The Use of Clinical Pharmacists in Primary Care Practices

A Strategic Business Plan
Existing Business

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Table of Contents

Project Summary

CMS's MIPS/MACRA programs continue to force healthcare providers to document and prove their focus on performance improvement, cost effectiveness, and clinical and quality outcomes. While worthwhile and noble; the operations, data collection, and implementation of these programs can negatively affect already overburdened physicians and practices. Furthermore, non-compliance can significantly decrease revenues. To address these requirements, practices need a solution that not only satisfies CMS's requirements but also contributes to the bottom line and advances care.

There is a growing body of literature stating that clinical pharmacists may help address the needs of practices and physicians to document clinical quality, perform medication reconciliations and drug utilization reviews, and promote evidence based medical therapy. This ultimately decreases adverse events and achieves goals of therapy. As members of the care team, clinical pharmacists can support the level of care that physicians provide to patients. The largest barrier for pharmacists to consistently provide direct patient care in outpatient settings is the lack of being recognized as a "healthcare provider", like Nurse Practitioners or Physician Assistants, by CMS. However, given that they are CMS recognized them as "healthcare professionals," pharmacists can independently provide Annual Wellness Visits, provided that they are practicing under direct supervision, are licensed in their state, and working within their scope of practice. As part of the care team providing direct patient care, pharmacists are able to close care gaps and pay for themselves, therefore expanding the practice's overall capacity. This business plan will explore the use of clinical pharmacists in practices to meet both clinical quality and financial goals while reducing physician burden.

Executive Summary

Healthcare systems have been experimenting with interprofessional collaboration in primary care to improve professional effectiveness and quality of practice among professionals. The use of nurse practitioners, physician assistants, behavioral health specialists and others have been well understood and documented; however a new arrow in the quiver of healthcare administrators is emerging: the use of clinical pharmacists. Clinical pharmacists are ambulatory care focused clinicians that can work alongside primary care physicians in the medical clinic setting. Differing from retail pharmacists, clinical pharmacists provide direct patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. The American Society of Health-System Pharmacists establishes standards for ambulatory care pharmacy to facilitate practice advancement. To be eligible for direct patient care in primary care settings, clinical pharmacists have typically completed a minimum of an accredited post-graduate residency program in ambulatory care.

St. Joseph's/Candler ("SJ/C") is the largest regional healthcare system in southeast Georgia. Based in Savannah, GA., St. Joseph's/Candler has over 40 medical clinic locations in a variety of medical specialties in both Georgia and the South Carolina low-country. Candler Hospital, one of the two anchor hospitals for SJ/C, is the second oldest continually operated hospital in the United States. The mission of the organization is: "Rooted in God's love, we [St. Joseph's/Candler] treat illness and promote wellness for all people."

Corporately, St. Joseph's/Candler is well positioned to take advantage of lucrative services within its market, including oncology and cardiac care. SJ/C enjoys strong community support and favorable patient satisfaction scores. The system maintains a robust physician network (i.e. medical group) that steer tertiary medical services to the system's member hospitals and physicians.

St. Joseph's/Candler is led by its Chief Executive Officer, who has been at the helm of the organization for over three decades. His tenure with the system affords a continuity that few other organizations enjoy. Similarly, the system's longtime Director of Pharmacy Services, has led the

pharmacy department through several growth spurts. His ability to pivot the business model of his department allowed for the current success of the clinical pharmacy program in the ambulatory clinics. The medical group is led by a Divisional Vice President, whose specialty is business development and general oversight. Under his leadership, the medical group has significantly expanded in scope and regional footprint. This growth includes maximizing the physician and clinics' patient care production by employing clinical pharmacists.

St. Joseph's/Candler largest competitor is a for-profit hospital that is owned by a national publicly traded corporation. Additional competitors include: private medical groups and sole proprietor physicians throughout numerous communities within the region.

Starting during fiscal year 2018 (April, 2017) St. Joseph's/Candler began to deploy clinical pharmacists to some of its larger primary care offices to primarily assist physicians and clinics with the completion of Medicare Annual Wellness Visits ("AWV"). These visits are not only lucrative for the healthcare system, but also serve as data collection interviews that contribute to the clinician's understanding and the patient's overall health. By having clinical pharmacists complete these visits rather than physicians, it significantly increased the practice's overall access, capacity, and output. Additionally, the increased AWVs allowed the system to meet data collection requirements of third-party payer quality incentive programs that contributed to the organization's bottom-line.

St. Joseph's/Candler was able to deploy its team of ambulatory care pharmacists to its larger primary care offices with a significant Medicare population for $65 per hour. These pharmacists were tasked with seeing a minimum of six Annual Wellness Visits per day; which are reimbursed by Medicare at ~$110 per visit, excluding additional billings. At this rate the medical group would incur approximately $660 ($110 x 6 visits) of additional revenue and $520 ($65 x 8 hours) of additional expense per 8-hour day. Because the other costs for the program were largely sunk, the program maintains a modest positive return-on-investment ("ROI") on the billings alone. When not performing AWVs, the clinical pharmacists continue to participate as members of the care team with other revenue generating activities including: chronic care management ("CCM"), transitions of care ("TOC"), or direct

patient care support with supervising providers. The break-even point of the program was within the first month using Generally Accepted Accounting Principles ("GAAP").

After its first complete fiscal year (the first year was partial), the program appreciated more than $75,000 in annual net income. In addition to this amount, quality bonuses from third-party payer programs have spiked, although the specific amounts contributed to the clinical pharmacy program have not been determined.

Part I: The Organizational Plan

Summary description of existing business

St. Joseph's/Candler is the largest health system in Southeastern Georgia and has numerous offices in the Low country of South Carolina. Based in historic Savannah, GA., St. Joseph's/Candler Health System was founded in 1997 by combining St. Joseph's Hospital and Candler Hospital, both individual institutions with storied pasts. The 384 bed Candler Hospital is Georgia's first hospital (first chartered in 1804) and the second oldest continuously operating hospital in the United States. The 330 bed St. Joseph's Hospital began in 1875 when the Sisters of Mercy, a Catholic ministry, took over the operations of the Forest City Marine Hospital in what is now the historic district of Savannah.

Still anchored by its two original hospitals in Savannah, St. Joseph's/Candler Health System has expanded to encompass two additional "micro-hospitals" throughout the region and a robust physician network with 40+ locations in Georgia and South Carolina encompassing a number of medical specialties from primary care to cardiothoracic surgery.

A multi-time *Magnet Designation for Excellence in Nursing Service Award* recipient, St. Joseph's/Candler's mission is: "Rooted in God's love, we [St. Joseph's/Candler] treat illness and promote wellness for all people."

