

**New Anesthesia Services in Office-Based Endoscopy:
An Anesthesia Business Plan**

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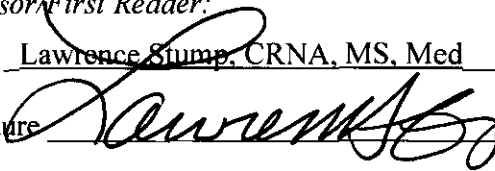
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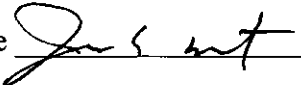
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Abstract

Purpose: Colonoscopy is the preferred method of screening for colorectal cancer in the United States. This screening tool has contributed to rapid and exponential growth in the number and complexity of gastrointestinal endoscopic procedures performed in the last few decades. In recent years, there has been an increased number of outpatient facilities that specialize in diagnostic endoscopic procedures, without an associated overnight stay. The patient's ability to tolerate diagnostic endoscopic procedures is crucial to perform a complete and thorough examination. Studies have demonstrated that patients prefer deep levels of sedation to tolerate these exams. Patient preferences, combined with the need for faster recovery times have created an increased demand for business relationships between gastroenterologists and anesthesia practitioners. Certified Registered Nurse Anesthetists (CRNAs), are well trained to administer this method of sedation. The purpose of this project is to answer the research question: Can a business plan be developed for CRNAs implementing office-based gastroenterology clinic practices, to address specific considerations for the provision of this type of anesthesia service?

Methods: Literature searches investigating the business of anesthesia and office-based facility standards were conducted to help identify considerations for newly established anesthesia services for outpatient endoscopy settings. Information obtained was used to develop a business plan to assist CRNAs to implement this type of collaborative practice. The American Association of Nurse Anesthetists (AANAs) conducts an annual survey to obtain member's compensation data. This data was incorporated into the business plan for an accurate comparison of hypothetical employment scenarios in outpatient office-based endoscopy.

Results: A business plan for an office based gastroenterology clinic that addressed the considerations necessary for starting anesthesia services was developed for this project. The business plan effectively describes essential elements of billing for services, facility readiness, and compensation models. The plan was utilized to establish an independent anesthesia practice capable of contracting services for office-based endoscopy.

Conclusion: The business plan created for this project was utilized to start an anesthesia business in Minnesota. The plan was determined to be effective as a solitary document in which to articulate components necessary for starting an anesthesia business operated by this practitioner. Pertinent data was collected from various sources and serves the purpose of sharing the vision and plan for business success. This project served to answer the research question of if an anesthesia specific business plan could be created to assist in the development of an office-based anesthetizing site, complete with elements necessary for addressing facility readiness and billing capabilities.

Data Sources: American Association of Nurse Anesthetists, Medscape, PubMed, Cochrane Library, CINAHL, and Google Scholar,

Keywords: Anesthesia business plans, anesthesia billing, outpatient anesthesia, gastroenterology, anesthesia

Introduction

Colorectal cancer is the third most common type of cancer in men and women in the United States.¹ Most colorectal cancer is caused by adenocarcinoma. These cancers initiate in the cells that make and secrete mucous in the colon.¹ Fecal occult blood tests and colonoscopy for the detection of colon polyps, are the primary diagnostic procedures used to screen for colon cancer. These procedures are effective techniques for early detection of the disease, and prevention of colorectal cancer.

A diagnosis of colorectal cancer obtained via screening has been found to occur two to three years before the onset of symptoms. Screening has been found to identify colorectal cancer at an early stage, and decreases colorectal cancer death rate by 60%.² The United States Preventive Services Task Force (USPSTF) recommends the use of high-sensitivity fecal occult blood testing, sigmoidoscopy, or colonoscopy beginning from age 50, and should remain ongoing until age 75.³ These recommendations, combined with a number of factors including reimbursement, procedural efficiency, and patient satisfaction, have produced an increased demand for endoscopy in an outpatient facility. The prevalence of office based gastroenterology clinics has increased by 300%.⁴

Physical discomfort may be associated with colonoscopies and esophageal endoscopies, which commonly necessitates the use of deeper sedation to assist patients to tolerate the examination. Propofol is a short acting medication that is used to decrease the patient's level of consciousness, and cause amnesia of events that occur while sedated. Propofol's maximum effect occurs in approximately 2 minutes and lasts 5-10 minutes depending on the amount administered to the patient.⁵ The shift toward using deep sedatives such as propofol, from intravenous

benzodiazepines and narcotics may be related to propofol's deep sedative effect, rapid onset of action, and short recovery time.^{4,5}

In the United States, the prevalence of anesthesia assisted sedation for upper and lower endoscopy procedures appears to be primarily driven by regional payer policies. Historically, American Gastroenterology Associations have agreed that anesthesia assisted sedation for colonoscopy is not warranted for average risk patients, and therefore most insurance payers concurred, limiting anesthesia reimbursement for high risk patients only.⁴ However, due to increased patient satisfaction, and decreased recovery time, propofol is a favorable method of sedation for office based gastroenterology.⁵ The benefits of anesthesia assisted sedation have resulted in acquiring positive opportunities for business associations between gastroenterologists and anesthesia providers.

In relation to the growing need for business affiliations amongst providers, questions arise regarding optimal anesthesia business arrangements. There are several factors to consider for starting up anesthesia services in an office-based setting including; facility accreditation, practice agreements, payment structures, and financial agreements between the gastroenterologist, anesthesia service provider, and the patients.^{5,6}

The author for this project was approached by an experienced physician gastroenterologist, to provide anesthesia to patients undergoing upper esophageal endoscopies and/or colonoscopies in the office setting. This request was the impetus for this project, and led to the development of the following research questions:

For an anesthesia business agreement with a gastroenterologist in a new endoscopy clinic:

1. *Can a business plan be developed for CRNAs implementing office-based gastroenterology clinic practices, to address specific considerations for the provision of this type of anesthesia service?*

Secondary investigation includes:

2. *What factors are necessary to consider in implementing an anesthesia business capable of direct billing?*
3. *For office based gastroenterology procedures, what are the typical billing arrangements for anesthesia providers?*
4. *What are essential elements necessary to include in a business plan to provide anesthesia services in an office-based setting?*
5. *Can a business plan be developed for anesthesia services based on current evidence, which addresses considerations specific to anesthesia billing, contractual agreements, insurances, and facility accreditation?*

Review of Literature

An extensive review of the literature was conducted between January 2016, and November 2016. A search of electronic databases was performed for background information on anesthesia and gastroenterology, anesthesia billing practice, anesthesia business agreements, anesthesia business elements, and gastroenterology clinic prevalence to determine the extent of information available. Dates were set to the year 2000, article language was limited to English, and because of the scope of this topic, no restrictions were placed on type of article or literature review searched.

The databases that were searched include CINAHL, Access Anesthesiology, PubMed, Scopus, Google Scholar, the Cochrane Library, and Health Management Database. Key words including; financial arrangement and anesthesia, anesthesia and business, anesthesia and gastroenterology, anesthesia and GI, anesthesia and endoscopy, anesthesia billing practice, anesthesia business agreements, anesthesia business elements, and gastroenterology clinic prevalence were used to acquire relevant information. Additionally, the websites of major anesthesia practice management firms including Broadston Consulting Firm (400 E 10th Street,

Waconia, MN 55387), Anesthesia Billing Consultants (255 West Michigan Avenue, Jackson, MI 49201), and Medical Group Management Association (104 Inverness Terrace East, Englewood, CO 80112) were investigated as significant resources for anesthesia business start-up tools and information.

