

**STAFF REPORT TO THE PUBLIC HEALTH COUNCIL
FOR A DETERMINATION OF NEED**

Applicant Name	Excel Surgery Center, LLC
Applicant Address	386 Merrimack Street, Suite #D Methuen, MA 01844
Filing Date	February 13, 2023
Type of DoN Application	Substantial Change in Service – Ambulatory Surgery
Total Value	\$1,200,000.00
Project Number	ESC-22101909-AS
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$60,000.00
Staff Recommendation	Approval
Public Health Council	April 19, 2023

Project Summary and Regulatory Review

Excel Surgery Center, LLC (Applicant) based at 386 Merrimack Street Suite #D, Methuen, MA, submitted this Application for a Notice of Determination of Need (DoN) for the development of a freestanding ambulatory surgery center (ASC) to be located at 386 Merrimack Street Suite #D, Methuen, MA (Proposed Project). The Applicant is a newly formed, private venture solely owned by a physician and not affiliated with a hospital, established for the purpose of developing a freestanding ASC. The Proposed Project is to renovate a 5,000 gross square feet (GSF) space to accommodate two operating rooms (ORs), three pre-operative beds, and three post-operative beds. The capital expenditure for the Proposed Project is \$1,200,000.00. The Community Health Initiatives (CHI) contribution is \$60,000.00.

This DoN Application falls within the definition of Ambulatory Surgery, which is reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

In this case, the Proposed Project is within the Primary Service Area (PSA) of an existing Hospital that is designated as an independent community disproportionate share or non- disproportionate share Hospital as defined by the Health Policy Commission's Massachusetts Hospital Cohort Designation and Affiliation Status and is not an existing joint venture or Affiliate of the Applicant.

Per regulation, in this case, the Proposed Project must either constitute a joint venture with the independent community disproportionate share or non-disproportionate share Hospital, or the Applicant must obtain a letter of support signed by the independent community disproportionate share or non-disproportionate share Hospital's chief executive officer and board chair.

Lawrence General Hospital is an independent community disproportionate share hospital located in the PSA of the proposed ASC. The Applicant received a letter of support from LGH.

Contents

Background: Excel Surgery Center, LLC; and Application Overview	3
Patient Panel.....	4
Factor 1a: Patient Panel Need.....	6
Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity.....	12
Factor 1: c) Efficiency, Continuity of Care, Coordination of Care	15
Factor 1: d) Consultation.....	17
Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel	17
Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending.....	18
Factor 1 Summary	20
Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation ..	20
Factor 2 Summary	21
Factor 3: Relevant Licensure/Oversight Compliance.....	21
Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis.....	22
Factor 5: Assessment of the Proposed Project's Relative Merit.....	23
Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application.....	23
Findings and Recommendations	24
Other Conditions.....	24
Appendix I: Required Measures for Annual Reporting.....	25
Appendix II: Procedure Definitions	28
APPENDIX III: CMS Price Procedure Lookup.....	29
REFERENCES.....	30

Background: Excel Surgery Center, LLC; and Application Overview

Excel Surgery Center, LLC (Applicant). The Applicant is a newly formed, private venture solely owned by a physician and not affiliated with a hospital, established for the purpose of developing a freestanding ambulatory surgery center (ASC) in Methuen, MA. The proposed ASC will be operated by board certified physician, Rami Rustum, MD. Dr. Rustum currently operates Merrimack Valley Pain Management Associates, PC (MVPMA).¹ MVPMA was founded in 2008 to provide pain management medical services to patients throughout New England.² Currently, the Applicant reports that Dr. Rustum has privileges at Lawrence General Hospital (LGH) in Lawrence, MA and Steward Holy Family Hospital in Methuen, MA. The proposed ASC will provide outpatient surgical services in a single medical specialty, pain management.

In compliance with 105 CMR 100.715(B)(2)(a)(3), the Applicant is affiliated with Mass General Brigham Accountable Care Organization, LLC, a Health Policy Commission (HPC) Certified Accountable Care Organization (ACO).³ The Department calculated the Primary Service Areas (PSAs) of the current list of independent community hospitals in Massachusetts and compared the PSAs to the location of the proposed ASC.⁴ The Proposed Project is within the PSA of an existing hospital that is designated, as an independent community hospital by the HPC, Lawrence General Hospital (LGH), therefore the Applicant obtained a letter of support from the CEO and board chair of LGH, as required under 105 CMR 100.715(B)(2)(b)(2).⁵

Application Overview

The Proposed ASC will consist of the following:

- 2 operating rooms (ORs), as well as related support and administrative areas
- 3 pre-operative beds
- 3 post-operative (Post Anesthesia Care Unit) beds
- Consultation Area
- Additional space including, lobby and waiting area that will provide ample space for social distancing requirements.
- Central sterile processing, clean supply areas, as well as administrative and patient support areas.

¹ Medical Director & Physician, Merrimack Valley Pain Management Associates, P.C. Board Certified in Anesthesiology & Pain Medicine. Pain Management Fellowship at BWH & Harvard Medical School.

² The clinic was founded in 2008 and the first year of operation was 2009.

³ HPC-Certified ACOs - LEAP 2022-2023. <https://www.mass.gov/service-details/the-hpc-accountable-care-organization-aco-certification-program>

⁴ All hospital inpatient discharges for the independent community hospitals were categorized by facility. Frequencies were calculated, by hospital, for Patient Home ZIP code, along with percentage of all discharges and cumulative percent, summing high frequency ZIP codes first. SouthCoast is Charlton Hospital, Tobey Hospital, and St Luke's Hospital combined. Massachusetts Case Mix Hospital Discharge Data, Federal Fiscal Year 2021. For Sturdy Memorial, Center for Health Information and Analysis' (CHIAs) Hospital Profile was used to calculate the PSA.

<https://www.chiamass.gov/assets/docs/r/hospital-profiles/2020/sturdy.pdf>

⁵ HEALTH POLICY COMMISSION. Bulletin on Independent Community Hospitals for Determination of Need Applicants. <https://www.mass.gov/doc/bulletin-hpc-2022-01-independent-community-hospitals/download>

Table 1: Overview of Proposed Project

	Current	Proposed	Total
Operating Rooms	0	2	2
Pre-operative Beds	0	3	3
Post-operative Beds	0	3	3

The proposed ASC will support surgical procedures that Dr. Rustum currently performs in hospital outpatient departments (HOPDs) and existing ASCs. By doing so, the Proposed Project will increase local, community-based access to outpatient surgical services in the ASC setting for clinically appropriate patients. The proposed ASC, which is approximately four to six miles (9 minutes) from MVPMA, will specialize in providing outpatient surgical services, with a focus on pain management. Procedures include but are not limited to epidural injection, lumbar and cervical facet joint injection, sacroiliac joint fusion, and spinal cord implants. The Applicant asserts that the proposed ASC will increase access to high-quality outpatient surgical services to address a growing demand. The proposed ASC will address Patient Panel need for such services as an alternative to receiving them in the hospital setting or at other ASCs located farther away. Moreover, performing outpatient surgical procedures in the ASC setting can result in cost savings to insurers and patients.

Patient Panel⁶

The Proposed Project is for a new entity, which has no existing Patient Panel. The discussion of Patient Panel in this analysis refers to the anticipated patients, as directed by the regulation. Thus, the Applicant relies on patient utilization data from Merrimack Valley Pain Management Associates, PC (MVPMA), to assess need for the Proposed Project. This is shown in Table 2.⁷ Staff find this is an acceptable way to define Patient Panel. The Applicant states that it will service all socioeconomic backgrounds, including populations in the Methuen area, Haverhill area, in Salem NH and southern NH, and Lawrence. The Applicant will also serve populations in the Andover, North Andover, and Middleton areas.

Table 2: MVPMA Patient Panel

2019	2020	2021	2022	Change Rate (%) 2019-2022
2,755	2,969	3,192	3,477	26%

⁶ As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder. Patient Panel also means: (1) If the Applicant or Holder has no Patient Panel itself, the Patient Panel includes the Patient Panel of the health care facilities affiliated with the Applicant; or (2) If the Proposed Project is for a new facility and there is no existing Patient Panel, Patient Panel means the anticipated patients; or (3) In the case of a Transfer of Ownership, Patient Panel also includes the Patient Panel of the Entity to be acquired.

⁷ The Applicant notes that the month of December, 2022 was projected. The actual number of patients will be almost the same as projected as patients are scheduled 4-6 weeks ahead of time.

Patient Information

Tables 3 and 4 present patient information for the MVPMA patient population during calendar year (CY) 2021. Staff notes the following observations about these data below:

- **Age:** Almost 60% of the patient population are age 65 and older.
- **Race/Ethnicity:** Most patients (52%) identified as White (non-Hispanic), followed by White (Hispanic), and Black or African (Hispanic).
- **Patient Origin:** Approximately one third of patients originate from Lawrence, MA.
- **Payer Mix:** Commercial payers and Medicare are the primary payer sources for MVPMA patients. The Applicant's projected payer mix for MVPMA patients from 2023 to 2025, does not show any projected changes in the payer mix.