S.W.O.T. Analysis

St. Joseph's/Candler's strengths are numerous. The system operates the second oldest continuously operated hospital in the United States making the system's longevity a major strength. This despite an ever changing healthcare landscape, both locally and nationally. The system has strategically positioned itself in the marketplace to take advantage of high revenue services such as oncology and cardiac care. Known throughout the region as the healthcare system of choice, St. Joseph's/Candler enjoys strong community support, loyalty, and rapport.

Over the last seven years, the health system has created an expansive physician network of employed and Physician Service Agreement ("PSA") physicians in a variety of medical specialties. These specialties include: family practice, internal medicine, urgent care, OB/GYN, podiatry, cardiology, otolaryngology, facial plastics, audiology, podiatry, endocrinology, neurology, radiation oncology, rehab medicine, hematology/oncology, sports medicine, vascular surgery, and cardiothoracic surgery. This robust network of physicians has created a strong internal referral source for lucrative diagnostic and inpatient services that has stabilized income streams and fueled growth. Being a 501(c)(3) not-for-profit organization, the system has also taken advantage of select governmental programs such as 340(b) pharmaceutical pricing; which reduces operational costs, especially for oncology infusions. Profits are reinvested in company infrastructure, physician recruitment, facility upgrades, and charitable care and causes. This strategy affords state-of-the-art buildings and equipment like CyberKnife and multiple Da Vinci surgical robots; which enhances the community perception of the organization and the care given.

Additionally, St. Joseph's/Candler experiences very stable senior leadership; many of whom are linchpins of Savannah society. The current system CEO has been in the same position for nearly 30 years, an unheard of tenure for such a position.

Despite its numerous strengths, St. Joseph's/Candler has several obvious weaknesses that are constantly being addressed and mitigated. Unlike its major competitor, the healthcare system lacks the financial backing of a large nationwide for-profit, publicly-traded, corporation and is solely reliant upon profits and investment returns for operating capital. Strategically, St. Joseph's/Candler has acquiesced certain services to its competitor, choosing to focus on predictable and familiar healthcare delivery offerings and models. For example, its competitor operates the only Level I trauma center in the region. Additionally, St Joseph's/Candler doesn't offer a comprehensive Children's' Hospital for pediatric care. The lack of these services and their accompanying intensive care units places the system at a disadvantage for certain patient populations. The previous sentence notwithstanding, trauma and children's' care are often majority funded by poorly reimbursed state Medicaid programs.

Furthermore, both St. Joseph's and Candler Hospitals are continually at or near capacity. While constantly being updated and expanded, both hospitals' censuses allow little margin for growth. The lack of in-the-building real estate occasionally hampers growth of new services or technology. The system has chosen to address these concerns by placing "micro-hospitals" in the key feeder communities within the region, thereby alleviating pressure at the two major hospitals.

St. Joseph's/Candler's is heavily investing in reaching the community where they live, work, and play. As customer/patient preferences evolve the healthcare system has chosen to expand its physician network throughout the region thereby minimizing travel for the consumer. These regional outposts can be as simple as a physician's office or as complex as a micro-hospital; which incorporates physician offices, an imaging center, ambulatory surgical center, endoscopy suite, urgent care, physical therapy, and time-share space for a rotating cadre of specialists. St. Joseph's/Candler continues to take advantage of the chaos and overall negative community perception of its major competitor; which erupted when the system was sold to Hospital Corporation of America ("HCA") and became a for-profit institution. This transition created a boom of physicians wanting to leave Memorial Health; many of which were highly regarded. Lacking non-compete clauses in their contracts, many of these physicians migrated to St. Joseph's/Candler. This further enhanced the community's perception that St. Joseph's/Candler is the regional healthcare institution of choice.

St. Joseph's/Candler also continues to expand its physician network as a feeder mechanism for lucrative services. Opportunities exist to continue to expand this network into other specialties that will prevent leakage of patients and healthcare dollars to other entities. These opportunities include: orthopedics, general surgery, rheumatology, neonatal services, pediatrics, and dermatology.

Threats to the health system include: pressure from insurers to send profitable diagnostic services to outside competitors and independent healthcare providers; and loss of market share to its major competitor, Memorial Health. Memorial Health was recently purchased by Healthcare Corporation of America ("HCA") and therefore has the financial backing and infrastructure of a publicly traded company. The system also faces pressure from other neighboring healthcare institutions, particularly in

South Carolina, where patient populations are less willing to drive to Savannah for care. These competitive threats include: Hilton Head Regional Healthcare and other hospital systems based in Charleston, S.C. Additional competitors include: private medical groups and sole proprietor physicians throughout numerous communities within the region. The largest of these is Savannah, GA. based SouthCoast health; which is a large independent multi-specialty medical group.

Being a not-for-profit healthcare system, St. Joseph's/Candler is also sensitive to state Medicaid reimbursement changes and spends considerable effort lobbying state legislators to mitigate financial impact of state budgets. Additionally, both Georgia and South Carolina are Certificate of Need ("CON") states and require regulatory approval for healthcare expansion, particularly for those services that are both expensive to deploy and profitable. States historically offer only one CON for a certain service for a prescribed geographical area, making acquiring a CON an often contentious legal affair.

Finally, there are several large employers in the area that control health benefits for tens of thousands of beneficiaries. Most notably, SCAD (internationally acclaimed Savannah College of Art and Design), Gulfstream (private jet manufacturer), and the Savannah Business Group (Chatham Steel and the Georgia Ports Authority among others) are dominant industries. These companies are self-insured and frequently bid out third-party administrator ("TPA") duties to a host of nationally recognized insurance companies. Depending on the TPA chosen, St. Joseph's/Candler could be out-of-network and lose thousands of customers overnight. Thankfully, St. Joseph's/Candler is currently in-network with each of the companies listed above.

Strategy

Like most healthcare institutions in the United States, St. Joseph's/Candler struggles to hire enough primary care physicians to meet patient demand. This is despite a highly desirable location, climate, low cost-of-living, institution infrastructure, and proximity to a major airport. It is estimated that there will be a shortage of up to 55,200 primary care physicians by the year 2032[1]. Not unlike other institutions and physician offices, St. Joseph's/Candler has looked to nurse practitioners and physician's assistants to fill

this gap. While this strategy has had some limited success, both locally and nationally, patients often rebel at the thought of only seeing their physician intermittently or annually for their primary care. Yet physicians are already overburdened by existing patient demand, especially for treatment of acute illness or chronic care conditions. Little time is left in the physician's day for wellness services. Clinical pharmacists help satisfy patient demand by becoming an integral part of the care team without attempting to replace the physician. Additionally, more proactive preventative measures will reduce acute care issues (i.e. hypertensive crisis' or adverse drug reactions). The American College of Clinical Pharmacy defines clinical pharmacy as "a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention"[2]. Clinical pharmacists can perform a variety of needed activities including:

- Medicare Annual Wellness Visits ("AWV") or similar type visits,
- Diabetes education,
- Medication reconciliations,
- Manage anticoagulation clinics,
- prevent medication related adverse reactions,
- Ensure antimicrobial stewardship,
- Administer vaccines,
- Promote evidence based medical therapy recommendations, and
- Advise physicians in pharmacology matters.