The literature search for this project identified gaps in information regarding the various components of an anesthesia business, such as contractual agreements between anesthesia providers and physicians, billing, facility accreditation, and business plans specific to anesthesia services. The search analysis of PubMed with the above terms provided around 35 articles. The Health Management Database and Business Source Complete returned two articles, and Access Anesthesiology provided one textbook chapter. The website searches of anesthesia practice management firms determined no significant tools or articles describing elements essential to starting up an anesthesia business. None of the articles found were systematic reviews or scientific studies that analyzed the cost effectiveness of start-up anesthesia services complete with billing rights. Nine articles were identified as having information useful to the project.

Office-Based Anesthesia Prevalence

The need for the provision of office-based anesthesia has grown exponentially in the last decade. In 2006, an estimated 53 million procedures were performed during 34.7 million ambulatory office visits. An estimated 19.9 million occurred in hospitals, and 14.9 million procedures occurred in freestanding centers. From 1996 to 2006, the rate of visits to free standing centers has increased by 300%, while the amount of outpatient procedures performed in hospital based ambulatory surgery centers remained unchanged.⁷ Patient advantages such as ease of scheduling, more personalized care, increased privacy, efficiency, and decreased nosocomial infection risk are important drivers in this increased provision of office-based procedures.⁷

While gastroenterologists and health insurance companies encourage high quality, cost effective endoscopies, acquiring accreditation as a facility and complying with state regulatory requirements, has proven to be difficult for many office-based gastroenterology practices.⁷ Barriers exist within the healthcare system that make it difficult for an office-based endoscopy center to be financially successful.⁷ These include; state health department regulations for office-based procedures that involve anesthesia, the existence of 5,000 ambulatory surgery centers (ASC) across America, direct competition for the market, and the impact of hospital systems and their lobbying efforts in protecting their share of the gastroenterology market.⁷

There are several regulations addressing the issue of providing anesthesia in the office-based setting. More than 30 states have enacted guidelines for anesthesia services. These guidelines and instructions have contributed to an increase in the cost of providing anesthesia services in office-based practices.⁷ To offset the increased cost, accredited facilities are able to charge a fee to cover the cost of items such as equipment and pharmaceutical agents which would otherwise not be included in the anesthesia generated revenue.^{5,7}

Many states require that office-based centers must be accredited by a national accreditation agency, or comply with ASA (American Society of Anesthesiologists) office-based anesthesia guidelines. Facility accreditation or use of ASA guidelines supports the credibility and reliability of procedures in anesthesia-assisted, office-based settings.⁷ The prevalence of office-based endoscopy centers within a state depends on the regulatory environment, accreditation requirements, market conditions regarding reimbursement and prevalence of ASCs, and the position of the hospital association in the state.⁷

Anesthesia with Endoscopy

In 2008, The Cochrane Collaboration conducted a systematic review to analyze the evidence associated with propofol sedation in endoscopy. The review discussed outcomes from patients, demonstrated the relative effectiveness of propofol sedation, and addressed patient acceptance and safety of propofol for colonoscopy, compared to traditional sedatives (narcotics and/or benzodiazepines). Several studies in the literature review met the inclusion criteria, and these studies revealed that recovery and discharge times were decreased, and patient satisfaction scores were increased with the use of propofol assisted sedation.^{3,9} Studies concluded that there was no difference in pain control between the use of propofol technique and other traditional agents. In context with healthy individuals, the review suggested that propofol for sedation during colonoscopy leads to faster recovery and shorter discharge times, and high patient satisfaction without amplifying the side-effects.⁹

Several broad and comprehensive retrospective studies analyzed the association of propofol sedation with the rate of adenoma detection.^{8,9} The study was performed at two facilities where over 12,000 endoscopic procedures were performed annually, and all colonoscopies were performed under anesthesia assisted propofol sedation. The study concluded that although patient satisfaction scores have significantly increased, there is no difference in adenoma detection rates between conscious sedation, and propofol assisted sedation.⁸

Another retrospective study published in 2016 examined 699 patients who underwent colonoscopies with either propofol sedation or lighter conscious sedation. The study demonstrated that there was no significant difference between the two types of sedation regarding adenoma detection rates. This research revealed that patient satisfaction scores have increased significantly with propofol sedation.⁷

The Business of Anesthesia

There are many aspects to owning an anesthesia business that are not directly related to administering anesthesia. Some elements identified in the literature include; accounting, scheduling, recruiting, credentialing, legal implications, billing, malpractice insurance, benefits packages, taxes, and marketing.¹⁰ Organizing a plan for the components that are essential to business operations may ensure financial and operational sustainability.

The ASA, in conjunction with the Society for Ambulatory Anesthesia (SAMBA) developed an official set of guidelines for office-based anesthesia.¹⁰ This resource provides information on standards of care for important aspects of office based anesthesia such as facility accreditation and administration, facility safety, preoperative care standards, and practice management. Other than the topics of facility accreditation and the inclusion of marketing, there was no information provided describing the factors that might be essential for incorporating and negotiating contractual agreements, insurance coverage and the concept of practice management.

The American Association of Nurse Anesthetists (AANA) provides practice management resources to all members. These resources include essential elements of new anesthesia services such as sample anesthesia practice agreements, a pro-forma invoice checklist that supports the monetary value of services, and information on different business entities.¹¹ AANA practice management resources provides a link to the U.S. Small Business Administration website, which offers guidance to develop a business plan.

Business Plan

The purpose of developing a business plan is to provide a proper description and analysis of the business including short and long-term strategic objectives.¹² A business plan offers guidance in business development by providing a framework for resource allocation such as

time, supplies and finances. Taking the time to document a business plan assists in identifying potential obstacles, and opportunities to move the business in the right direction. An effective business plan helps to market the business to potential investors or business partners while attracting new global investment opportunities, and provides a benchmark for improvement as growth occurs.¹² There are several components of a business plan that vary depending on the needs, nature and objectives of the business.

Elements of a Business Plan

Executive Summary

The executive summary is often regarded as the most important element of a business plan, and written at final stage after covering all components of the plan.¹² It explains the status of the company, strategic aim, objectives, and significance of product or services offered by company. Elements of the executive summary include a mission statement, company information, growth highlights, and brief description of services, financial information, and forecasting for the future. An executive summary provides a solid understanding of information about the company, and demonstrates a desire to learn more about different business perspectives.¹²

Strategic Overview

The strategic overview provides an in-depth, yet concise description of the company including; its history and proprietors, differentiated product, and services provided other than those of the competitors.¹² In addition to a company description and services, the strategic overview includes a description of consumers, marketplaces, and competitive advantage, that make the business successful and progressive.