Table 3: Overview of MVPMA Patient Population (CY21)

	MVPMA
Total Patients	3,192
Gender	
Male	45%
Female	54%
Total	100%
Age	
0-17	0%
18-64	45%
65+	55%
Total	100%
Race/Ethnicity⁸	
White (non-Hispanic)	52%
White (Hispanic)	20%
Black or African American (non- Hispanic)	20%
Black or African American (Hispanic)	5%
Asian	2%
Two or more races	1%
Total	100%
Patient Origin⁹ / Top Ten Cities/Towns	
Lawrence	33%
Methuen	25%
Haverhill	9%
North Andover	7%

⁸ MVPMA does not collect data based on patients' race or ethnicity. The Applicant estimated race/ethnicity of MVPMA patients based on the geographical cities/towns serviced by the clinic.

⁹ Top 10 cities/towns.

Lowell	4%
Andover	4%
Salem, NH	3%
Chelmsford	3%
Lynn	2%
Boston Area	2%
Other	8%
Total	100%
Payer Mix¹⁰	
Commercial	30%
Medicare	30%
Medicaid	19%
Worker's Compensation	20%
Other ¹¹	1%
Total	100%

Table 4: ACO and APM Contract Percentages (CY21)

	MVPMA patients	MVPMA surgical patients
Total Patients	3,177	250
ACO and APM Contracts	65%	65%
Non-ACO and Non-APM Contracts	35%	35%

Factor 1a: Patient Panel Need

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. The Applicant attributes Patient Panel need for an ASC focused on pain management procedures to the following factors:

1. Growing demand for pain management procedures
2. An Aging Population
3. Difficulty Scheduling Patients in existing HOPDs and ASCs

1. Growing demand for pain management procedures

Chronic pain is one of the most common reasons adults seek medical care and it is the number one reason for disability and loss of function.^a Chronic pain is defined as pain that persists past the normal time of healing (usually characterized as pain for at least 3 months). High-impact chronic pain (HICP) identifies those with significant levels of life interference (i.e., work, social, and/or self-care activities). Estimates of the prevalence of chronic pain in the U.S. vary widely.^b The Applicant explains that this variation is due to a lack of uniform criteria for defining and classifying pain as a

¹⁰ Medicare and Medicaid only account for patients who reside in Massachusetts.

¹¹ The category titled (Other), refers to patients who may have military/ VA insurance, privately insured businesses, out of state insurances and self-pay.

symptom or disease, in addition to different factors such as age, area/location of pain, type of pain, and duration of pain.

- The CDC reported that an estimated 20.4% of U.S. adults (50.0 million) had chronic pain¹² and 8.0% of U.S. adults (19.6 million) had high-impact chronic pain¹³ (With higher prevalence associated with advancing age).^{14,c}
- A study looking at pain trends among American adults (U.S. adults ages 25–84) from 2002–2018 found that pain prevalence¹⁵ increased from 49% in 2002 to 54%, or 10% more Americans experienced chronic pain in 2018.^d
- A study using a new chronic pain module in the National Health Interview Survey (2019), a household-based annual survey of self-reported health status of U.S. adults, found that 50.2 million adults (20.5%) reported pain on most days or every day.^{e,16}
- A study of the prevalence of chronic pain stated that the prevalence of chronic pain among U.S. adults in 2019, varied by age: 31% of adults aged 65 years and older suffered from chronic pain, compared to 26% of adults aged 45 to 64 years.^f

The Applicant asserts that, accounting for patients suffering from chronic pain on daily basis (20%), patients suffering from chronic pain frequently or for a few days of the week/ month (40%) and patients with pain symptoms from diabetes mellitus and vascular disease (5-10%), up to 65-75% of the American population suffers from chronic pain of some kind.

The Applicant states that the pain management field has experienced significant improvement in treating complicated and debilitating pain conditions, including but not limited to cancer pain, spinal stenosis, pelvic pain, disc problems, fibromyalgia, and headaches.^g Medicare, Medicaid, and other insurers have approved a variety of minimally invasive procedures in the field of pain management, that can only be performed in the ASC or Hospital Outpatient Department (HOPD) setting. These procedures, which emerged in the last 15-20 years, were revolutionary in their effectiveness in treating chronic pain, and reducing the need for more invasive open spine surgery which brought the possibility of added complications.¹⁷

The Applicant states that interventional pain management, defined as a multidisciplinary approach to providing a full range of treatments and services, including minimally invasive techniques, for patients suffering from chronic and/or acute pain, has been shown to relieve, reduce, or manage

¹² Pain on most days or every day in the past 6 months.

¹³ Chronic pain limiting life or work activities on most days or every day in the past 6 months.

¹⁴ The CDC analyzed 2016 National Health Interview Survey (NHIS) data. NHIS is a cross-sectional, in-person, household health survey of the civilian noninstitutionalized U.S. population, conducted by the National Center for Health Statistics (NCHS).

¹⁵ “Any pain” in which those who responded affirmatively to any of the five pain sites (joint, low back, neck, facial/jaw pain, and headache/migraine) were coded as having pain.

¹⁶ The most common pain locations were back pain and hip, knee, or foot pain.

¹⁷ Procedures include: Spinal Cord Stimulator Implant for chronic neck, back or pelvic pain following failed spine surgery, or nerve damage due to surgery, Diabetes Mellitus, vascular disease, chemotherapy or radiation therapy, limb amputation, and endometriosis. Pain Pump Implant for chronic diffuse pain condition, and cancer pain. Kyphoplasty procedure for vertebral fracture from trauma, osteoporosis or cancer metastatic disease. Vertiflex procedure to treat spinal stenosis. MILD procedure to treat spinal stenosis. Nerve ablation procedures for specific pain procedures.

pain, improve quality of life, and allow patients to return to everyday activities with reduced reliance on medications. The Applicant cites reports that demonstrate a need for more physicians in general, and in the field of pain management specifically, to meet the growing demands of the aging population in the United States.^{h,i} As chronic pain increases with increasing age, it can be expected that demand for interventional pain management procedures will increase.

2. An Aging Population

The Applicant asserts that patients in the region will require greater access to the low acuity surgical services provided by the proposed ASC due to changing population demographics. The UMass Donahue Institute (UMDI) findings demonstrate that the Massachusetts population is expected to increase by 13% from 2010 to 2040, and between 2020 and 2040, the age 55+ age cohort will increase by approximately 18% and by 2040 it will comprise 35% of the Commonwealth's population.^j Additionally, the population of Merrimack Valley, comprising Lawrence, Haverhill, Lowell, and Salem NH, increased by 8.7% since 2000, and is expected to increase by 8.5% by 2030, which is a higher growth rate than the state of Massachusetts (7.8%).^k The majority of residents in the Merrimack Valley in 2015, were concentrated in Lawrence, Haverhill and Methuen.^l The Applicant also states that with actively growing industrial projects and businesses, the region can expect an increasing number of injured workers on the job, that will require the services of the proposed ASC to evaluate and treat such patients so that they may be able to return to work as soon as possible.

The Applicant asserts that Dr. Rustum's practice serves a growing, retiring population. Pain prevalence increases with increasing age.^m Over 60% of chronic pain patients are age 60 and older.ⁿ Many of these patients have other medical problems such as chronic heart conditions, chronic obstructive pulmonary disease (COPD), asthma, renal failure, diabetes mellitus, strokes, degenerative joint and disc disease, arthritis, etc. The Applicant states that these patients may require interventional or minimally invasive pain procedures on an outpatient basis to treat debilitating pain and to improve quality of life. Cancer incidence and prevalence increases with age and cancer pain is prevalent in older populations and requires the administration of special injections that can be administered locally or specific procedures to relieve pain and improve quality of life.^{o,p,q} Older adults also experience debilitating back pain and rely on procedures to relieve pain and improve quality of life. The Applicant states that the most common treatment for aging patients is spine surgical procedures, such as the MILD procedure, Vertiflex, Spinal cord simulator, Pain pump implant, nerve ablation specially for spinal stenosis, disc diseases, and diffuse severe arthritis.

The Applicant states 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.¹⁸ Dr. Rustum is a cancer specialist. And Dr. Rustum specializes in doing Vertiflex procedures, a minimally invasive procedure approved for the ASC and HOPD setting, for patients suffering from spinal stenosis for whom injections or medications have

¹⁸ The Applicant notes that Dr. Rustum is the only physician in the Merrimack Valley area who performs The MILD procedure. Based on a search of physicians within 25 miles of Merrimack Valley. <https://www.vertosmed.com/find-physician/>

failed, and for those who may not be good candidates for spine surgery.¹⁹ When access to such services is available locally, it means that older patients do not need to travel to Boston to access services, and older adults benefit through improved quality of life and activity.