Once acclimated to their use, patient survey results show that patients don't typically view clinical pharmacists as an encroachment on their one-on-one time with their physician; rather they are viewed as an additional visit with a member of the physician's team.

As third-party payers shift from fee-for-service to an outcome based reimbursement model, there is seemingly a gap between the infrastructure needed to meet quality metrics and the additional revenues needed for their implementation. As a means of addressing this dichotomy, St. Joseph's/Candler implemented the cost neutral clinical pharmacist program that is flexible enough to account for both billing mechanisms.

Short, intermediate, and long-term goals (i.e. mission) of the program remain consistent: to assist the physician with completing quality metrics on select patient groups thereby increasing reimbursement,

either through additional fee-for-service collections or through quality bonuses achieved through the overall reduction of the cost of care. Additionally, the program is designed to focus on patient wellness and satisfaction. Patients appreciate the extra time that a clinical pharmacist can spend with them diving into patient-centered socio-economic determinants of health and their increasingly complex medication regimens.

Regardless of clinical and patient benefit, any clinical pharmacy program needs to demonstrate a positive financial return-on-investment to remain sustainable long-term. The additional costs of the pharmacist salary, and their associated benefits, need to be outweighed by the billings and receipts generated by their services, or at least meet break-even. It is the strategy of St. Joseph's/Candler to remain at or above break-even for the program. Currently, the program is surpassing that objective.

An unforeseen side benefit of the program is the job satisfaction enjoyed by the clinical pharmacists themselves. As the use of clinical pharmacists has decreased in certain areas (i.e. anticoagulation management) due to pharmaceutical advances, their graduate and post graduate training have provided an avenue to migrate into medical offices of a community practice health system and develop a rapport with both physicians and patients. This job satisfaction is a contributor to overall health system goals regarding employee turnover which subsequently supports continuity of care, increased patient satisfaction, and downstream capture of patient care services and revenue.

Ultimately, the program is designed to be a win/win/win/win/win. The physician, clinical pharmacist, patient, healthcare administration, and insurance companies all benefit from the program. The physician benefits from the additional clinical help in the medical practice, the pharmacist wins through increased exposure and job satisfaction, the patient wins through better health outcomes, administration wins via additional revenues and less staff turnover, and insurance companies win via more complete clinical data and better health outcomes.

Strategic relationships

Like many large healthcare institutions, St. Joseph's/Candler has layers of leadership that need to embrace the clinical pharmacy strategy for the program to be successful. The key local stakeholders within the project are:

- Director, Clinical Pharmacy Services;
- Manager Pharmacy Services;
- Executive Director of Operations, Physician Network;
- Vice President, Physician Network; and the
- Physicians and Practice Managers at various practice locations.

Each of these individuals has a vital role in ensuring the success of the program and represent varying departments within a large integrated delivery system. Specifically, they represent both pharmacy and physician network (medical group) leadership; which work in-tandem with each other to ensure operational and financial success of the program. Additionally, physician buy-in is essential for billing, patient steerage, and overall clinical outcomes management. Finally, practice managers establish practice procedures for patients and office staff that assist in the day-to-day operations of the project.

Summary description of the new business:

The program provides clinical pharmacy support to physicians and clinics in St. Joseph's/Candler's larger primary care offices. This service is used to improve health outcomes, provide additional clinical support to already overburdened offices, and contribute a break-even or slight financial benefit to the health system. The program is intentionally designed so that the physician, clinical pharmacist, patient, healthcare leadership, and the patient's insurance company all benefit.

The strengths of the program are primarily three-fold: more thorough and focused clinical care, robust collection of clinical quality data that impacts patient care and insurance incentive programs; and the additional support the physician's care team receives. Furthermore, the pharmacy team has seen a spike in employee satisfaction among its members.

Since its inception, the program has been very popular with physicians. Physicians appreciate the additional resource added to their team and the care their patients receive. Patients, however, have taken

longer to warm to the idea of meeting with a pharmacist for their Annual Wellness Visit, initially seeing it as an encroachment of time with their designated physician, but when collaboratively scheduled with other necessary components of care (i.e. labs), the initial independent pharmacist visit is palatable. Patient receptivity continues to increase after their first visit with the pharmacist. A high level of critical assessment and clinical application develops between patient and pharmacist. Patients state that they enjoy the extra time with a clinician who can more fully delve into issues that affect their health.

Ultimately, the program is proving to be a benefit for all parties: the physician, clinical pharmacist, patient, healthcare leadership, and insurance companies. The physician benefits from the additional clinical help in the medical practice, the pharmacist wins through increased exposure and job satisfaction, the patient wins through better health outcomes, administration wins via additional revenues and less staff turnover, and insurance companies win via more complete clinical data and better health outcomes.

Weaknesses of the program are primarily related to cost and operational implementation that will not further burden already busy practices. Clinical pharmacists are not inexpensive. The physician network purchases the clinical pharmacists' time from the health system at $65 per hour; which covers their salary and associated benefits. This expense equates to a nearly thirty-five thousand dollars ($35,000) of extra expense per month for St. Joseph's/Candler Physician Network (medical group) must offset. This offset is accomplished by the extra revenue generated by Medicare Annual Wellness Visits and other money-making services performed by the clinical pharmacists. While the clinical pharmacy program also contributes to data collection that can later be mined for health plans and insurance company incentive programs, the extra revenue generated from these programs are not factored into any ROI calculation of the clinical pharmacist program itself. This is primarily because no algorithm currently exists to quantify the contribution made by the clinical pharmacists to the data collection needs and the overall success of third-party payer incentive programs. This would be difficult to develop given the annual shift of benchmarks for star measures and MIPS and that pharmacist provision of care is not directly linked to pharmacists given lack of CMS provider status.

Operationally, ensuring that the clinical pharmacists see at least six AWVs per day has proven to be most challenging. Strapped practices have little time and human capital to call and encourage patients to schedule an Annual Wellness Visit. This is true even with technological innovations that communicate with patients (i.e. automated messaging, portal messaging, texts, etc.). This is exacerbated by patients not understanding the Medicare program and why a clinical pharmacist wants to see them rather than their physician. The initial conversation with patients can take some coercing, but once patients experience their first meeting with a clinical pharmacist they generally have high praise for the service. At this time, the clinical pharmacists have to use a portion of their clinical time to mine patient data, call, and schedule their own Annual Wellness Visits. This clerical work of scheduling does erode the time the clinical pharmacist can engage in revenue generating services or meaningful patient care tasks. The previous sentences notwithstanding, it has proven very successful to identify candidates when scheduling them for labs, typically the week before the in-person follow up with the physician. This allows for all preventative services to be reviewed with the lab draw and doesn't pose an additional trip to the primary care office to see a care team member. It also prevents the pharmacists from evaluating any labs that are outside their scope for review. Furthermore, it also ensures the patient will return for the in-person physical and follow up with the physician; which prevents patient leakage.