Service Offering

The service offering section provides a description of the products or services that the business offers.¹² It is important to describe what makes the business stand out from other businesses, and how it benefits consumers and the life cycle of the products or services. This section involves the listing of intellectual property owned by the business, and any research and development activities performed by the specific business.¹²

Market Analysis

This section of the business plan describes detailed knowledge and evaluation of the industry or market in which the business operates.¹² Elements essential to this section include; industry description and outlooks, critical needs of the consumer, size of the primary target market, market share assessment, pricing and gross margin levels, competitive analysis by product line or service, regulatory restrictions, and legal and legitimate compliance of the business.¹²

Marketing Strategy

This section of a business plan explains different techniques and strategic campaigns that are used by organizations to market businesses.¹² Components of a marketing strategy include; a market penetration strategy, a growth strategy, distribution channels, and a communication strategy. Once the marketing strategy is developed, a sales strategy can be developed. This section explains how the business will reach and sustain customers for their targeted range of product or service.¹²

Organization and Management

In this section of the business plan the leadership hierarchy, management team, and legal structure are defined.¹² The section addresses overhead costs, hiring policies, applicable insurances, and method of service delivery. An organizational flow chart can aid in displaying the hierarchy of roles within the organization. This section assists the potential investors and consumers to understand the function, effectiveness, and performance of the organization. It describes the expectations of an advisory board; in providing business expertise, skills, and intellectualities necessary to manage the business. The board members must be provided in the plan along with their specific roles and their individual expertise, and level of involvement with the company.¹²

Financial Management/Projections

The financial section of a business plan should be developed after analyzing and evaluating the external market trend and developing the clear business objectives. A financial projection ensures that all resources are allocated efficiently.¹² This section includes proper documentation of all the previous, current, and forecasted financial statements. These monetary statements include projected cashflow for the first year, a projected balance sheet, an income statement and a break-even statement. Details about accounting records and procedures are listed, along with a description of funding and investment requirements as well as potential funding sources. It reflects a projection for return on investments to keep the potential investors informed about their funding prosperity.¹²

Operations (Standards of Anesthesia Care)

In the office-based setting, the anesthesia standards of care (Figure 1) are similar to the standards of anesthesia care in the hospital setting, yet reflect some of the unique and specific

responsibilities considered before administering anesthesia in the office-based setting. Per the American Association of Nurse Anesthetists Standards, most office-based settings are unregulated, which emphasizes the importance for the anesthesia provider to have uniform policies in specific areas of practice.¹¹

| | |
|--|---|
| 1. Patient selection criteria | 7. Minimal preoperative testing, including required consultations |
| 2. Monitoring equipment with back up electrical source | 8. Ancillary services (e.g., laboratory, pharmacy, consultation with outside specialists) |
| 3. Adequate numbers of personnel around for planned surgery and anesthesia | 9. Equipment maintenance |
| 4. Treatment of foreseeable complications | 10. Response to fire and other catastrophic events |
| 5. Patient transfer to other healthcare facilities | 11. Recovery and discharge of patients |
| 6. Infection control practices, including OSHA standards | 12. Procedures for follow-up care |

Figure 1. Standards for Office Based Anesthesia Practice and Facility Accreditation

Malpractice Insurance

Malpractice insurance is the type of liability insurance that protects a medical provider from liability associated with wrongful practices that result in bodily injury, property damage, and personal injury such as mental anguish. There are two basic types of malpractice insurance; occurrence coverage and claims made policies. Occurrence policies cover a claim that takes place during the policy period, regardless of the time in which the claim is made, and extends even after the policy is cancelled.¹³ Claims-made policies only cover claims that occurred during the time in which the policy is in effect, and coverage ends when the policy ends. Usually, providers can purchase an additional policy, called a tail policy, which gives the policyholder additional time to report claims that happened during the policy period.¹³

Every malpractice policy delineates two sets of limits. The first limit is the amount that the insurance company will pay for any single claim.¹³ The second limit is the aggregate amount

that the insurance company pays out during the annual term of the policy.¹³ In most states, the usual and customary single claim limit for anesthesia providers is \$1,000,000, with an additional \$3,000,000 allocated as the annual aggregate limit.¹³ If a provider is insured as part of a facility, their aggregated limit may be reduced by other provider's claims paid. For example, a CRNA who is insured by their employer for \$3,000,000 annually, but a coworker has had a claim paid for \$700,000. The aggregate limit left for both employees is then \$2,300,000.¹³

Case Documentation

The documentation standard of care for anesthesia practice providers in the office-based setting is the same as those for anesthesia in hospital settings. The standard is to document, "relevant anesthesia-related information on the patient's medical record in an accurate, complete, legible, and timely manner."¹¹ Important components to include are; informed consent, pre-anesthesia and post-anesthesia evaluations, course of anesthesia involving monitoring modalities and drug administration, and discharge documentation. In addition to regular case documentation, the anesthesia provider should ensure that there is a systematic mechanism for documenting compliance with U.S. Drug Enforcement Agency rules, Board of Pharmacy regulations, Food and Drug Administration Requirements, and U.S. Department of Transportation regulations for accountability and appropriate storage of anesthetic gases.¹¹

The Affordable Care Act (ACA) Meaningful Use Initiative is a federal rule that sets specific objectives for eligible professionals (EPs), to qualify for Centers for Medicare & Medicaid Services (CMS) Incentive Programs. One of the objectives is to utilize an electronic medical record (EMR) to improve quality, safety, efficiency, and reduce health disparities.^{15, 16} Office-based facilities are exempt from the federal incentive program, however the initiative highlights the benefits of accurate and automatic clinical data documentation.¹⁶ This will

facilitate ease with managing case data when generating the anesthesia statement of charges for insurance payers, and clients.¹⁶

Implementation/Conclusion

This section of the business plan provides a clear and concise set of decision points, timeframes, and specific actions that need to be performed for initiating the business, and achieving success.¹⁷ The business plan concludes at this stage, and should be completed with a description of how the business will be successful in meeting the objectives in future, and why the business should be supported.

Anesthesia Billing

Anesthesia providers may be unaware of the value of the services they provide. This topic is may not be extensively addressed in anesthesia education programs, yet a component of an anesthesia provider's salary is based on the revenue that company generates. Anesthesia services are billed by categorizing the procedure with a preassigned base unit amount and adding the sum of the time units.

Base units. All surgical procedures correspond to an anesthesia code that has been assigned a base unit. Most insurance payers and the Center for Medicare and Medicaid Services (CMS) utilize the unit guidebook, *Crosswalk 2016*, a publication of the American Society of Anesthesiologists. The resource specifically describes the anesthesia service for a diagnostic or therapeutic procedure, as a primary source for unit valuation. The guidebook explains that each insurance payer can modify the number of base units assigned to any procedure.⁶ Base units range from three to 20 units. The numerical value for base units in anesthesia cases was developed on factors such as anesthetic risk, anticipated surgical problems, anesthesia skill level required, and general time required for case preparation.¹⁸

Total units. The total anesthesia fee includes the sum of all units multiplied by a pre-negotiated value for each unit. Each 15-minute period is assigned one unit of value. Patient conditions that require more preparation and attention, such as age or comorbidities increase the number of units applied to the total number. The total unit value combines the sum of base units, time units, and modifiers. The monetary value of that unit total is submitted to the payer (Figure 2).^{12, 18}