3. Difficulty Scheduling Patients in existing HOPDs and ASCs

The Applicant states that Dr. Rustum's current pain management practice, MVPMA, receives referrals for its services from all specialties including, orthopedics, OB/GYN, spine surgery, neurology, general surgery, urology, oncology, and pediatrics. Dr. Rustum's practice has been the preferred practice to refer patients for acute and chronic pain management by Greater Lawrence Family Health Center (GLFHC) in Lawrence, MA since 2009. GLFHC, a federally qualified community health center with locations in Lawrence, Methuen and Haverhill, serves over 62,000 patients annually across the Merrimack Valley. GLFHC is the largest, multi-clinic medical facility in Northern Boston and Merrimack Valley area, providing a comprehensive range of medical care to uninsured/underinsured and low-income patients.

Dr. Rustum specializes in treating patients who have lost a limb (amputees). The Applicant states that these patients deal with many medical specialties over the course of their care. Dr. Rustum coordinates their treatment with vascular surgeons, physical therapists, podiatry specialists in addition to the clinics specialized in providing prosthesis. The Hanger Clinic Inc, headquartered in Texas, is a leading national provider of products and services that assist in enhancing and restoring the physical capabilities of patients with disabilities or injuries.²⁰ The Hanger Clinic has been depending on Dr. Rustum to treat its patients from northern Boston to NH and ME. The Hanger Clinic provided a letter of support for the Proposed Project.

Currently, Dr. Rustum performs pain management procedures on an outpatient basis at nearby hospitals and ASCs. However, over the past three to four years, Dr. Rustum has been having trouble scheduling such patients in nearby hospitals due to a lack of hospital nursing staff; scheduling delays, which reduce patient satisfaction; reluctance on the part of patients to having their procedures performed in the hospital due to the risk of contracting an infection; and hospitals' desire to focus on bigger and more complicated surgeries. This issue was further highlighted during the COVID-19 pandemic when hospitals were required to shut down operating rooms and when hospitals experienced staffing shortages. The Applicant asserts that the result is a delay in effective and required pain management treatment, and in some cases, the temporary substitution with narcotics treatment while awaiting scheduling of surgical procedures. Members of the Patient Panel currently experience a wait time of 4-6 weeks to schedule Vertiflex spine procedures for spinal stenosis and a wait time of 6-8 weeks to schedule other outpatient pain surgical procedures. Table 5 shows Dr. Rustum's procedures performed, and procedures delayed greater than 6-8 weeks and/or procedures experiencing scheduling changes in HOPDs, for CY21. See Appendix II for a description of

¹⁹ Vertiflex Superior infraspinal space is an FDA-approved system designed to relieve back pain by restoring the normal space between the vertebrae. It is a minimally invasive procedure and a solution for back pain for patients for whom medications or injections have failed. It may also be a good option for those who may not be good candidates for spine surgery. The procedure takes 20-30 minutes and can be performed in the ASC or hospital setting.

²⁰ Hanger Clinic Website: <https://hangerclinic.com/>

procedures in Table 5. All delays were experienced at HOPDs. And because hospitals were recovering from the pandemic and started to reopen in mid-2021, the surgical procedures listed in 2021 were all done at North East Ambulatory Center in Stoneham, Ma, which is approximately 21 to 27 miles from MVPMA.

Table 5: Procedures Performed and Delayed

Procedure (2021)	Performed in an ASC	Procedures performed at an ASC that were delayed at HOPDs	% Delayed
Spinal Cord Stimulator Implant	45	11	24%
Spinal Cord Stimulator Trial	50	10	20%
Pain Pump Change/ Revision	22	7	32%
Spinal Cord Stimulator Revision	32	14	44%
MILD Procedure (Minimally invasive lumbar decompression)	39	18	46%
Vertiflex Procedure	44	18	41%
Kyphoplasty	19	5	26%
TOTAL	251	83	33%

The Applicant offers additional information about the 83 delayed procedures:

- **38** patients were rescheduled to have their procedures done at an ASC in 2022.
- **13** patients elected not to seek the treatment, due in part to a change in secondary insurance or because they changed their mind.
- **22** patients were started on opiates.
- **10** patients were lost to follow-up or went elsewhere.

The Applicant provided a breakdown of the cities/towns or patient origin for procedures performed in 2021 to better understand patients currently receiving procedures performed by Dr. Rustum. This is shown in Table 6.

Table 6: Procedures Performed by Patient Origin (2021)

Town	# Of Procedures	Share of Procedures
Methuen	68	27%
Lawrence	51	20%
Haverhill	31	12%
Lowell	17	7%
Salem, NH	14	6%
Andover	12	5%

Other ²¹	58	23%
Total	251	100%

The payer mix for the performed procedures is as follows: Medicare with secondary Medicaid coverage (40%), Medicaid (5-6%), Commercial (23%), and Worker's Comp (31%).

The Applicant asserts that the proposed ASC will increase community-based access to outpatient pain management procedures for patients referred from physicians of different specialties. The proposed ASC will have two operating rooms. One operating room is the minimum required by the Centers for Medicare & Medicaid Service (CMS), and a second room is added to prevent interruption of services, and if technical problems or issues occur in the first room. The Applicant expects the first year of operation of the ASC to be 2024. The projected volume of the proposed ASC is 1,200 procedures annually. The Applicant determined projected ASC volume from the following:

- The Applicant reported 251 procedures performed in 2021; however, the Applicant was averaging 500-550 procedures annually prior to 2021. The number of procedures in 2021 decreased because the performing physician had to reduce his surgery cases due to unexpected events. There was no interruption in care for patients.
- The Applicant is experiencing an increase in referrals from primary care physicians (PCPs), spine surgeons, and other private entities that are specialized in coordinating the treatment of patients experiencing motor vehicle accidents and Workmen's Compensation, that do not go through medical insurance.
- The Applicant is experiencing an increase in referrals to take over patients from other pain physicians who are planning to retire.
- The Applicant plans to hire one physician with interventional pain management expertise, and one nurse practitioner or physician assistant to accommodate increasing demand for the proposed ASC's services.

The Applicant will shift procedures that would have otherwise been performed at a HOPD or an ASC located farther away, to the proposed ASC, increasing timely access to such services closer to where MVPMA patients reside.

Analysis

Chronic pain is prevalent, and increasing age is a risk factor for chronic pain and for high impact chronic pain (chronic pain accompanied by activity/life participation limitations).^{r,s} The CDC notes that pain is a component of many chronic conditions.^t Chronic disease is prevalent; nearly half of all Americans suffer from at least one chronic condition, and chronic disease increases with increasing age; 95% of adults aged 65 and old have one chronic condition and more than half of older adults have three or more chronic conditions.^{u,v} Pain is prevalent in patients with cancer.^w

Advances in the administration of anesthesia and analgesics, as well as financial benefits and incentives, have resulted in in the migration of surgical procedures from the inpatient setting to the outpatient setting.^x Through the proposed ASC, the Applicant can improve Patient Panel access to

²¹ Indicates count less than 11, which have been suppressed to protect patient privacy.

pain management procedures closer to where patients reside. In addition, increasing Patient Panel access to the procedures offered by the proposed ASC, can improve quality of life, and reduce patient reliance on medications, including opiates. Based on the data available as of November 1, 2022, there were 2,281 confirmed opioid-related overdose deaths in 2021 in Massachusetts and DPH estimates that there will be an additional 11 to 29 deaths once all cases are finalized.^{y,22} Table 7 shows opiate-related overdose deaths by county. The proposed ASC will be in Essex County.

Table 7: Number of Opioid-Related Overdose Deaths, All Intents by County, MA Residents: 2021^z

County	Count
Barnstable	80
Berkshire	62
Bristol	291
Dukes	5
Essex	288
Franklin	36
Hampden	213
Hampshire	44
Middlesex	356
Nantucket	4
Norfolk	162
Plymouth	167
Suffolk	294
Worcester	279
Total	2,281

Studies state that interventional techniques in pain management can be helpful for older adults as part of a multidisciplinary strategy to manage pain and with fewer side effects than pharmacologic interventions.^{aa,bb} It is noted that these procedures are performed in an outpatient setting for clinically appropriate patients and cannot address the needs of all older adults.

The Applicant has demonstrated that expanding Patient Panel access to outpatient surgical services can address increasing demand for such services and reduce delays in accessing treatment and the resulting prolonged suffering and loss of functioning.

Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity

Public Health Value: Improved Outcomes and Quality of Life

²² In the first nine months of 2022, there were 1,340 confirmed opioid-related overdose deaths and DPH estimates that there will be an additional 41 to 70 deaths, yielding approximately 1,696 total confirmed and estimated opioid-related overdose deaths.

The Applicant states that clinical staff will implement appropriate process improvement initiatives at the proposed ASC by reviewing quality of care outcomes, identifying best practices and implementing necessary process changes to ensure high quality services. Medical staff of MVPMA is currently implementing these initiatives, and the Applicant expects that these initiatives will be adjusted for implementation in the proposed ASC within two months of operation. Staff has included reporting on the progress of implementing these initiatives in the annual reporting measures in Appendix I.