Site limitations (i.e. work space) for the clinical pharmacist can also be problematic for practices with a smaller physical footprint and building size, but clinical pharmacy team members have demonstrated adaptability to this barrier given they practice most efficiently ambulating around nursing stations for easy access.

Opportunities abound within the program. Not only does it contribute to the overall service offerings, but also demonstrates the health system's engagement in the health of its patients. Another opportunity is to expand the program to additional offices as conditions warrant. As primary care offices grow, they reach a critical mass of patient volume where implementing a clinical pharmacist can be justified financially, thereby adding expansion opportunities. Furthermore, the program allows St.

Joseph's/Candler to take advantage of third-party payer incentives for health data and quality care metrics thereby increasing revenue to the medical group.

St. Joseph's/Candler also has the opportunity to leverage an existing partnership with a local school of pharmacy to extend pharmacist care hours; thereby expanding the program while increasing the net income and return-on-investment. This partnership satisfies student experiential and research needs of the pharmacy school faculty while keeping them engaged in real-world applications of their academic discipline. Finally, there is an opportunity to hire an "air traffic controller" ("ATC") for the pharmacist team who would serve as a clerical support person to identify patient care gaps thereby reducing non-revenue generating time spent by the pharmacists.

The primary threat to the program is changes in reimbursement by Medicare. Because the break-even to positive ROI is predicated in reimbursement figures comparable to the 2020 Medicare Annual Wellness Visits reimbursement rates (currently $110.61 for the local area)[3] the program is subject to pricing changes instituted by CMS. In recent years Medicare has pushed AWVs to patients with broad marketing campaigns; therefore CMS reversing course on wanting all beneficiaries to have an annual wellness visit is unlikely. There is a remote threat that the health system's administration would want to redeploy resources, especially those of the clinical pharmacists, to other areas within the system. Again, this is an unlikely scenario for ambulatory care trained pharmacists.

Products or services:

The service offered by the clinical pharmacy program is primarily a one-on-one visit by a patient with a pharmacist that focuses on clinical data collection, wellness and disease state counseling to include self-care and monitoring, medication reconciliation, regimen compliance, and inventory. These services provide patients with an opportunity for an in-depth appointment with a member of the physician's care team in a familiar setting (i.e. the same office where they see their primary care physician). The primary financial drivers of these visits are the completion and billing of Medicare's Annual Wellness Visits and any adjunct screenings. Other wellness focused services are also deployed to meet the clinical data

demands of certain commercial insurance company incentive programs. Future use of clinical pharmacists may include assistance with transitions of care ("TOC") and chronic care management ("CCM"), both of which are billable to Medicare and select third-party payers.

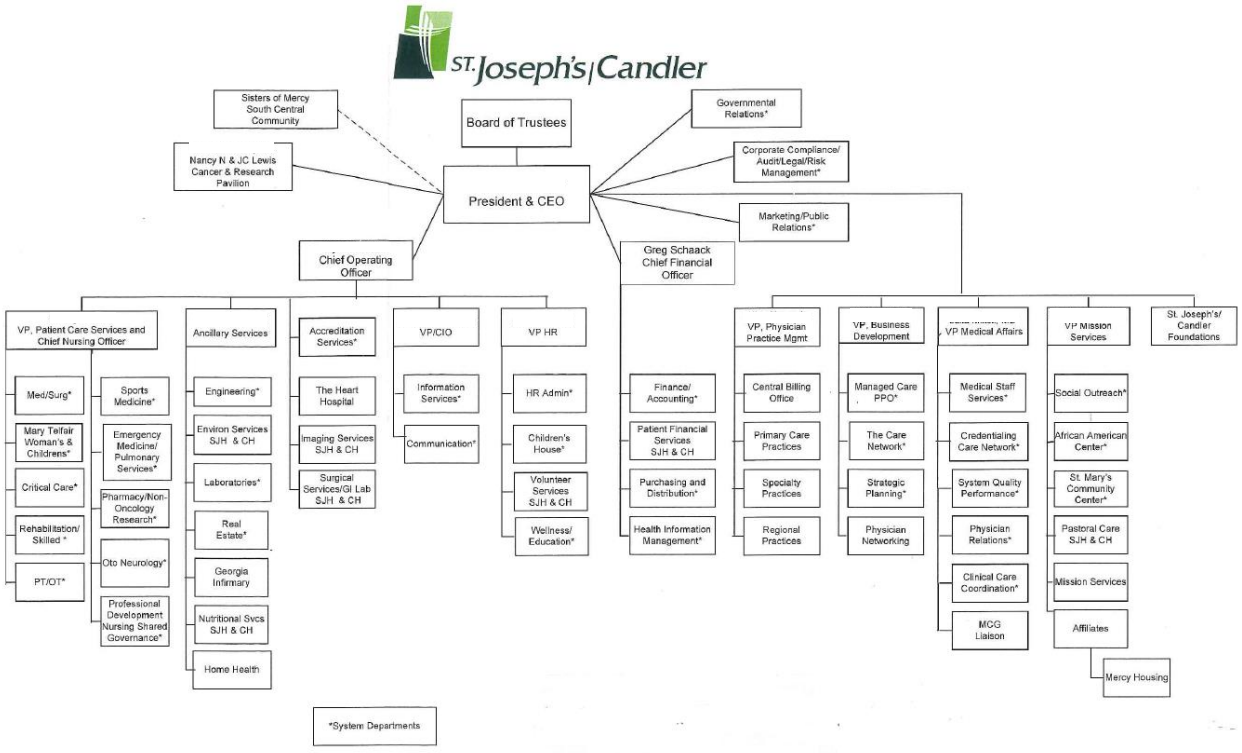
Secondarily, the program is meant to promote evidence based medical therapy that affects patient wellness including: antimicrobial stewardship, medication titration or de-prescribing and adherence, prior authorization assistance, and vaccine recommendations. Ambulatory care clinical pharmacists that work in primary care settings are trained, tested, and credentialed on assessment of evidence based medical therapy professional guidelines per The American College of Cardiology and American Heart Association (ACC/AHA), The American Diabetes Association (ADA), American Academy of Clinical Endocrinologists (AACE), Center for Disease Control (CDC) and the Infectious Disease Society of America (IDSA). These disease states in primary care are chronic and include anticoagulation, hypertension, hyperlipidemia, diabetes, heart failure, depression, infectious disease, etc.

Finally, the program supports humanistic measures (i.e. increased direct patient care time, longer question and answer visits, and medication acquisition through the increasing red tape of pharmacy benefit administrators and patient assistance programs) that increases patient and physician satisfaction and promotes patient and prescriber relationships and continuity of care.