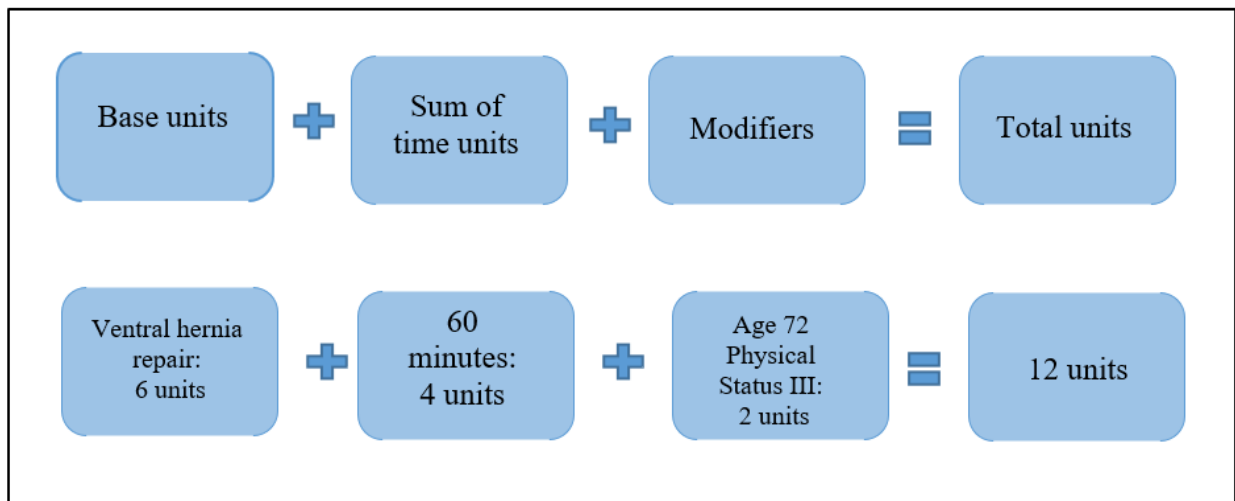


Figure 2. Anesthesia Billing Example

Many factors affect the total revenue that an anesthesia provider generates. Three primary factors are; payer mix, case volume, and devaluation of certain providers by payers.⁶ The ratio of patients to payer type, called payer mix, is the number of patients enrolled in various insurance plans. An example of payer mix is to have 60% of patients that receive a service insured by Medicare, 20% insured privately, 10% self-pay, and 10% uninsured.¹⁴ Payer mix greatly influences the bottom line for healthcare organizations, therefore reimbursement for the same procedure may vary greatly based on insurance coverage.¹⁵ The CMS 2016 reimbursement rate varies by region, and ranges from \$21-\$23 per unit.¹⁴ Conversion factors are calculated based on

theoretical efforts and productivity required of the provider, and costs for productivity enhancing technology.

There are different methods and techniques to manage anesthesia billing in the office-based setting. Commonly the gastroenterologist performs the billing for anesthesia services, and either employs the anesthesia provider directly or hires a person as an independent contractor.⁷ An employed individual is someone whose services the employer, such as the gastroenterologist, can regulate. The gastroenterologist guides the employed individual by directing, what or how a person performs the anesthesia services. The employer directs economic factors in the relationship such as, the amount of money paid to the employee and shift length that they will be providing services. Generally, an employer will withhold income taxes, Social Security and Medicare taxes, and unemployment tax on wages paid to an employee.⁸ An example of an employed anesthesia provider is one who works directly for an organization or is receiving a regular wage, and benefits such as time off and health insurance.¹⁶ Usually, employed individuals are subject to regular and timely performance evaluations.

An independent contractor is a service provider whose services are not regulated by the payer, and are typically paid a flat fee for services rendered.¹⁶ Independent contractors are subject to self-employment regulations for, state and federal income tax withholding. Contracts for independent providers usually do not include benefits such as vacation time, liability insurance or health insurance. An independently contracted anesthesia provider is one who receives a pre-negotiated rate for anesthesia services, but does not receive any additional benefits, and would not be subject to performance evaluations.¹⁶

Legal Issues and Anti-Kickback Legislation

One topic that has influenced business relationships in healthcare is federal legislation that restricts the exchange of money or goods for business contracts. In 1972, the United States Congress enacted the Federal Anti-Kickback Act to prevent healthcare providers from referring patients to specialists based on incentives they receive after some period. These laws are intended to protect patients from receiving inappropriate referrals for medical care they do not need, or that is improper or inadequate. The Anti-Kickback Act is a criminal statute that prevents the exchange of anything of value for the referral of federal healthcare program services.¹⁵ Conviction for a single violation of this statute, could result in penalties of up to \$25,000, imprisonment for up to 5 years, and permanent exclusion from federal healthcare programs for providers on both sides of the transaction.¹⁵

Through the evolution of relationships between anesthesia providers and office-based proceduralists, financial agreements have been called into question regarding compliance with federal reimbursement program guidelines.¹⁵ The Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) is the appointed organization to audit and oversee all U.S. Health and Human Services programs. This department regularly monitors and investigates the integrity and efficiency of government reimbursement programs such as the Center for Medicare and Medicaid Services (CMS), who reimburse for anesthesia services delivered to enrolled participants.^{16, 17}

OIG monitors the financial arrangements between anesthesia providers and proceduralists, who participate in federal reimbursement programs. OIG has issued an advisory bulletin concerning contractual joint ventures, such as anesthesia providers and gastroenterologists, that might lead to a violation of federal anti-kickback laws.¹⁷ The OIG

advisory was issued in relation to reports in which one party in the agreement was charging the other party a financial amount, in exchange for anesthesia billing rights. OIG ruled this scenario as a “kickback” scenario, in which anesthesia services are being billed for twice, which is a violation of federal law.¹⁷ An example of such an arrangement would be for a gastroenterologist to charge the anesthesia provider a fee for the service contract.

In response to concerns from healthcare providers regarding the prohibition of certain types of services, Congress authorized OIG to designate certain types of health service relationships that would not be subject to prosecution. These relationships are known as “safe harbor” relationships, and were designed to protect legitimate business arrangements, such as the sale of one practitioner’s practice to another. There are 23 anti-kickback safe harbor relationships listed in The Code of Federal Regulations.¹⁶

In 1989, Congress included a provision in the Omnibus Budget Reconciliation Act of 1989, which barred physician self-referrals for clinical laboratory services. Omnibus Budget Reconciliation Act of 1993, later expanded the prohibited services to include a broader range of health services, and applied to both Medicare and Medicaid.¹⁶ These legislative actions were named The Stark Law, after the congressman who authored them. The Stark Law relates to the federal anti-kickback law. These federal regulations impose specifications on any business relationship between an anesthesia provider, and a proceduralist such as a gastroenterologist.¹⁶

While contracts between anesthesia providers and proceduralist vary, three common employment models form the basis of most contracts.¹⁷ The fee-for-service model occurs when the anesthesia provider conducts the anesthesia, and takes responsibility for billing and collection for their services. In this model, there is little to no financial exchange between proceduralists and anesthesia providers, and therefore very little risk in violating federal law.¹⁷

The employment model occurs when the anesthesia provider is an employee of the proceduralist, and has turned over anesthesia billing to the proceduralist.¹⁷ This type of arrangement allows the anesthesia provider to be paid a regular salary, and the proceduralist to retain revenue more than the cost of employing the provider. This model carries very little risk of violating federal law, but could violate some state regulations, based on fee splitting restrictions.¹⁷ An example of fee splitting would be if a practitioner referred a patient to another specialist, and then received payment from him or her for the referral.