The Applicant asserts that the Proposed Project will improve health outcomes and quality of life of the Patient Panel in the following ways:

Improved Patient Experience: The Applicant states that the proposed ASC's location was chosen because it would be able to accommodate the space that is required and because of the location's accessibility and convenience for patients. Through the Proposed Project, the Patient Panel will have access to state-of-the art technology in a new facility designed to improve patient satisfaction and convenience, which the Applicant states will further drive patient demand. The Applicant states that patients enjoy the convenience of an ASC to the hospital setting because it is easier to navigate, and patients experience reduced wait times when their procedures are performed in the ASC setting. Moreover, ASCs provide patients with greater choice over where they can receive their care.

The Applicant asserts that the proposed ASC will provide ease of access for patients because it is relatively new construction, there will be ample parking onsite with designated accessible parking spaces, and the floors of the facility will be limited to no more than three to allow for easier use of elevators. In addition, the facility will have wide elevators to accommodate wheelchairs and medical structures, and the facility will have automatic doors. The facility will be easily accessible from major highways (I-495, 213, I-93), and the proposed ASC's location is within a 10-mile radius of the majority of MVPMA's current patient population. The Applicant notes that the proposed ASC will be surrounded by other medical practices with whom it will share patients, making it convenient for patients to access these services in one location.²³

Improved patient outcomes: The Applicant states that ASCs are designed to provide care for specific categories of lower acuity surgical cases and for patients who have lower risk for any complications after surgery. Growth of minimally invasive procedures has led to the ability to perform more procedures on an outpatient basis. These procedures result in less complexities than other types of procedures, and fewer surgical cuts, incisions, and blood loss. Anesthesia needs can be met in the ASC due to developments in the delivery of anesthetics. The types of surgical procedures that are being performed in the ASC setting continues to increase over time, with estimates indicating approximately one third of outpatient surgeries are now performed in ASCs.

Clinical outcomes in ASCs are comparable to those of HOPDs. ASCs are associated with decreased mortality, morbidity, and hospital admission rates. Recovery times for procedures performed in

²³ The Application states that this includes but is not limited to an Urgent Care Clinic, Quest Laboratory, LabCorp, Northeast physical therapy and rehabilitation, Radiology services, primary care offices, Internal Medicine Offices, a Rheumatology Clinic, Cardiology Offices, and a Vascular Surgery clinic.

ASCs are typically shorter, which is due to the evolution of medical devices and pharmaceuticals administered in connection with surgery. Rates of revisit to the hospital one-week post-surgery are lower for ASC patients than HOPD patients. Infection rates for procedures performed in an ASC are half the rate of those performed in HOPDs. Patients experience improved pain levels and less nausea when the procedure is performed in an ASC. ASCs have better 30-day outcomes, including reductions in pneumonia, renal failure, and sepsis. Patients experience, reduced rates of disability, improved quality of life and productivity, and a reduction in days missed from work, which the Applicant states can improve a patient's socioeconomic status.

Reduce reliance on opioids: Increasing access to outpatient surgical procedures in the ASC setting can assist in reducing the impact of the opioid epidemic, through offering patients a faster, effective, treatment that can eliminate the need for narcotics. The Applicant states that there are patients whose chronic pain is currently being managed with opioids by other physicians such as primary care physicians (PCPs), orthopedic surgeons and in some cases pain physicians who have not incorporated interventional pain management therapies into their treatment. The Applicant states that these patients can be screened and evaluated for the possible benefits from non-opioid, interventional pain therapies or surgical pain treatment, that will be provided at the proposed ASC. The treating physician will decide the candidacy of a patient to undergo one of many interventional pain procedures (or surgical pain procedures) including but not limited to: Steroid injections, Nerves Radiofrequency Lesioning procedures, Verteflex procedure, MILD procedure and possibly Spinal Cord Stimulator/Pain Pump trials or implants. These procedures, the Applicant states, are considered minor interventional surgical procedures.

Increasing access to outpatient surgical services, can make scheduling procedures faster, reducing wait times for treatment, as well as time that patients use narcotics while waiting for treatment. The evaluation and determination for need of medications including narcotics will take place at MVPMA. MVPMA currently provides information to patients on the long-term use of narcotics. To ensure safe opioid prescribing practices, MVPMA currently uses narcotic contracts and applies all Drug Enforcement Agency (DEA) regulations, and these practices will be continued with the proposed ASC. The Applicant notes that MVPMA does not take over opiate prescriptions from other offices whose patients' pain is managed long-term through the use of narcotics. And, it tries not to initiate opiate treatment for chronic pain unless the patient is terminally ill.

Analysis: Improved Outcomes and Quality of Life

Chronic pain is a public health issue that affects more Americans than heart disease, cancer, and diabetes combined.^{cc} Chronic pain impacts physical, psychological and social functioning,^{dd} and it is associated with reduced quality of life, disability, lost productivity, and opioid dependence.^{ee,ff} Chronic pain is one of the key underlying causes of the opioid crisis.^{gg} The opioid crisis has resulted in an unprecedented number of overdose deaths associated with prescription opioids, heroin, and synthetic opioids.^{hh} Opioids can lead to addiction, in about 10% of people, and opioids have side effects.ⁱⁱ

Staff find that the proposed ASC can improve health outcomes and quality of life, and patient functioning. However, staff note racial and ethnic disparities in pain management. Studies have

shown that non-White patients are undertreated for pain.^{jj, kk, ll} Staff note that while the Applicant reports serving a diverse population, it does not currently collect race/ethnicity information on MVPMA patients. The race/ethnicity information provided in Table 3 were estimated by the Applicant. The Applicant has provided several measures that will become part of annual reporting to DPH. The Applicant notes that it will be reporting to CMS's Ambulatory Surgical Center Quality Reporting (ASCQR) Program.²⁴ Staff reviewed the suggested measures and has included reporting on the race/ethnicity, patient origin, and payer mix of ASC patients in the annual reporting measures in Appendix I.

Public Health Value: Health Equity

The Applicant asserts that the proposed ASC will increase access to high-quality surgical services for all patients by offering a low-cost alternative for outpatient surgical procedures in the community setting. To ensure health equity for all populations, the Applicant states that the Proposed Project will not adversely affect accessibility of the Applicant's services for the poor, medically indigent, and/or Medicaid eligible individuals; and the Applicant will not discriminate based on ability to pay or payer source. The Applicant outlined its efforts to increase healthy equity for the Patient Panel.

- **Cultural Competency.** The Applicant states that it will employ culturally competent staff. In addition, the proposed ASC will offer ongoing training in cultural competency to new and existing staff members.
- **Interpreter Services.** The Applicant plans to develop a robust translation services program. To address language barriers, the Applicant will offer multiple tools including Language Line, which provides phone and video interpretation services from trained professional linguists in more than 240 languages 24 hours a day, seven days a week, and InDemand, which offers medical interpreting solutions including video interpretations, allowing clinicians to provide limited English proficient (LEP), and Deaf and Hard of Hearing (DHH) patients with access to high quality healthcare.
- **Price Transparency.** The Applicant will provide price transparency tools that will allow patients to assess affordability of procedures, and financial counselors to assist patients with understanding their insurance benefits.

Analysis: Health Equity

Staff finds that the Applicant's planned language access services are appropriate for patients receiving care at the proposed ASC. Further, the Applicant has described procedures that seek to support health equity among the Patient Panel. The Applicant has appropriately outlined at a high level a case for improved health outcomes and has provided reasonable assurances of health equity for the Patient Panel. Staff has included reporting on implementation of interpreter services in the annual reporting measures in Appendix I.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

Efficiency. The Applicant states that the proposed ASC will be designed to utilize industry-defined

²⁴ CMS.gov. Ambulatory Surgical Center Quality Reporting (ASCQR) Program. <https://qualitynet.cms.gov/asc/ascqr>

best practices for quality, efficiency, and effectiveness. ASCs are tailored to a limited set of medical specialties and associated low-risk procedures, which create clinical and operational efficiencies that lead to more efficient use of resources. ASCs do not accommodate emergency or inpatient needs, which allows greater control over scheduling leading to reduced wait times for appointments. The hospital setting accommodates a range of medically complex procedures, including emergency events. Hospital operating rooms, including those dedicated to outpatient surgery, are designed with enough space and equipment to handle a wide range of procedures in multiple clinical specialties. The operating rooms must be flexible to handle a range of services from routine elective procedures to patients in need of immediate invasive surgery. ASCs focus on a subset of medical specialties and surgical procedures, including minimally invasive and noninvasive surgeries. Performing a limited set of procedures allows ASC personnel to gain high proficiency and efficiency performing these procedures, leading to clinical staff becoming highly proficient in providing the select surgical services and procedures, and achieving clinical and operational efficiencies. ASCs allow for more procedures to be scheduled in a day, due to the lack of interruptions, and ASCs can adhere uniformly to a surgical schedule, allowing for greater throughput pre- and post- surgery. All these factors contribute to shorter wait times for patients.