Administrative plan:

The program is run via a joint venture between the Department of Pharmacy and the Physician Network of St. Joseph's/Candler. Since the physician is ultimately responsible for clinical outcomes and is the avenue for medical billing, the physician group has supreme operational control. Corporately, the Department of Pharmacy and the Physician Network represent two different divisions of St. Joseph's/Candler. The Department of Pharmacy reports to the Chief Nursing Officer ("CNO") of the hospitals and healthcare system whereas the Physician Network reports to the Chief Executive Officer ("CEO"); thereby making the program a collaborative effort between both divisions.

Specifically, the corporate architecture and organizational chart for St. Joseph's/Candler is as follows:



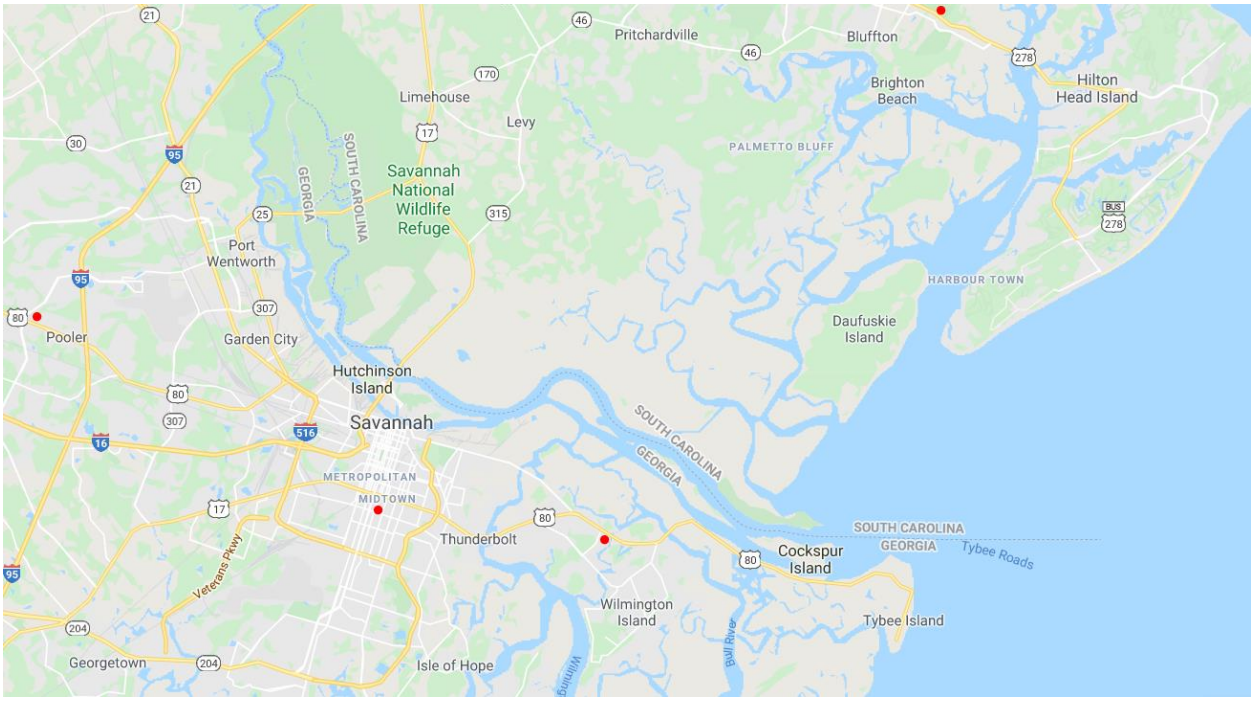
Within the Physician Network, the organizational architecture is led by the Vice President of the Physician Network, who serves as the *de facto* CEO of the division. Assisting the Vice President is the Executive Director of Operations who serves as the *de facto* COO. Both positions are charged with the overall operational and financial success of the physician group and are assisted by Directors of individual service lines (primary care, women's services, and specialty clinics). For the clinical pharmacy program, the Director of Primary Care is involved in the day-to-day management of the primary care offices where the clinical pharmacists perform their duties. Due to their geographical disbursement, most primary care offices have a local practice manager who oversees the practice's daily operations.

Pharmacy services and clinical supervision are overseen by the Director of Pharmacy who is assisted by the Manager of Pharmacy Operations. The primary care physicians stationed at each medical practice maintain clinical oversight of all healthcare delivered to the patient but often consult with pharmacy leadership on salient matters.

Approval for clinical pharmacist placement is jointly made by administration, pharmacy leadership, and the prospective clinic's physicians. These determinants are primarily based on patient volume, pharmacist supply, available clinical space, physician program acceptance, and a foreseen break-even or positive return on investment per clinic.

Three-year operational plan:

The clinical pharmacy program was scheduled to launch in three primary care offices in various locations, namely: Pooler practice, Islands practice, and the Eisenhower practice. Each of these locations had a critical mass of patients, especially Medicare patients, which made the program financially viable from a *pro forma* standpoint. After the success of the first three locations, a fourth practice, Bluffton, was added about a year later. There is a plan to add a fifth practice to the project, Rincon, during the summer of 2020.



(Red dot indicates current location of practices where clinical pharmacists are deployed)

While St. Joseph's/Candler has numerous other primary care locations, there are no current plans to continue the project beyond those locations already identified as they do not have the practice volume

to financially sustain the program. Administration will continue to assess clinical pharmacy needs and may make additional recommendations regarding the growth of the program as conditions warrant.

A minimum of three full-time primary care physicians at a single location typically provides an adequate supply of patients to justify the cost of the clinical pharmacist. This level is at Medicare's current reimbursement rates for an Annual Wellness Visits. Clinical pharmacists are expected to perform a minimum of six Medicare Annual Visits per work day, but also incorporate other patient care co-visits and monitoring as their daily operating hours allow. This minimal volume of AWVs assures financial sustainability. Once the six AWVs threshold is met, the clinical pharmacist can use other available time for unpaid or low reimbursed services such as: patient counseling, prior authorization assistance, physician consulting, anticoagulation abetment, and other services. Schedules are established for specific days of the week between practice sites and are reproducible and stable every month of the year. This promotes rapport with providers and support staff as well increases efficiency of operations overall.

Financial performance of the program is monitored monthly by multiplying the volume of billed services by the expected reimbursement rates. Clinical pharmacist expenses are then subtracted from this sum to ensure a positive project net income. Quarterly, there is an inspection of expected reimbursements versus actual receipts to assure long-term financial viability.

While clinical pharmacists meet weekly with physicians to go over patient cases, quality, and performance improvement, usually in an *ad hoc* fashion, there are formal quarterly meetings with program leadership to review progress, billings, sustainability, pitfalls, and other administrative matters.