The third arrangement recognized is the company model. This model entails the proceduralist forming a separate company for anesthesia services, which employs the anesthesia provider, and bills for those services directly.¹⁷ This facilitates the anesthesia reimbursement to go directly back to the proceduralist. The OIG has warned that because of this revenue going back to the proceduralist, it is considered a “kickback” of anesthesia reimbursement, and is a violation of federal anti-kickback regulation.¹⁷

CRNA Compensation and Benefits

The AANA has conducted an annual survey of CRNA compensation and benefits for more than 25 years. In 2016, AANA surveyed 35,596 AANA members for information related to CRNA compensation. Thirty seven hundred and ninety eight AANA members responded to the online survey.¹⁹ The survey revealed that 33% of CRNAs report themselves as being an employee of a group, 6% report themselves as being an employee in other settings, 13% report being an independent contractor, and 3% report themselves as being an owner/partner in a group.¹⁹ AANA reports that the median annual salary for CRNAs who are employed by a group is \$168,000, and \$161,000 for those who reported employment in other settings.¹⁸ Annual salary data reported does not include other sources of income such as overtime pay, or any bonuses or

incentives. Median annual income reported for CRNAs that reported themselves as an owner or partner was \$243,500, and \$204,500, for independent contractors.¹⁹

The AANA survey reports that there are numerous benefits that can be quantified as income in addition to monetary remuneration. The benefits reported were health, malpractice, dental, life, disability, and vision insurances, and reimbursement for continuing education, professional association dues, college tuition, wellness credit, and daycare.¹⁹

A thorough review of the literature revealed no consolidated source for information on which type of business relationship is most beneficial for anesthesia providers in situations where they enter a business agreement with some type of procedural practitioner. The literature revealed various factors that must be considered when developing an anesthesia business plan. The purpose of this project, is to analyze components of developing a new anesthesia business, objectively articulate the cost of start-up anesthesia services, compare various compensation avenues to serve as a guide for future anesthesia start-up businesses, and compose an anesthesia business plan.

Theoretical model

The theoretical model that explains why an anesthesia provider would want to pursue independent billing models, comes from a theory of motivation called the Self Determination Theory (SDT), described by Psychologists Edward Deci and Richard Ryan.²⁰ This theory provides a framework of motivation for human behavior. It explains the importance of balancing intrinsic and extrinsic motivating factors, to achieve a healthful psychological balance and success in life.²⁰ These motivating factors contribute to an individual's autonomy, competence, and relatedness, which results in the highest quality motivational factors and engagement for activities, referred to as self-determination (Figure 3).

An anesthesia provider's drive toward independent practice, including business relationships with other providers, can fulfill the described sense of autonomy, competence, and relatedness within the SDT framework. The degree to which any of these three elements is present, will have a robust determination on an individual's wellness in a setting.²⁰ When these factors are absent, as in some employment situations, individual wellness and workplace productivity may become low. This can contribute to stagnation of professional growth. On the contrary, when intrinsic and extrinsic motivational factors are optimized, personal wellness and productivity moves to high levels and professional growth prospers. The growth enables all patients, proceduralists, and anesthesia providers to benefit from the wellness gained in self-determination.

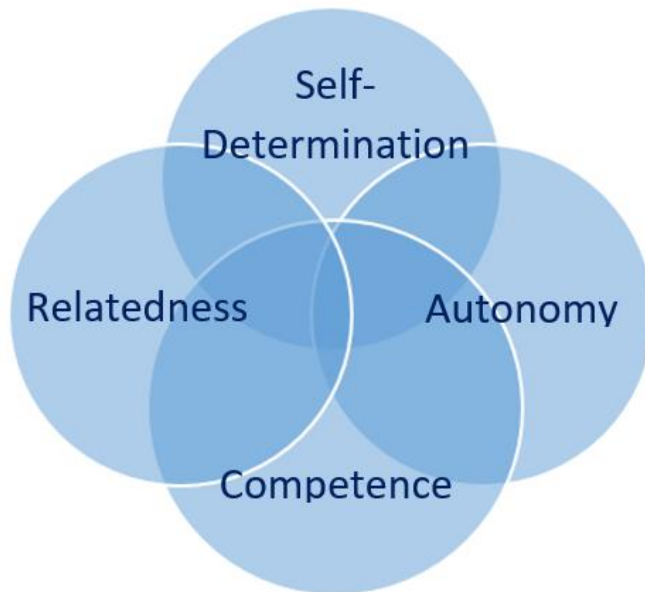


Figure 3. Motivation for Self Determination Theory

Methodology

Information for the formulation of the business plan created for this project was obtained from a review of the literature, and consultation with professionals including; a small business

attorney, a certified public accountant, an insurance provider, and a practice management specialist. The general components of a business plan specific to anesthesia start-up services was assembled into one document. The business plan developed, is meant to be clear and concise, to serve as a guide for anesthesia business entrepreneurs wishing to start collaborative practices in office-based settings. The purpose of this business plan is to provide a written description and analysis of an office-based anesthesia business, including both short and long-term goals. It provides a 3-4-year projection and outlines the route the business intends to take, to achieve the annual milestones and revenue projections of the business.

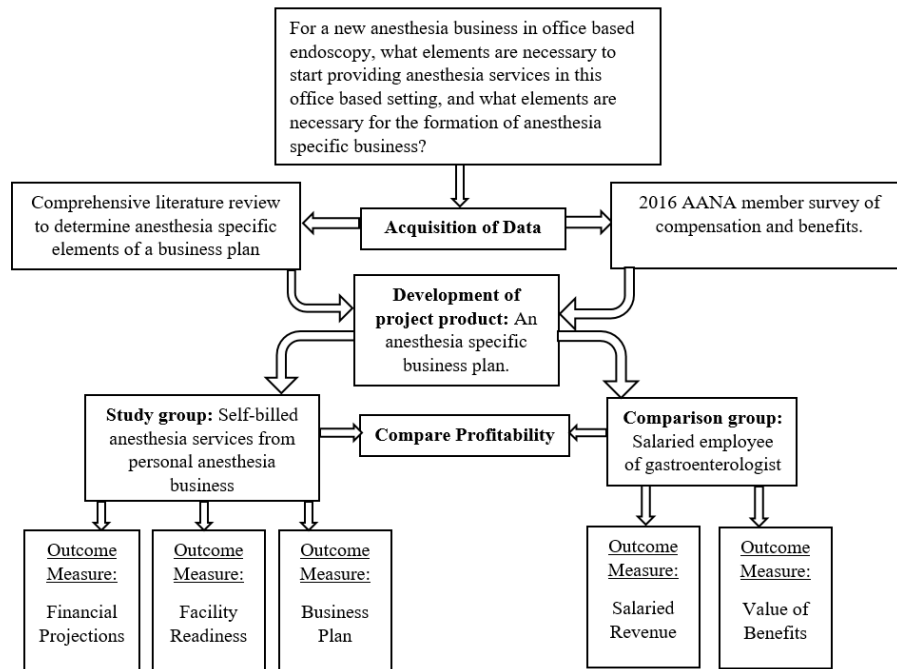


Figure 4. Conceptual Model

Ethics

This study was presented to the University of Michigan/Flint Institutional Review Board (IRB) Research Compliance Specialist. It was determined that this study was exempt from IRB

approval. No compensation was given to respondents for their involvement in the research or study. The cost of this project was minimal and was incurred by the researcher.