Care Coordination and Continuity of Care. The proposed ASC will provide transparent, online, administrative processes, for patients to allow for greater communication between staff and patients. The proposed ASC will provide online preregistration and cost transparency tools, allowing patients to register at home, instead of requiring them to do so in the clinical setting. The technology platform is available in over 70 languages to ensure all patients within the community have access to pre-registration capabilities. The Applicant will implement price transparency tools allowing patients to estimate prices for their procedures, as well as online payment portals. The Applicant states that currently, MVPMA patients can access their medical records through a patient portal, and those without access to technology have three options for receiving patient information: 1) receiving a hard copy in person, 2) receiving a copy of the medical records by certified mail, and 3) having the records mailed/emailed to a family member or proxy.

Strategies for timely communication among providers ensures higher quality outcomes for patients, including those with comorbidities and psychosocial support needs. Pre-registration tools interface with an electronic medical record (EMR) system to amalgamate patient health information that is reviewed by surgeons and anesthesiologists. EMR functionality allows surgeons to share operative notes and postoperative discharge instructions with primary care physicians (PCPs). The EMR tracks a patient's preoperative medications to ensure appropriate dosing as well as necessary prescriptions. Administrative leaders will engage surgeons in developing policies and procedures that will assist in increasing communication with PCPs. An assigned case manager will follow-up with patients to assess post-discharge needs.

The Applicant detailed several processes that will be in place to ensure patients have the appropriate discharge information to support a safe and speedy recovery. Upon discharge, a nurse manager will provide discharge instructions for all patients. Patients will receive detailed written instructions from their care team, a nurse will review the instructions with the patient and family at discharge, and each patient will receive a brightly colored folder with discharge instructions to take

home at the time of discharge. The surgeon has the option to record the post-operative message which details the surgery and reviews post-operative instructions. The video will be embedded into electronic postoperative instructions along with the hard-copy instructions. The electronic information will be emailed to the patient, using HIPAA-compliant protocols.

Analysis

The Applicant described how the proposed ASC will provide clinically appropriate care in a more efficient setting for patients and providers. In addition, the Applicant sufficiently described how the ASC's processes will support care coordination for patients across providers. Staff has included reporting on implementation of policies and procedures that assist in increasing communication with PCPs in the annual reporting requirements in Appendix I.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report.

Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel

The Department's Guideline^{dd} for community engagement defines "community" as the Patient Panel, and requires that at minimum, the Applicant must "consult" with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."^{ee}

To fulfill the community engagement requirement, the Applicant conducted information sessions/community forums to inform community members about need for the Proposed Project, the benefits of the ASC in terms of improved health outcomes, and the cost and convenience of performing low-acuity outpatient procedures in the ASC setting. The Applicant provided the flyer used to advertise the informational sessions, as well as the slides that were presented at the information sessions, which include a description of the facility and its location, the facility's advanced technology and resources, and the cost benefits of ASCs.

- MVPMA Informational Session September 9, 2022. Eight people were in attendance: six MVPMA patients (four from Methuen and two from Lawrence) and two nonpatients.
- MVPMA information Session September 16, 2022. Seven MVPMA people were in attendance; five patients from Methuen and two patients from Lawrence.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the minimum required community engagement standard of Consult in the planning phase of the Proposed Project.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

The Applicant asserts that the Proposed Project will meaningfully contribute to the Commonwealth's cost containment goals and compete on the basis of TME and provider costs through providing clinically appropriate patients with access to surgical services in a more cost-effective setting. The Applicant states that healthcare expenditures for elective and same day surgical procedures will decrease, reducing overall provider costs and directly impacting TME.

The Applicant maintains that the two goals of ASCs are: 1) ensure patients have the best surgical/procedural experience, including high quality outcomes; and 2) provide cost-effective care that leads to cost savings by government and third-party payers, as well as patients. Services provided in the ASC setting are performed by the same physicians that would perform the procedures in the hospital.

The Applicant cited several facts demonstrating the cost-effectiveness of ASCs:

- ASCs provide a lower cost, high quality alternative to outpatient procedures provided in an HOPD. ASC reimbursement is 45-49% of HOPDs. In one instance, procedures performed in an ASC were 84% of the cost of the same procedure performed in the HOPD, due in part to overhead costs that are required of hospital surgical service, including staffing, laboratory, medication and imaging costs.
- Annually, ASCs perform more than 8 million procedures for Medicare beneficiaries. Medicare beneficiaries save more than 2.6 billion each year when surgery is performed in an ASC, and studies show if half of eligible surgical procedures were shifted from HOPDs to ASCs, Medicare would save an additional \$2.5 billion annually, and commercial payers could save as much as \$55billion.^{mm}
- Patients typically pay less coinsurance for procedures performed in an ASC as compared to the hospital setting.

The Applicant provided Medicare reimbursement rates²⁵ for selective procedures to be performed in the ASC and HOPD settings for comparison purposes.²⁶ Table 8 shows a comparison of prices for Spinal Cord Stimulator Implant.²⁷ The Applicant states that this comparison shows a net savings of \$7,363.25 and a cost reduction of 20.25% resulting from performing the procedure in an ASC.

Table 8: 2022 ASC FINAL Payment Rates, Spinal Cord Stimulator Implant

2022F	ASCs	HOPDs
-------	------	-------

²⁵ Represents 80% of the total costs, the other 20% will be covered by patient or secondary insurance.

²⁶ American Society of Interventional Pain Physicians. ASC and HOPD Final Payment Rates (2022). As of November 3, 2021. Please see DoN application materials for the full list of payment rates.

²⁷ A surgical procedure, like a cardiac pacemaker, which involves implanting one or two leads in the spine, then tunneled under the skin and connected to a small battery. The procedure is meant to treat intractable back/leg pain. CPT Codes 63650 + 63685.

Procedure: Spinal Cord Stimulator Implant ²⁸	Code: 63650	Code: 63685	Code: 63650	Code: 63685
Total Cost	\$4,571.47	\$24,424.28	\$6,295.50	\$30,063.50
Total (Code 63650 +63685)	\$28,995.75		\$36,359.00	

Table 9 provides a comparison of prices for Paravertebral facet joint nerve Ablation; L/S, single level.²⁹ The Applicant states that this comparison shows a net savings of \$967.59 and a cost reduction of 54% resulting from performing the procedure in the ASC setting.

Table 9: 2022 ASC FINAL Payment Rates, Paravertebral facet joint nerve Ablation; L/S, single level

2022F	ASCs	HOPDs
Paravertebral facet joint nerve Ablation; L/S, single level ³⁰	Code: 64635	Code: 64635
Total Cost	\$825.71	\$1,793.30

Analysis

Surgical costs to both patients and payers can be less when procedures are performed in the ASC setting.^{nn,oo} Because ASCs have lower prices than HOPDs, patients can be responsible for lower out-of-pocket costs at the proposed facility.^{pp} These lower costs are expected to improve access: about one in ten adults have delayed or forgone care due to cost.^{qq} Medicare payment rates for surgical services performed in HOPDs are almost twice as high as in ASCs.^{rr} Studies have found that ASCs are less costly than HOPDs in the Medicare and non-Medicare context and that price growth at ASCs has been slower than at HOPDs.^{ss,tt}

Chronic pain is costly: In 2012, the annual economic cost of pain in the United States was estimated at more than \$600 billion.^{uu,vv} Studies have found that unaffordable out-of-pocket costs and insufficient insurance coverage can lead to individuals going without needed care, particularly preventive care and office visits.^{ww} Affordability of care, difficulty paying medical bills can lead people to avoid necessary care, and adults with lower incomes were more likely to go without much needed care than adults with higher incomes.^{xx} This included going without needed doctor, specialist, prescription drug, or mental health care.^{yy} ASC patients' out-of-pocket costs can be reduced through lower deductible and coinsurance payments.

²⁸ A surgical procedure, like a cardiac pacemaker, which involves implanting one or two leads in the spine, then tunneled under the skin and connected to a small battery. The procedure is meant to treat intractable back/leg pain. CPT Codes 63650 + 63685.

²⁹ The procedure is meant to treat intractable back pain as a result of diffuse arthritis in the spine. Most patients require light sedation as it could be painful.

³⁰ The procedure is meant to treat intractable back pain as a result of diffuse arthritis in the spine. Most patients require light sedation as it could be painful.

Staff examined publicly available Medicare reimbursement rates (further broken down) for Spinal Cord Stimulator Implant and for Paravertebral facet joint nerve Ablation; L/S, single level and found that in each case, the procedure is less costly when performed in an ASC as compared to a HOPD.³¹ This comparison can be found in Appendix III.