Admittedly, the program's success is largely predicated on the Medicare's Annual Wellness Visit push, as well as its current reimbursement levels for the service. There is little that can be done to ensure that this national program continues beside basic advocacy to federal officials and policymakers. Given the popularity of the program with St Joseph's/Candler physicians, it is unlikely that health system leadership would redeploy the clinical pharmacists to other areas unless there were substantial changes in reimbursement or system priorities. The best way to secure continued leadership approval for the

program is to ensure an at least break-even profitability between all Fee-for-Service ("FFS") revenue generated and cost savings attributed to the clinical pharmacists.

Incorporation strategy

Once a practice is identified as being a good candidate for the clinical pharmacy program, medical group leadership approaches the practice's physicians about expanding the service to their particular office. This initial meeting explains the program to the physicians, outlines expectations, provides them with resources, sets accountability, and allows the physicians to ask questions. Oftentimes at this initial meeting, the physicians are also introduced to one or more clinical pharmacists that would be working at the clinic so that a preliminary rapport can be established.

The local practice manager collaborates with the clinical pharmacist to identify workspace, a possible exam room that can be used for the program, as well as pulling reports that identify patients in need of an AWV. It is the practice manager's responsibility to educate the clerical office staff about the new service and to be available to answer basic patient questions. The clinical pharmacist often works in conjunction with the practice to schedule the patients for AWVs, ensuring that at least six Annual Wellness Visits are scheduled per day. Oftentimes eight to ten Annual Wellness Visits are scheduled per day to account for inevitable no-shows so that the average will be at least six per day. The AWVs are schedule for 30 to 45 minutes per visit.

Once a "go-live" date is established and patients have been scheduled, the clinical pharmacist starts at the practice and is given a few days to move in, acclimate to their new surroundings, learn standard operational procedures, complete life-safety protocols, and introduce themselves to the staff. The clinical pharmacist also uses this time to discuss strategy and clinical expectations with the practice physicians as ultimately the clinical pharmacists scope of practice is determined, in the state of Georgia and South Carolina, by an established and certified agreement dictated by the supervising physician. The previous sentence notwithstanding, the physicians usually perceive the clinical pharmacists as clinical peers and almost universally start to use the pharmacists' knowledge base to refine their own clinical

practice. Physicians are encouraged to talk to their patients in the course of another visit type about the program; this affords the patients a better understanding of the program and they are usually more willing to schedule AWVs with a clinical pharmacist in the future when approached.

Once go-live is initiated and several days' worth of patients have been served, the clinical pharmacist will meet with the physician(s) to review clinical documentation and refine clinical expectation in light of actual patient visits and medical documentation. After an initial probationary period of up-to three month of rigorous physician oversight, the program usually stabilizes into a regular cadence of formal quarterly meetings and regular "curbside" check-ins with the physician.

Regulatory and accreditation bodies

There are no formal national regulatory or accreditation bodies for clinical pharmacy services in a physician practice. Pharmacists must practice within their scope as defined by the State residency of the practice they work in. To be eligible for employment in primary care for St. Joseph's/Candler, National Board Certification with the Board of Pharmacy Specialties is encouraged and expected by at least in the second year of employment. This is in addition to satisfying the requirements of a Pharmacy Doctorate program and completion of a minimum of a one year post graduate residency of an accredited program.

Exit strategy

There is currently no exit strategy identified with the program. The program is primarily predicated on Medicare's Annual Wellness Visit reimbursement and other adjunct services performed as part of an AWV. If Medicare were to substantially change its reimbursement or requirements, the program would be in jeopardy of closing.

Being a part of a large regional healthcare system, if the program were to cease, the ambulatory care pharmacists would be reabsorbed by the Pharmacy Department and reassigned other duties. It is doubtful that all clinical pharmacists currently deployed at physician offices could be reabsorbed. As such, there would also be a high likelihood of some layoffs if the program was shuttered. With the loss of

the resource, physicians would have to perform their own AWVs; which would take away from other services for follow-up care, physicals, and sick care. The administration of the program is performed by health system leadership who have broad scopes of responsibility and the loss of this particular program would not adversely affect their specific positions.

Part II: The Marketing Plan

Overview and goals of marketing strategy

There are three main constituencies with the clinical pharmacist program, namely: administration, physicians, and patients. Arguably a case can be made for also adding clinical pharmacists themselves to the list. The basis of the program is simple: to complete Medicare Annual Wellness Visits using clinical pharmacists; thereby expanding the physicians' capacity for other services, collect needed clinical data to enhance patient care, and use the billings from Medicare to pay for the service. It is not intended to be a primarily money-making or money-losing venture. To ensure programmatic success, physicians, administration, and most importantly, patients themselves need appreciate the value.

The marketing strategy is relatively simple: first, gain approval from the health system's administration, including the Department of Pharmacy. This approval largely hinged on the financial impact of the program and the available human capital needed for implementation.
Secondly, win physician approval to add another clinician to their team. This required explaining the clinical pharmacists' capabilities and expertise and how their skills and assistance would improve patient care. Financial considerations for physician compensation were also explained.

Finally, patients need to be educated on the service and why it is important to meet with the pharmacist. Admittedly there is some amount of finesse when approaching patients for the first time regarding the service. Although Medicare's Annual Wellness Visits are a well-established CMS program, patients are ill informed about the benefit and are often initially skeptical about the service. Some patients have gone so far as to report the program for fraud due to their lack of understanding and

obstinance. Consequently, there is a significant amount of marketing and education to the patient at the onset of the service. This marketing is primarily performed verbally as part of another office visit or over the phone and is most effective when it is performed by the physician. Thereafter, patient retention, satisfaction, and acceptance are very high.

Marketing analysis

Once health system administration and physicians have been informed about the program and have given their blessing to proceed, the target market becomes Medicare beneficiaries. Medicare instituted AWVs on January 1, 2011 under the direction of the Affordable Care Act. Despite being a Medicare benefit for nearly a decade, patients are still ill informed about the service. Therefore, significant patient education is sometimes needed for patients to understand their Medicare benefit and be willing to undergo the service. Frequently patients need to be educated that the service is intended as a "hands off" visit (i.e. meeting) between them and a member of their physician's care team. In this meeting the patient can expect:

- A review of their medical and family history,
- Developing or updating a list of their current providers and prescriptions,
- Collection of height, weight, blood pressure, and other routine measurements,
- Detection of any cognitive impairment,
- Providing personalized health risk assessment
- A discussion and list of risk factors and treatment options available to the patient,
- A screening schedule for appropriate preventive services, and
- Advance care planning.