Design

This research project was designed to utilize several resources toward the development of a business plan to assist in the implementation of an anesthesia practitioner business that collaborates with an outpatient, office-based gastroenterologist. The following sources were used to obtain information for the development of the business plan created for this project.

Small Business Administration

The business plan was developed using a template from the website of the United States Small Business Administration (SBA). The website served as a resource for business plan components, and incorporated elements unique to anesthesia. Within the business plan, AANA provided the anesthesia specific components such as practice and documentation standards.

Financial Data and Start Up Costs

Financial data for the business plan was provided by the 2015 AANA compensation and benefit survey, the 2016 ASA compensation survey, and legitimate quotes from experts from the respective fields of business development components. The cost of each aspect of business start-up, such as practice contracts, that would require specific professional fees was determined by obtaining cost estimations from respective professionals in the state of Minnesota. The data was entered into a spreadsheet to summate the relative costs for a business start-up. This portion of the project assisted in defining common elements that are essential to starting up an anesthesia business that is equipped to manage self-billing, and demonstrate the accomplishing this.

Reimbursement

Data from ASA's 2016 Annual Compensation Survey of Members was utilized to calculate reimbursement rates.²¹ This per unit reimbursement rate was then multiplied by conversion factor average for endoscopic procedures. The 2016 Relative Value Guidebook was utilized to determine unit quantity per procedure.²² These values were entered into a spreadsheet to demonstrate billable anesthesia dollars per procedure.

Production Levels and Utilization

To estimate the production level of clinics that specialize in outpatient gastroenterology, data from an article in *Becker's GI & Endoscopy* was utilized.²³ Regarding case volume, Doctor Barry Tanner, President and Chief Executive Officer (CEO) of Physician's Endoscopy states that, "The key is to maximize utilization of each available procedure room".²¹ This CEO explains that, "there is an average of 251 operating days per year, and full utilization for a GI procedure room operating eight hours each day would be approximately 16 cases per day (30-minute time slots per case), or roughly 4,016 annual cases. Sixteen cases per day is rarely achieved due to cancellations, no shows, etc. However, this resource suggests that aiming for 80 percent utilization is certainly reasonable (around 3,200 cases annually). Achieving this utilization per room, and if the ASC is not overbuilt, should result in a successful GI ASC".²¹

Doctor Stephen Sears, a physician gastroenterologist in Colorado acknowledges that at the ASC where he practices, proceduralists average 12 procedures per day, or one every 30 minutes.²³ Based on the 2016 AANA survey of Certified Registered Nurse Anesthetists, a range of per case, per hour, and per day wages was entered into a spreadsheet to demonstrate gastroenterologist-paid anesthesia service revenue. This data represents anesthesia provider revenue for a financial agreement where the facility bills for anesthesia services, and the

anesthesia provider is either an independent contractor, or a salaried employee of the facility. A comparison of the two types of billing models was constructed to demonstrate billable anesthesia service amounts.

Expert Consultation

Anesthesia specific business components were discussed extensively with Broadston Consulting Firm (BCS). BCS is an independent firm that specializes in the practice management of nearly every type of anesthesia practice setting. The firm was contacted based on the recommendation of 3 independent anesthesia providers. BCS was contacted via telephone, and continued discussions occurred via electronic mail and occasional in person meetings.

Based on the advice provided via telephone and electronic mail from BCS, an ad hoc list was made for various essential components of a CRNA self-billed practice model. Professional contacts were established based on professional recommendation with a local attorney, an accountant, and an insurance provider for the establishment of a limited liability corporation, a practice agreement, the establishment a state and federal tax identification for the newly formed corporation, and malpractice insurance.

Contact was made with the attorney, accountant, and insurance providers via telephone, and all correspondence and practice documents were completed via electronic mail.

Compensation Models

Salary data was collected from the 2016 AANA compensation and benefit member survey so that various reimbursement models could be listed for a side by side comparison. The conversion factor utilized for this comparison was taken from the American Society of Anesthesiologist's (ASA) 2016 compensation survey of providers. The survey revealed that the

national average commercial conversion factor for 2016 was \$71.02 per unit, and the national average conversion factor for Medicare services was \$21.99 per unit.²³

Analytic plan

An analytic plan for implementation determined the time scale required to complete specific research until the expected research outcomes were gathered. Gathering or collecting the information is a single stage, and after complete analysis and evaluation of salary data, business expense, self-employment outlay (such as insurances), and regulation of office-based anesthesia care, the acquired information was entered in formal document. It took 12 months to complete the implementation of the project. Financial estimates for necessary start-up services were requested and submitted from June 2015 through January 2016. A reliable and proper spreadsheet was used in the project that incorporates all the figures and financial calculations. These calculations were performed manually by two independent Master's prepared individuals to increase interrater reliability. The calculations were combined and analyzed to determine the elements of a business start-up.

Dissemination plan

The dissemination of this project is in the form of a poster presentation for CRNAs at the AANA Annual Congress in August 2017, and Minnesota Association of Nurse Anesthetists (MANA) annual education meeting in October 2017. In addition to a side-by-side cost comparison, the poster will include a list of resources that are important to access for an anesthesia business start-up, resources allocation, sample practice agreement, important information on implementation, and a list of facility standards for office based settings.

Discussion

The literature was extensively reviewed to develop a business plan to start an anesthesia business for the provision of anesthesia in an office-based gastroenterology setting. Nonclinical factors of business startup were addressed by category, and provided in the business plan as points of consideration. The following information was incorporated into the business plan created for this project, based on knowledge obtained from resources mentioned in the methodology section of this document. The practice established as a result of this investigation is Capital Anesthesia Care, LLC.

Professional Advisors

Working with professional advisors such as attorneys, accountants, insurance advisors, and investors is necessary in establishing and maintaining a properly functioning business. Anesthesia business experts recommend using a variety of different advisors, and seeking new perspectives from peer recommendations whenever possible.²⁴ Clear communication is important to ensure that the advisor understands the provider's vision and goals. The professional relationship with these advisors should be long term to maximize business results.²⁴

A small business attorney was utilized for the practice established by this author, to set up a limited liability corporation. The attorney charged a fee of \$150.00 to set up the legal entity. This involved one meeting to define the business needs for incorporating, and communicate official roles and responsibilities of the business owner. An accountant was contracted for income tax allocation. The accountant charged a fee of \$250.00 for evaluation of revenue and tax filings. Malpractice insurance was purchased for an annual fee of \$4400 per year for full time self-employed coverage. The policy coverage is for \$1,000,000 per claim and \$3,000,000 aggregated occurrence policy.

Billing and Practice Management

There are many benefits to being self-employed in an office-based setting. These benefits include flexibility, control and financial growth, however there are many responsibilities with running a personal business. The potential success and growth of a growing practice may require the use of a practice management company to track records and bill patients for third party payers for their services. Utilizing a practice management service can help the anesthesia provider to achieve and maintain the maximum level of reimbursement for their services.