Staff find that the proposed ASC competes on the basis of price, costs, TME, and other measures of healthcare spending by providing a lower-cost alternative for outpatient procedures. And that with patient access to cost transparency tools and financial counselors, the Applicant will provide information to ensure patients understand the anticipated costs of the procedures and can assess affordability.

Factor 1 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that with the standard reporting requirements, the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f). The Applicant proposed specific outcome, and process measures to track the impact of the Proposed Project which staff has reviewed, and which will become a part of the reporting requirements. These measures are shown in Appendix I.

Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation

Cost Containment

Relying on the Health Policy Commission's recommendations regarding health care delivery and payment system reform (Better health and better care at a lower cost across the Commonwealth), the Applicant asserts that the Proposed Projects aligns with the Commonwealth's cost containment goals because it provides qualifying lower acuity patients with access to high-quality pain surgical services in a cost-effective setting. As discussed in Factor 1, when performed in the ASC setting, these procedures can result in cost savings to insurers and patients, given lower reimbursement and coinsurance payments than when performed in HOPDs, without compromising quality of care or health outcomes. The ASC setting supports efficiencies and clinical expertise, that can result in care and cost efficiencies, and reductions in provider costs, and TME.

Analysis: Cost Containment

The Applicant provided a list of procedures, demonstrating cost savings when they are performed in the ASC setting versus the HOPD setting, thereby demonstrating the proposed ASC's alignment with the Commonwealth's cost containment goals. When procedures are performed in the ASC setting, it has the potential to reduce healthcare spending without compromising the quality of care.²²

Improved Public Health Outcomes

As described above in Factor 1, the ASC setting allows for the development of clinical expertise

³¹ Medicare Procedure Price Lookup. <https://www.medicare.gov/procedure-price-lookup/>

around performing a set of specific specialty surgeries annually, that lead to greater clinical expertise among ASC staff and contributes to care efficiencies that lead to improved process and clinical outcomes. Additionally, patient experience is improved through accessing surgical services in the ASC setting as compared to the hospital setting.

Analysis: Public Health Outcomes

The Applicant has discussed how surgeries performed in the ASC setting can be more efficient, convenient, and cost-effective without compromising the quality of care. Staff notes lower acuity surgeries performed in an ASC outpatient setting can result in fewer and lower infection rates than HOPDs.^{aaa} Additionally, the procedures at the proposed ASC can alleviate pain and suffering and improve quality of life and functioning of patients allowing them to return to and participate in daily activities.

Delivery System Transformation

The Applicant asserts that patients will have assistance with social determinants of health (SDoH), needs and care management through a variety of processes, some of which were discussed in Factor 1. Prior to discharge, patients are linked to a care manager who screens for SDoH needs, and individuals with positive screens are linked to a care manager to assist with accessing local community resources to address identified SDoH needs. The Applicant states that MVPMA currently screens patients for tobacco smoking (active or passive), daily physical activity, and if the patient feels safe. Case managers will develop relationships with primary care practices and social work resources within the accountable care organizations (ACOs) that refer patients to the ASC, to help facilitate the referrals and ensure patients are linked with appropriate community resources to address SDoH needs.

Analysis: Delivery System Transformation

The Applicant has demonstrated how the proposed ASC will support SDoH screening which has the potential to improve the continuity of care and health outcomes.

Factor 2 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that with the standard reporting conditions, the Applicant has demonstrated that the Proposed Project has met Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted a report performed by Naffah & Company, P.C. (CPA Report).

The CPA analysis included a review of numerous documents in order to form an opinion as to the reasonableness and feasibility of the projections regarding the Proposed Project including, the financial results of MVPMA for the nine months ended September 30, 2022, and the projected results of Excel Surgery Center for year one through five of operation (Projections).³² The review of the reasonableness of the assumptions used and feasibility of the Projections included analysis of key metrics that fall into three categories: operating, liquidity, and solvency.

Revenues: Projected volume of the proposed ASC was based on historical case volume data of the existing MVPMA's Patient Panel and a gradual ramp-up schedule until year five. Payer mix was based on the multiple disciplines of Excel that were indicated in the Projections, and reimbursement rates were based on current Medicare-ASC rates. The Projections reflect Medicare Rates of Reimbursement for all services. Management took the most conservative approach to project revenue because private pay and commercial insurance payers may pay more for certain services. The CPA compared the projected revenue to the Medicare rates at standard rates for 2022.

Expenses: The CPA analyzed Salary and Benefits, as well as Other Operating Expenses for reasonableness and feasibility as related to the Projections of Excel Surgery Center. Salaries and benefits are projected to increase by 4% each year in years two through four and increase by 7% per year after year four. Most other expenses are projected to increase on average by a range of 4% to 6% per year in years two through five of the Projections.

Lease agreement, Capital Expenses, and Cash Flows

The CPA reviewed the lease terms, projected capital expenditures, and future cash flows of Excel Surgery Center. Based on that review, it was determined that 5,000 square feet of space would be leased to Excel Surgery Center by RNL Capital Holding, LLC, a party related to Excel Surgery Center and MVPMA through common ownership. Rent and common area maintenance charges will be approximately \$20 per square foot for years one through five. The CPA determined that the projected capital expenditures, facility lease, and resulting impact on the cash flows of Excel are

³² Primary Sources of Information Utilized: Historical balance sheet and revenue expenses, for existing results of MVPMA for the nine months ended September 30, 2022; Excel's projected revenue and expenses for years one through five; Management's report of historical volume of surgeries and procedures performed by MVPMA physicians for the nine months ended September 30, 2022 and the projected volume of Excel's surgeries and procedures for years one through five; Determination of Need application instructions dated March 2017; Determinative of Need narrative draft received from Management on October 31, 2022; Medicare rates and base rate calculations, received from Management on October 31, 2022; Excel draft DoN Application as of October 31, 2022; Listing of Excel employee positions for the projected fiscal years one through five; and Capital expenditure assumptions of \$400,000 for the projected year one.

reasonable.

CPA's Conclusion of Feasibility

As a result of its analysis the CPA states that, "we determined that the project and continued operating surplus are reasonable and based upon feasible financial assumptions. Accordingly, we determined that the Projections are feasible and sustainable and not likely to have a negative impact on the Patient Panel or result in the liquidation of the assets of Excel Surgery Center, LLC or Merrimack Valley Pain Management Associates, PC."

Analysis

Staff is satisfied with the CPA's analysis of the Applicant's decision to proceed with the Proposed Project. As a result, staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

Factor 5: Assessment of the Proposed Project's Relative Merit

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

The Applicant considered and rejected one alternative to the Proposed Project.

- **Maintain status quo** – This alternative entails continuing to serve patients through existing ORs at their current site of care which includes HOPDs and more distant ASCs. This alternative was dismissed because the operational, clinical efficiencies and patient-centered experience that would be provided by a locally sited, community-based ASC would not be afforded to the Patient Panel. Additionally, this alternative was dismissed because it would not address the need to reduce wait times for the procedures, that would be offered through the proposed ASC.

Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives. As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application

Summary and relevant background and context for this application: This is a DoN project for the establishment of a freestanding Ambulatory Surgery Center (ASC) not affiliated with an

existing hospital. In turn, the proposed project by the Applicant, Excel Surgery Center, LLC, does not require the submission of CHI forms.

As an ASC, Excel Surgery Center, LLC, will contribute their full CHI contribution to the Community Health and Healthy Aging Statewide Funds (CHHAF) to fulfill Factor 6 requirements. With fulfillment of the below conditions, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended Conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project and recommends that the Department approve this Determination of Need, subject to all applicable Standard and Other Conditions.

Other Conditions

1. The total required CHI contribution of \$60,000 will be directed to the Massachusetts Statewide Community Health Funds.
2. To comply with the Holder's obligation to contribute to the Massachusetts Statewide Community Health Funds, the Holder must submit the payment, a check for \$60,000, to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - a. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
 - b. The Holder must promptly notify DPH (CHI contact staff) when payment has been made.

Payment should be sent to:
Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro

Appendix I: Required Measures for Annual Reporting

The Holder shall, on an annual basis, commencing with approval of this DoN, and continuing annually for a period of five years after the Project is complete, report on the following data elements, pursuant to 105 CMR 100.310(A)(12). Reporting will include a description of numerators and denominators.

- 1. Patient Satisfaction:** Satisfied patients with their care are more likely to seek additional treatment when needed. They are more likely to serve as a source of referring other patients to the Proposed Project. The Applicant will review patient satisfaction levels with the ASC's surgical services.

Measure: The percent or number of patients indicating "Good" or satisfactory rating for measured subcategories.

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 subcategories:

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

Included in the annual report will be

- the number of surveys administered,
- the survey response rate,
- a description of the subcategories that were measured and the range of the rating scale,
- a description of the calculation of overall patient satisfaction, and
- a description of policy changes instituted as a result of the Holder's review of categories receiving lower ratings.

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 annual number of patients with surgical site infections and rate of 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.

