any?

Answer:

Our current patients panel at Merrimack Valley pain management Associates has been enjoying portal patient access to their medical records for the past 8 years.

However, we are aware of good number of patients who may have limited access to technology.

We usually give the patient the option of:

- 1- Give hardcopy to the patient by hand
- 2- sending copy of the medical records by certified mail.
- 3- Mailing/emailing the records to a chosen family member by the patient or proxy person

We continue to work with our patients trying our best to meet the demands and wishes in the best possible secure and professional way

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Factor 1e: Community Engagement

Q16. The application states that two information sessions were conducted to fulfill the community engagement requirement (pg.11).

- a. How many attendees were at each of the information sessions?
- b. Explain how the attendees were representative of the Patient Panel.

Answer:

- a. The first session was attended by 8 people

The second session was attended by 7 people

- b. In the first session, we had 6 current patients + 2 none patients from Methuen.

4 out of the 6 patients live in Methuen and 2 patients live in Lawrence.

The second session was attended by 5 patients living in Methuen and 2 patients living in Lawrence