An anesthesia practice management company can assist the provider with many nonclinical tasks such as service proposals, charge development, provider credentialing, and service level issues such as patient account services. A practice management company can help ensure that the anesthesia performance is measurable and available quickly.^{23,24} The practice management company selected for the business described in this project is Broadston Consulting Services (BCS) practice management firm requested a rate of 5% of anesthesia revenue for billing services. The firm offered to manage all aspects of anesthesia billing including patient consultations prior to services rendered, all the way through the continuum of interactions to follow up after reimbursement occurs.

Compensation

There are many different compensation avenues for anesthesia services in the office-based setting. One common way, is for the anesthesia provider to be reimbursed by the surgeon, proceduralist, or facility. In these scenarios, the anesthetist is typically paid by the day, hour, or case. The anesthesia reimbursement fee is based on regional trends. Utilizing a set daily or hourly reimbursement fee can help mitigate loss of revenue related to suboptimal case volume,

as is the sometimes the situation when working with a proceduralist new to the geographic area, who has not built an effective referral base.²⁵

Another common way for the anesthesia provider to be reimbursed is to bill insurance payers and patients directly. In these reimbursement scenarios, it is necessary for the anesthesia provider to establish fees with the insurance payers for the conversion factor, the value of time units per hour, and any policy for discounting the conversion factor for exceptional cases such as cash cases.

Regardless of what model of reimbursement the anesthesia provider utilizes, to maximize reimbursement fees, it is important for the provider to know the value of the services in which they are providing. An analysis of hypothetical or past case scenarios should be performed to determine the worth of services. In addition to the value analysis, the anesthesia provider should organize proper billing forms, formulate collection messages and procedures, evaluate accounts receivable, and secure a contract with a billing agency.

For the practice established as a result of this research project, a side by side comparison for reimbursement scenarios was performed using national averages for conversion factors, case volumes, and the 2016 AANA compensation member survey.¹⁹ Calculations for the self-billed model of reimbursement was completed based on 12 cases per day, with a 7 unit per case average.²¹ A patient payer mixture of 60% Medicare services and 40% private insurance payer services was utilized. This payer mixture and conversion values are based on the ASA Compensation Survey of Members, which documented that the national average commercial insurance conversion factor in 2016 was \$71.02 per unit, and \$21.99 for Medicare services (Table 1, Graph 1).²¹

Gross profit for self-billed anesthesia services in an office-based gastroenterology business performing 12 cases per day with a 60/40 insurance payer mixture for 221 services days per year was calculated to be \$729,163 annually, or \$34,94.57 per day (Table 2). These figures contrast with an annual gross profit of \$221,000 for employment at a rate of \$1000 per day, for 221 service days per year (Table 2).

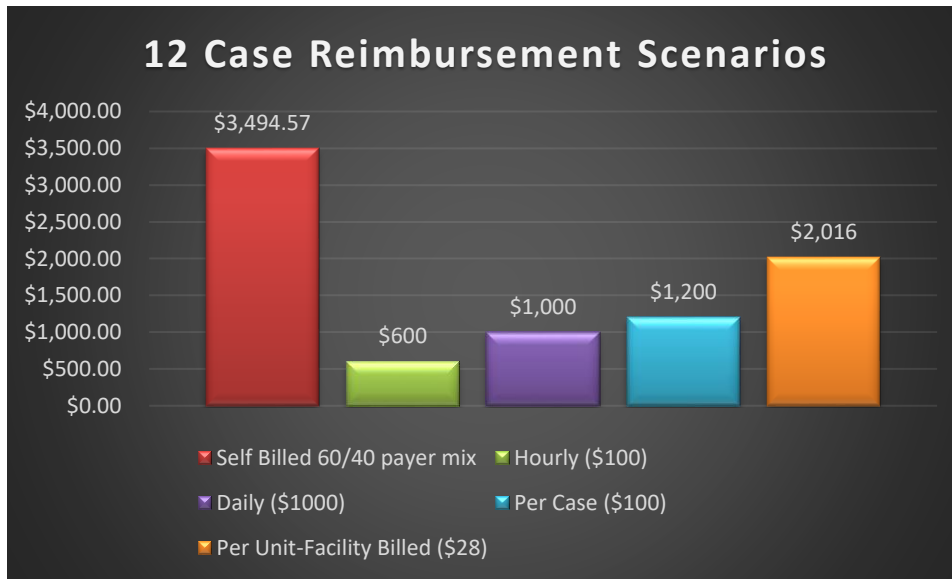
Anesthesia Profit Projection Per Day

Self Billed (60/40 payer m Hourly (\$100) Daily (\$1000) Per Case (\$100) Per Unit-Facility (\$28)

Cases (7units/case)

| | | | | | |
|----|------------|---------|---------|---------|---------|
| 6 | \$1,747.28 | \$400 | \$1,000 | \$600 | \$1,008 |
| 12 | \$3,494.57 | \$600 | \$1,000 | \$1,200 | \$2,016 |
| 18 | \$3,544.77 | \$1,000 | \$1,000 | \$1,800 | \$3,024 |

Table 1



Graph 1

| | Self-billed* | Employed or 1099** |
|---------------------|----------------------|--------------------|
| Gross Profit | \$877, 134.56 | \$251,000 |

* 12 cases per day, 251 days per year, 60% Medicare/Medicaid (\$21.99/unit), 40% Private Payer (\$71.02/unit)

**\$1000/10hr day

Table 2

Operating expenses for a self-billed business were calculated to be \$471,612.14 annually. These figures include a budget for malpractice, health, and disability insurance plans based on rates quoted from AANA Insurance Services. Operating expenses for employed individuals was calculated to be \$132,600. A 25% tax rates utilized for both employment scenarios, and six weeks of unpaid vacation was calculated into each of the scenarios (Table 3). Net profit self-billed anesthesia services was calculated to be \$405,702.42 annually, and \$132,600 annually for employed anesthesia services. (Table 4).

| | Self-billed | Employed |
|----------------------------|---------------------|------------------|
| 5% practice management fee | \$43,856.75 | \$0.00 |
| 6 weeks unpaid vacation | \$104,837.00 | \$30,000.00 |
| Taxes (25%) | \$193,074.39 | \$55,250.00 |
| Insurances | \$10,000.00 | \$0.00 |
| Accounting and Legal | \$4,000.00 | \$0.00 |
| Retirement (15%) | \$115,844.00 | \$33,150.00 |
| Total expenses | \$471,612.14 | \$118,400 |

Table 3

| Net Profit | | |
|-------------------|---------------------|------------------|
| | Self-billed | Employed |
| Gross profit | \$877,314.56 | 251,000.00 |
| Expenses | \$471,612.14 | \$118,400 |
| Net Profit | \$405,702.42 | \$132,600 |

Table 4

Annual case minimums were calculated for self-billed services based on a 60/40 payer mix, and the same conversion factors for such. An annual case volume of four cases per day or 884 cases per year would be the breakeven point for services rendered in a self-billed setting. This would provide an annual net compensation rate of \$141,907.00 (Table 5). This is an important production figure to keep in mind when considering providing services to a newly established proceduralist, whose referral base may be limited while getting established.