Patients need to also understand that this service is not a "physical" as that term is commonly used in public vernacular. The marketing for this service ideally occurs by the physician themselves, who can explain the patient's need to schedule an AWV while the patient is undergoing another service (i.e. follow-up visit for a chronic condition). Alternatively, members of the clerical staff, who have been tasked with calling patients, educate them and schedule the visit. The ambulatory care pharmacists can also assist in educating the patient about the service in a pre-service phone call or during the visit itself.

While not typical, Medicare does afford the opportunity for a clinician to perform additional services on the same date of service (i.e. office visit). These services are billed with a 25 modifier. The overall goal of these conversations is to get the patient to physically schedule the AWV. This demographic, once they have an appointment on the practice's schedule, rarely no-shows or cancels the appointment outright.

Medicare Annual Wellness Visit services are a commodity medical service provided by any participating primary care physician or his/her staff. While this makes the service widely available, patients would not under normal circumstances, have their primary care delivered in one venue and an AWV delivered in another. As such, there is little overt competition for the service once the patient has established a patient-physician relationship. Theoretically, physicians could perceive the completion of AWVs by clinical pharmacists as an encroachment on physician services, but this issue is largely moot. St. Joseph's/Candler ambulatory care pharmacists practice under the physicians supervision, in the same EMR, and quality and revenue tangibles are associated with the Physician's NPI. They are essentially an extension of the physician and part of the care team. Physicians, especially those in primary care roles, are busy and in high demand. They typically welcome the additional help that a clinical pharmacist can bring; this is true not only for the completion of AWVs but for previously described patient care services.

Customers/patients are increasingly savvy about their health and there is a renewed emphasis on wellness, nutrition, exercise, and quality-of-life. Many seniors are maintaining active and healthy lifestyles. Numerous businesses and communities specifically cater to this demographic within St. Joseph's/Candler's service area. Jimmy Buffet's Margaritaville community Latitude in Bluffton, S.C. is one example. This demographic increasingly demands that their healthcare providers partner with them to optimize their health so that they can enjoy their golden years with vigor and vitality. This trend will continue as the baby-boomer generation continues to age and account for a growing portion of the nation's healthcare output. The Annual Wellness Visit is one service offering that helps fulfill senior's desire for enhanced healthcare while also benefiting the clinician and institution. Seniors often appreciate the extended conversation they have with a clinician, albeit a clinical pharmacist, about their health. This is time they rarely have with their physician due to the physician's schedule.

Marketing strategy

The marketing for the service is primarily word-of-mouth as it is an extension of the other primary care services offered by the medical practice. There are several criteria to receive the service. Listed in order, the requirements are:

- The patient must be an established patient with the practice/physician,
- The patient must be a Medicare Part B or Medicare Advantage beneficiary, and
- The patient must be due for the service.
    - Exclude patients who are not insured via a Medicare or a Medicare Advantage Plan,
    - Exclude patients who are eligible for a Welcome to Medicare Visit, also called the Initial Preventative Physician Examination ("IPPE"), and
    - Exclude patients who have had the service in the last 365 days.

Once the patient meets the criteria for the service, they are identified and placed on lists for further follow-up. The practice then requests that the patient schedule the AWV at the conclusion of an already existing appointment, usually at check-out. Alternatively, the practice will contact eligible patients via a phone call, text, e-mail, letter, or portal message to request that they schedule their annual AWV. When directly asked to schedule the AWV appointment, there is greater than an 80% chance that the patient will book the appointment. Once booked, most patients will keep the appointment.

Current operations the marketing plan; therefore no expenses are planned for marketing, and no budget is required. The cost for these marketing methods is largely sunk with existing expenses for the technology and human capital; consequently, there is little if any incremental cost. Letters are rarely used as they are more expensive and less timely than electronic communication and have a poor follow-up rate. No additional materials or marketing expenses have been produced or explored. There is no line item marketing budget for the service as it has not been needed.

Implementation of marketing strategy

Traditional marketing states that there are four "Ps" of marketing, namely: product, placement, price and promotion. The product, in this case, is something that the patient's physician and insurer want them to undergo ultimately because the basic components of this preventative service are rooted in strong

evidence based medical recommendations that prevent morbidity and mortality. It keeps patients healthier and alive longer. This is a compelling incentive for patients to have the service. The patient frequently is also seeking enhanced healthcare offerings that the AWV satisfies. The placement of the product is within the confines of the patient's physician's office, a highly trusted individual; which provides additional credibility. The price is free for the patient as Medicare has no cost sharing for the service. No additional time or travel is needed if it can be strategically combined with other office services. Finally, the promotion is primarily performed by the physician or a member of the physician's staff. Additionally, Medicare or Medicare Advantage programs also promote the service to the patient and, sometimes offer incentives to the patient for completion of the service.

The primary mode of marketing is word-of-mouth. Not only is this type of marketing essentially free, it's also the most highly effective form of marketing known. The use of technology (e-mails, texts, etc.) is also employed. Medicare Advantage programs are also highly incentivized by the federal government to capture quality data on their members, therefore partnerships can be developed with these insurers. These Medicare Advantage plans often can contact patients or create and disseminate marketing materials on behalf of the physician. This is especially true when the insurer can demonstrate a strong ROI for themselves based on completed AWVs through filed claims.

Part III: Financial Documents

Summary of financial needs

AWVs reimbursement can significantly contribute to supporting the cost of a pharmacist, particularly in medium-to-large-sized practices[4]. Although slightly profitable, the program is designed to be break-even via normal billings and collections. The previous sentence notwithstanding, there are material additional revenues brought in by the program from quality incentives from third-party payers. These funds, although substantially earned via data collection from Annual Wellness visits, are not directly attributed back to the program as the cost accounting mechanisms needed for such a calculation are unjustified.

The largest expense of the program is the cost of the clinical pharmacist time. This is currently billed at $65 per hour per pharmacist as an intra-company transfer. This figure includes the clinical pharmacist's time and all associated benefits. Because the program is implemented at a large healthcare system with multiple physicians' offices throughout the region, there was no need for financing or other funding sources. Initial cost outlays were largely sunk costs, including a computer for the ambulatory care pharmacists and basic office materials (pens, paper, etc.). These items were largely acquired from the practice's stockpile of office supplies or already provided by the health system as part of the employee's basic accoutrement. In a few cases, additional start-up costs were needed for office furniture (i.e. desk) or other necessary items. The costs for these incidentals were, and continue to be, inconsequential.

There was a financial timing difference at the beginning of the program. The organization initially outlaid approximately one-half of a month of clinical pharmacist's expenses (i.e. wages) before reimbursement was recouped from Medicare. This amounted to approximately $10,000 in initial expenses and was quickly reimbursed in subsequent months. This figure was the sum total of capital needed to start the project.