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

Measure: The annual rate of compliance for all surgical procedures performed at Excel Surgery Center.

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.

- 4.** The Holder shall report on implementation of policies and procedures that assist in increasing the ASC's communication with PCPs (Factor 1c).
- 5.** The Holder shall report on implementation of process improvement initiatives at the proposed ASC (Factor 1b).
- 6.** The Holder shall report on progress in reduction of wait times for scheduling surgical procedures (Table 5). The Holder shall provide a description of how wait time is calculated.
- 7.** The Holder shall report on ASC surgical volume stratified by race and ethnicity, patient origin (zip code), and payer mix.
- 8.** The Holder shall report on the following outcome measures:
 - a. All cause hospital transfer/admission upon discharge for all surgical procedures at Excel Surgery Center (CMS measure ASC-4).

The percentage of ASC admissions (patients) who are transferred or admitted to a hospital upon discharge from the ASC.

- b. Unplanned Hospital Visits (number and rate) within 7 days post discharge from Excel Surgery Center for all surgical procedures performed at Excel Surgery Center.

The measure defines a hospital visit as any emergency department (ED) visit, observation stay, or unplanned inpatient admission.

- 9. The Holder shall report on implementation of language access services, as described in Factor 1b, and demonstrate compliance with Office of Health Equity interpreter services requirements for the proposed ASC.

Appendix II: Procedure Definitions

Procedure
Spinal Cord Stimulator Implant An implanted device that sends low levels of electricity directly into the spinal cord to relieve pain. ^{bbb}
Spinal Cord Stimulator Trial Spinal cord stimulators require two procedures to test and implant the device: the trial and the implantation. ^{ccc}
Pain Pump Change/ Revision A “pain pump” is a method of giving medication directly to your spinal cord. The system uses a small pump that is surgically placed under the skin of your abdomen. ^{ddd}
Spinal Cord Stimulator Revision Revisions are surgeries to remove the old implants and replace them with new components.
Vertiflex Procedure The Vertiflex Procedure is a minimally invasive treatment that has been clinically proven to provide effective long-term relief from the pain associated with LSS. ^{eee}
MILD Procedure (Minimally invasive lumbar decompression) Outpatient, minimally invasive procedure to treat spinal stenosis.
Kyphoplasty Injects special cement into your vertebrae — with the additional step of creating space for the treatment with a balloon-like device. Kyphoplasty can restore a damaged vertebra’s height and may also relieve pain. ^{fff}

APPENDIX III: CMS Price Procedure Lookup

Procedure Price Lookup, Spinal Cord Stimulator Implant

	ASCs		HOPDs	
Procedure: Spinal Cord Stimulator Implant ³³	Code: 63650	Code: 63685	Code: 63650	Code: 63685
Total Cost	\$4,991	\$24,792	\$6,716	\$30,433
Doctor Fee	\$421	\$370	\$421	\$370
Facility Fee	\$4,570	\$24,422	\$6,295	\$30,063
Medicare Pays	\$3,992	\$19,833	\$5,372	\$28,803
Patient Pays	\$998	\$4,958	\$1,343	\$1,630
Total (Code 63650 +63685)	\$29,783		\$37,149	

Procedure Price Lookup, Paravertebral facet joint nerve Ablation; L/S, single level

	ASCs	HOPDs
Paravertebral facet joint nerve Ablation; L/S, single level ³⁴	Code: 64635	Code: 64635
Total Cost	\$1,018	\$1,987
Doctor Fee	\$194	\$194
Facility Fee	\$824	\$1,793
Medicare Pays	\$814	\$1,589
Patient Pays	\$202	\$396

³³ A surgical procedure, like a cardiac pacemaker, which involves implanting one or two leads in the spine, then tunneled under the skin and connected to a small battery. The procedure is meant to treat intractable back/leg pain. CPT Codes 63650 + 63685.

³⁴ The procedure is meant to treat intractable back pain as a result of diffuse arthritis in the spine. Most patients require light sedation as it could be painful.

REFERENCES

- ^a Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1001–1006. DOI: <http://dx.doi.org/10.15585/mmwr.mm6736a2>
- ^b Yong, R. Jasona,*; Mullins, Peter M.b; Bhattacharyya, Neilc. Prevalence of chronic pain among adults in the United States. *PAIN* 163(2):p e328-e332, February 2022. | DOI: 10.1097/j.pain.0000000000002291
- ^c Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1001–1006. DOI: <http://dx.doi.org/10.15585/mmwr.mm6736a2>
- ^d Zajacova A, Grol-Prokopczyk H, Zimmer Z. Pain Trends Among American Adults, 2002–2018: Patterns, Disparities, and Correlates. *Demography*. 2021 Apr 1;58(2):711–738. doi: 10.1215/00703370-8977691. PMID: 33834222; PMCID: PMC8035485.
- ^e Yong, R. Jasona,*; Mullins, Peter M.b; Bhattacharyya, Neilc. Prevalence of chronic pain among adults in the United States. *PAIN* 163(2):p e328-e332, February 2022. | DOI: 10.1097/j.pain.0000000000002291
- ^f Prevalence of chronic pain among U.S. adults in 2019, by age Published by John Elflein. Dec 3, 2020. <https://www.statista.com/statistics/1189525/chronic-pain-adults-prevalence-by-age-us/>
- ^g Interventional Pain Medicine. Welcome to Interventional Pain Medicine. <https://reader.elsevier.com/reader/sd/pii/S2772594422000723?token=B63C4B78C28A69F416EBF09FAF692D5C1D469C93E45B9E189CFC9B12C8A0436C1B0852C520AA0FE8268E34D426A757A3&originRegion=us-east-1&originCreation=20230120174514>
- ^h AAMC.org. We need more doctors. <https://www.aamc.org/news-insights/we-need-more-doctors>
- ⁱ Henry Ford Health. Few Doctors Have Adequate Training to Effectively Treat Chronic Pain. August 12, 2013. <https://www.henryford.com/news/2013/08/few-doctors-have-adequate-training-to-effectively-treat-chronic-pain>
- ^j UMass Donahue Institute. Population Estimates Program. Massachusetts Population Projections. <http://www.pep.donahue-institute.org/>
- ^k Merrimack Valley Planning Commission. 018-2023 Merrimack Valley Comprehensive Economic Development Strategy Embracing Resilience & Equity for a Prosperous Region. <https://mvpc.org/wp-content/uploads/FINAL-2018-2023-MV-CEDS-SEPT-2018-mod.pdf>
- ^l Merrimack Valley Planning Commission. 018-2023 Merrimack Valley Comprehensive Economic Development Strategy Embracing Resilience & Equity for a Prosperous Region. <https://mvpc.org/wp-content/uploads/FINAL-2018-2023-MV-CEDS-SEPT-2018-mod.pdf>
- ^m Domenichiello AF, Ramsden CE. The silent epidemic of chronic pain in older adults. *Prog Neuropsychopharmacol Biol Psychiatry*. 2019 Jul 13;93:284–290. doi: 10.1016/j.pnpbp.2019.04.006. Epub 2019 Apr 17. PMID: 31004724; PMCID: PMC6538291.
- ⁿ Overview of Persistent Pain in Older Adults. Ivan R. Molton and Alexandra L. Terrill University of Washington Medical Center. <https://www.apa.org/pubs/journals/releases/amp-a0035794.pdf>
- ^o National Cancer Institute. Age and Cancer Risk. <https://www.cancer.gov/about-cancer/causes-prevention/risk/age>
- ^p Hachem GE, Rocha FO, Pepersack T, Jounblat Y, Drowart A, Lago LD. Advances in pain management for older patients with cancer. *Ecanermedscience*. 2019 Dec 3;13:980. doi: 10.3332/ecancer.2019.980. PMID: 32010204; PMCID: PMC6974363.
- ^q American Cancer Society. Other Medical Treatments for Cancer Pain. <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/pain/other-medical-treatments-for-cancer-pain.html>
- ^r Domenichiello AF, Ramsden CE. The silent epidemic of chronic pain in older adults. *Prog Neuropsychopharmacol Biol Psychiatry*. 2019 Jul 13;93:284–290. doi: 10.1016/j.pnpbp.2019.04.006. Epub 2019 Apr 17. PMID: 31004724; PMCID: PMC6538291.
- ^s Pitcher MH, Von Korff M, Bushnell MC, Porter L. Prevalence and Profile of High-Impact Chronic Pain in the United States. *J Pain*. 2019 Feb;20(2):146–160. doi: 10.1016/j.jpain.2018.07.006. Epub 2018 Aug 7. PMID: 30096445; PMCID: PMC822465.
- ^t Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1001–1006. DOI: <http://dx.doi.org/10.15585/mmwr.mm6736a2>
- ^u National Council on Aging. Center for Healthy Aging for Professionals. Get the Facts on Healthy Aging Jan 01, 2021. <https://www.ncoa.org/article/get-the-facts-on-healthy-aging>
- ^v Raghupathi W, Raghupathi V. An Empirical Study of Chronic Diseases in the United States: A Visual Analytics Approach.