| Case Minimums | | | |
|----------------------|--------------|--------------|--------------------|
| Case volume | Self-billed | Employed | Annual case volume |
| 3/day | \$102,931.24 | \$118,400.00 | 663 |
| 4/day | \$141,907.16 | \$118,400.00 | 884 |

Table 5

Facility Accreditation

Official accreditation of an outpatient office-based facility serves multiples purposes. First, it provides patients and healthcare providers an official commitment to the highest-level patient safety and care. It provides a nationally recognized benchmark of quality, it facilitates referrals, and increases a practice’s competitive edge. Facility accreditation means that it has met a set of eligibility standards that include practitioner licensure, and patient care and procedure minimum volumes. It also means that the facility has undergone an onsite survey within three years to educate and provide guidance to practitioners there on standards of patient care.²⁵ The

other benefit of having an official accreditation designation is that it makes the providers eligible for reimbursement from insurance payers such as CMS.²⁵

There are four major accrediting organizations that provide oversight concerning the safety of office-based outpatient facilities: The Joint Commission (TJC), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), and Healthcare Facilities Accreditation Program (HFAP).^{25, 26} Anesthesia providers should take responsibility for ensuring facility compliance with these accredited standards of care before assuming care for patients at an outpatient office-based setting. The facility where Capital Anesthesia Care was established is accredited by AAAASF. This author verified that the components of accreditation were met, and the facility was compliant with them prior to initiating services at the site.

Facility Administration

Before entering a practice agreement for services at a facility, there are several elements of facility administration that should be evaluated by the anesthesia provider. As regulated by state law, a legitimate medical director should be designated, who is ultimately responsible for the facility and all personnel.²⁷ The medical director for CAC's contract was the sole endoscopist at the facility. An official policy and procedure manual that addresses the facility's standards for provider accreditation, documentation, record keeping, quality improvement activities, professional liability, and policies for clinical care issues.²⁸ These policies were in place at the start of CAC's services, however, they were not documented in a policy book initially. CAC verified by sight that all healthcare providers at the facility hold a valid license to practice, and are certified in Advanced Cardiac Life Support (ACLS). Upon the start of business, CAC verbally agreed to write a plan to assess and improve anesthesia outcomes, which includes data

keeping on quality indicators such as recovery times, negative outcomes such as corneal abrasions or nerve injuries, temperature management, and patient satisfaction. This quality improvement plan will include peer review, risk management, and benchmarking with minimally an annual review.²⁹

It is important to complete a review of liability coverage with the insurance underwriter to ensure that all healthcare providers at the facility are appropriately licensed and credentialed, and have adequate malpractice insurance coverage.³⁰ Vicarious liability is the tort that imposes responsibility upon one person for the failure of another, and is a common concern for anesthesia providers in the office-based setting.³⁰

Facility Safety

The equipment and engineering standards for construction in an office-based setting are far less than that of a hospital. Many office-based settings are not designed for general anesthesia to occur in them. Anesthesia providers should visually inspect aspects of the facility to assume responsibility for it, and ensure patient care.³¹

Fire Safety

Most hospitals have a two-stage fire alarm, sprinkler system throughout, fire separation areas with wide corridors and stairs, a protected air supply, and elevators that can accommodate beds.^{26, 27} Office buildings may not meet that standards of the National Fire Protection Association (NFPA). The anesthesia provider should ensure that there is a functional fire safety plan, including evacuation drills on a periodic basis.

Ventilation

The control of temperature and humidity, including properly designed ventilation system is less regulated in office-based settings than those of hospitals. The NFPA's standards regarding

gas supplies may not apply unless stipulated through an accrediting organization.²⁷ Proper storage, ventilation, back up supply with alarmed monitors needs to be ensured.

Equipment Safety

The Society for Ambulatory Anesthesia provides a set of recommendations for equipment safety.^{32, 33} First, they recommend that anesthesia and life support equipment be fully factory supported. This means that the manufacturer provides technical support, parts availability, and service training. Second, the anesthesia machines should not be obsolete. Third, the facility should have backup power systems in place for life support equipment, and should have a minimum of two sources of power. The emergency backup power unit should provide at least 90 minutes of power to all life safety devices. Fourth, a periodic inspection and test should be completed on all emergency power systems. Finally, ground fault circuit interrupters should be used if there are no line isolation monitors to prevent electrical shock.^{29, 30, 33}

Conclusion

There is a general lack of information in the literature regarding the steps to starting new anesthesia services in an ambulatory office-based setting. This study has shown that it is possible to create a business plan that is effective in addressing all steps necessary to safely and effectively provide services in a facility. The plan articulates elements that ensure the facility is compliant with state and federal regulations, while maximizing reimbursement for the anesthesia business.

While the AANA provides segmented brief documents on several aspects of new anesthesia business, this study has provided an outline to assist individual providers with developing a plan to ensure all essential elements of new services and business are addressed.

The major strength of the business plan, is that it is a single, clear and concise document that serves as a reference for business startup and maintenance.

Study Limitations

This study was limited by the willingness of the gastroenterologist to comply with facility accreditation standards, signing over the anesthesia billing rights, and coordination of the anesthesia practice management firm. These issues created a barrier for progress in the development of a new anesthesia business. Another limitation of this study is the amount of cases the gastroenterologist was performing that required anesthesia services. It was difficult for the gastroenterologist to break into the independent gastroenterology market and receive the patient referrals needed to support the business. There was a need for the gastroenterology business to utilize anesthesia services as a marketing tool for referrals, yet there were not enough cases to support the outlay of hiring an anesthesia provider.

Recommendations

To streamline the process while working with a potential service provider such as a gastroenterologist, a clear timeline of essential tasks should be set so that both the anesthesia provider and the medical service provider have a way of benchmarking progress and anticipating potential setbacks. The anesthesia provider should keep copies of all licensing, insurance, and credentialing paperwork for ease of access on short term notice.

There is an element of marketing that needs to be done from the anesthesia provider to the gastroenterologist when negotiating the anesthesia contract. Independently practicing gastroenterologists are aware that many anesthesia-gastroenterology practice agreements involve the gastroenterologist billing for anesthesia services and then simply reimbursing the anesthesia provider a fraction of that amount with an hourly salary. This notion created a barrier for this

author in negotiating the anesthesia contract. The gastroenterologist was skeptical of signing over the anesthesia billing rights to CAC, yet at the same time he was not willing to take on the outlay of paying an anesthesia provider a contracted compensation rate. It was very important for this author to regularly reassure the gastroenterologist on the benefit of the anesthesia-billed practice agreement, and demonstrate how it was going to decrease upfront cost for the facility.

For this study, the gastroenterologist was very eager to initiate practice at the facility, even before it was accredited. This created a problem for the anesthesia provider that required constant vigilance to ensure that accreditation standards had been complete, and the facility was compliant with them.

Implications for Practice

The purpose of any business plan is to produce a document that describes the business entity, and provides a clear vision for success and growth. Taking the time to establish these directives will ensure that CRNAs will address components of new business that they are not otherwise familiar with. This project demonstrated that it is possible to create a valid and relevant business plan, which addresses anesthesia specific practice elements. The project also serves as a written comparison of compensation models for anesthesia services in the office-based gastroenterology setting.

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