Int J Environ Res Public Health. 2018 Mar 1;15(3):431. doi: 10.3390/ijerph15030431. PMID: 29494555; PMCID: PMC5876976.

^w van den Beuken-van Everdingen MH, Hochstenbach LM, Joosten EA, Tjan-Heijnen VC, Janssen DJ. Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. *J Pain Symptom Manage*. 2016 Jun;51(6):1070-1090.e9. doi: 10.1016/j.jpainsymman.2015.12.340. Epub 2016 Apr 23. PMID: 27112310.

^x Joshi, Girish P. MBBS, MD, FFARCSI^{*}; Vetter, Thomas R. MD, MPH[†]. Causes of Delays in the Ambulatory Surgery Center Setting: A Keen Grasp of the Obvious?. *Anesthesia & Analgesia*: December 2021 - Volume 133 - Issue 6 - p 1402-1405 doi: 10.1213/ANE.0000000000005445

^y Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents. <https://www.mass.gov/doc/opioid-related-overdose-deaths-among-ma-residents-december-2022/download>

^z Number of Opioid-Related Overdose Deaths, All Intents by County, MA Residents: 2010-2021.

<https://www.mass.gov/doc/opioid-related-overdose-deaths-by-county-december-2022/download>

^{aa} Schwan J, Slimani J, Tawfik VL. Chronic Pain Management in the Elderly. *Anesthesiol Clin*. 2019 Sep;37(3):547-560. doi: 10.1016/j.anclin.2019.04.012. Epub 2019 Jun 18. PMID: 31337484; PMCID: PMC6658091.

^{bb} Brooks AK, Udoji MA. Interventional Techniques for Management of Pain in Older Adults. *Clin Geriatr Med*. 2016 Nov;32(4):773-785. doi: 10.1016/j.cger.2016.06.003. Epub 2016 Aug 4. PMID: 27741969.

^{cc} Tsang A, Von Korff M, Lee S, Alonso J, Karam E, Angermeyer MC, Borges GL, Bromet EJ, Demyttenaere K, de Girolamo G, de Graaf R, Gureje O, Lepine JP, Haro JM, Levinson D, Oakley Browne MA, Posada-Villa J, Seedat S, Watanabe M. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. *J Pain*. 2008 Oct;9(10):883-91. doi: 10.1016/j.jpain.2008.05.005. Epub 2008 Jul 7. Erratum in: *J Pain*. 2009 May;10(5):553. Demyttenaere, K [added]. PMID: 18602869.

^{dd} Domenichiello AF, Ramsden CE. The silent epidemic of chronic pain in older adults. *Prog Neuropsychopharmacol Biol Psychiatry*. 2019 Jul 13;93:284-290. doi: 10.1016/j.pnpbp.2019.04.006. Epub 2019 Apr 17. PMID: 31004724; PMCID: PMC6538291.

^{ee} Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1001–1006. DOI: <http://dx.doi.org/10.15585/mmwr.mm6736a2>

^{ff} Weintraub, Karen. What is chronic pain? USA TODAY explores the problem and potential solutions. December 11, 2022. <https://www.usatoday.com/story/news/health/2022/12/11/what-chronic-pain-treatment-and-pain-management-beyond-opioids/10841327002/>

^{gg} Healthy People 2030. Chronic Pain. <https://health.gov/healthypeople/objectives-and-data/browse-objectives/chronic-pain>

^{hh} U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: <https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html>

ⁱⁱ Weintraub, Karen. What is chronic pain? USA TODAY explores the problem and potential solutions. December 11, 2022. <https://www.usatoday.com/story/news/health/2022/12/11/what-chronic-pain-treatment-and-pain-management-beyond-opioids/10841327002/>

^{jj} Weintraub, Karen. What is chronic pain? USA TODAY explores the problem and potential solutions. December 11, 2022. <https://www.usatoday.com/story/news/health/2022/12/11/what-chronic-pain-treatment-and-pain-management-beyond-opioids/10841327002/>

^{kk} Mary E Morales, MD, R Jason Yong, MD, MBA, Racial and Ethnic Disparities in the Treatment of Chronic Pain, *Pain Medicine*, Volume 22, Issue 1, January 2021, Pages 75–90, <https://doi.org/10.1093/pm/pnaa427>

^{ll} Practical Pain Management. Special Report: Race, Pain Management, and the System. <https://www.practicalpainmanagement.com/resources/practice-management/special-report-race-pain-management-system>

^{mm} Healthcare Bluebook and HealthSmart. Commercial Insurance Cost Savings in Ambulatory Surgery Centers. January 2, 2017. <http://www.advancingsurgicalcare.com/advancingsurgicalcare/reducinghealthcarecosts/costsavings/healthcarebluebookstudy>

ⁿⁿ Joshi, Girish P. MBBS, MD, FFARCSI^{*}; Vetter, Thomas R. MD, MPH[†]. Causes of Delays in the Ambulatory Surgery Center Setting: A Keen Grasp of the Obvious?. *Anesthesia & Analgesia*: December 2021 - Volume 133 - Issue 6 - p 1402-1405 doi: 10.1213/ANE.0000000000005445

^{oo} Condon, Alan. Becker's ASC Review. ASCs vs. HOPDs: 12 insights on the federal reimbursement gap. October 12, 2021.

<https://www.beckersasc.com/asc-news/ascs-vs-hopds-12-insights-on-the-federal-reimbursement-gap.html>

^{pp} Crawford DC, Li CS, Sprague S, Bhandari M. Clinical and Cost Implications of Inpatient Versus Outpatient Orthopedic Surgeries: A Systematic Review of the Published Literature. *Orto Rev (Pavia)*. 2015 Dec 30;7(4):6177. doi: 10.4081/or.2015.6177. PMID: 26793295; PMCID: PMC4703913.

^{qq} [How does cost affect access to care?](#) PETERSON-KFF Health System Tracker. Jan. 14, 2022

^{rr} Medpac. Ambulatory surgical center services/ Chapter 5. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch5_SEC.pdf

^{ss} Medpac. Ambulatory surgical center services/ Chapter 5. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch5_SEC.pdf

^{tt} Becker's ASC Review. ASCs vs. HOPDs: 12 insights on the federal reimbursement gap. October 12, 2021. <https://www.beckersasc.com/asc-news/ascs-vs-hopds-12-insights-on-the-federal-reimbursement-gap.html>

^{uu} Gaskin DJ, Richard P. The economic costs of pain in the United States. *J Pain*. 2012 Aug;13(8):715-24. doi: 10.1016/j.jpain.2012.03.009. Epub 2012 May 16. PMID: 22607834.

^{vv} Science Daily. Chronic pain costs U.S. up to \$635 billion, study shows. September 11, 2012. <https://www.sciencedaily.com/releases/2012/09/120911091100.htm#:~:text=Based%20on%20their%20analysis%20of,from%20%24299%20to%20%24334%20billion.>

^{ww} Health Policy Commission. 2021 Annual Health Care Cost Trends Report. Chartpack. <https://www.mass.gov/doc/2021-cost-trends-report-chartpack/download>

^{xx} Health Policy Commission. 2021 Annual Health Care Cost Trends Report. Chartpack. <https://www.mass.gov/doc/2021-cost-trends-report-chartpack/download>

^{yy} Health Policy Commission. 2021 Annual Health Care Cost Trends Report. Chartpack. <https://www.mass.gov/doc/2021-cost-trends-report-chartpack/download>

^{zz} Badlani N. Ambulatory surgery center ownership models. *J Spine Surg*. 2019 Sep;5(Suppl 2):S195-S203. doi: 10.21037/jss.2019.04.20. PMID: 31656875; PMCID: PMC6790806.

^{aaa} Becker's ASC Review. Benchmarking study of 1,000,000 surgeries in ASCs demonstrates minimal surgical site infections, emergency department visits and readmission rates. August 24, 2017. <https://www.beckersasc.com/asc-news/benchmarking-study-of-1-000-000-surgeries-in-ascs-demonstrates-minimal-surgical-site-infections-emergency-department-visits-and-readmission-rates.html>

^{bbb} Johns Hopkins Medicine. Spinal Cord Stimulator. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-pain-with-spinal-cord-stimulators>

^{ccc} John Hopkins Medicine. Spinal Cord Stimulator. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-pain-with-spinal-cord-stimulators>

^{ddd} University of California San Francisco Health. Intrathecal Drug Delivery. <https://www.ucsfhealth.org/treatments/intrathecal-drug-delivery#:~:text=Intrathecal%20drug%20delivery%2C%20also%20known,area%20around%20your%20spinal%20cord.>

^{eee} Pain.com. The Vertiflex™ Procedure. <https://www.pain.com/en/chronic-pain-solutions/vertiflex-procedure.html>

^{fff} Johns Hopkins Medicine. Kyphoplasty. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/kyphoplasty>