Pro forma cash flow statement (budget)

Clinical Pharmacy Program			
Budget			
	FY18 (partial year)	FY19	FY20
Revenue	$ 50,000.00	$ 200,000.00	$ 450,000.00
Salaries	$ 55,000.00	$ 199,000.00	$ 375,000.00
Incidentals	$ 3,000.00	$ 1,000.00	$ 750.00
Expenses	$ 58,000.00	$ 200,000.00	$ 375,750.00
Net Income	*$ (8,000.00)*	*$ -*	*$ 74,250.00*

Three-year income projections

According to the budget, above, the projected three year income projection was $66,250.00; whereas a "year" is defined as the fiscal year of the organization. This income does not include potential revenue generated from third-party payer quality programs where the success of such programs relies on

the collection of data from AWVs. The potential revenue generated by third-party payers is not booked by the organization until realized and therefore is not input into any *pro forma* financial projection. Additionally, these revenues cannot be allocated back to one specific program. No current mechanism has been developed by the healthcare's accounting department for such an allocation as it is not necessary.

Projected balance sheet

Clinical Pharmacy Program		
Projected Balance Sheet		
As of June 30, 2018		
Assets		
	Accounts Receivable	$ 15,000.00
Liabilities		
	Accounts Payable	$ 16,900.00
	Retainied Earnings	$ (1,900.00)
Equity		*$ (1,900.00)*

Break-even analysis

Clinical Pharmacy Program						
Break-Even Analysis						
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Revenue (cumulative)	$ 6,905.20	$ 23,319.20	$ 41,148.20	$ 57,788.60	$75,617.60	$101,678.98
Expenses (cumulative)	$ 16,900.00	$ 33,800.00	$ 50,700.00	$ 67,600.00	$84,500.00	$101,400.00
Total	$ (9,994.80)	$(10,480.80)	$ (9,551.80)	$ (9,811.40)	$ (8,882.40)	$ 278.98

The above represents the actual break-even for the program that also accounts for the timing difference between the incurred expense and when the program was reimbursed by Medicare. Not accounting for this timing difference, the project broke-even in its first month.

Profit & loss statement (income statement)

Clinical Pharmacy Program				
Profit and Loss Statement				
		FY18 (partial year)	FY19	FY20 (COVID)
Revenue		$ 87,164.00	$355,202.73	$429,908.32
	Salaries	$ 50,700.00	$254,600.00	$355,905.00
	Incidentals	$ 2,313.12	$ 712.56	$ 654.89
Expenses		$ 53,013.12	$255,312.56	$356,559.89
	Net Income	*$ 34,150.88*	*$ 99,890.17*	*$ 73,348.43*

Balance sheet

Clinical Pharmacy Program		
Balance Sheet		
As of June 30, 2020		
Assets		
	Accounts Receivable	$ 59,093.32
Liabilities		
	Accounts Payable	$ 32,535.00
	Retainied Earnings	$ 26,558.32
Equity		*$ 26,558.32*

Financial statement analysis

All financial statements shown are for the clinical pharmacy program only and do not reflect the balance sheet, profit & loss statement, or statement of cash flows of the individual medical clinics or the health system as a whole. Because of the simplicity of the program and its revenues and expenses, the financial reports involved are elementary.

Fiscal year 2018 was for a partial year as the program started late in the year fiscal year (April, 2017). The fiscal year of the organization is July 1st to June 30th. Fiscal year 2020 was impacted by the COVID-19 pandemic; which affected the volume of patients seen by the program and ultimately negatively impacted the net income of the program.

The program has performed better than expected from a financial perspective. While designed as a break-even proposition, the program does generate material net income with little more than the costs of the salary and benefits of the clinical pharmacists. All other expenses, including: billing, rent, utilities,

information technology services, management, mal-practice insurance, etc. are “sunk” and incorporated in already existing expenses of the organization.

Business financial history

St. Joseph’s/Candler Health System is a non-profit organization with a very stable history, including managing the second oldest continual operated hospital in the United States. For fiscal year 2020, revenues exceeded $2.6 billion and net income was greater than $30 million. Moody's Investors Service confers an "A3" rating for the health system with a “stable” outlook. The health system’s financial position is very strong and affords significant investment and charitable outreach.

St. Joseph’s/Candler’s Physician Network (i.e. medical group) is operated as a for-profit wholly owned subsidiary of St. Joseph’s/Candler Health System and has a separate Tax-ID. St. Joseph’s/Candler Physician Network enjoys revenues of greater than $50 million annually. Like most hospital owned medical groups, the SJ/C Physician Network intentionally has a negative net income. The previous sentence notwithstanding, efforts are made to mitigate losses from the medical group as much as possible. Both institutions are vibrant and growing.

Part IV: Innovative Elements and Expected Business Outcomes

In a context of limited resources, different healthcare systems have been experimenting with interprofessional collaboration in primary care to improve professional effectiveness and quality of practice among professionals[5]. The use of clinical pharmacists in physician clinics, however, is novel. A search of the literature from a business or administrative perspective regarding the use of clinical pharmacists in a medical group setting shows little, although quality outcomes related to ambulatory pharmacy care are numerous. As with any fresh approach to healthcare, there is a learning curve and a certain level of patient and clinical acceptance must be obtained as a prerequisite for programmatic success. While the use of nurse practitioners, physician assistants, therapists, diabetic counselors, and behavioral health specialists are well documented, the deployment of clinical pharmacists is an innovation within medical groups.

Pharmacist provided direct patient care has been quantitatively assessed as effective on safety and patient-based outcomes, including medication adherence, patient knowledge, and health-related quality of life[6]. In addition, clinical pharmacists-physician quality circles in ambulatory care are cost-effective[7]. When ambulatory care pharmacists engage in patient care to their full capacity, physician time is saved, access to care is improved, and clinical and economic outcomes are enhanced[8].

As explained earlier, the program is designed to be a win for all parties concerned, including for the physician, clinical pharmacist, patient, healthcare administrator, and the insurance company. The physician benefits from the additional clinical help in the medical practice, the pharmacist wins through increased exposure and job satisfaction, the patient gains through better health outcomes, administration reaps additional revenues and less staff turnover, and insurance companies receive more complete clinical data and better health outcomes.

While the general public cannot usually articulate the difference between a retail and clinical pharmacist, their trust in the profession is unquestioned. Clinical pharmacists are highly trained individuals. Because of their unique training, pharmacists have a deep understanding of pharmacology, drug efficacy, prescription prices, alternative treatments, side-effects, and drug-on-drug interactions. When meeting with the patient, this rote knowledge is a significant benefit. Physicians also rely on the training of the pharmacist as their doctorate pharmacy training is far superior to the pharmacology training a physician receives.

When conducting an AWV or other service, the pharmacist's collection of health data contributes to the overall understanding of the patient and the patient's optimal health threshold. Unlike a majority of physician-patient interactions, the focus of the clinical pharmacist visit is prevention and wellness rather than disease management. This is accomplished through a deeper understanding of social determinants of health, including: tobacco use, exercise frequency and rigor, alcohol consumption, illicit drug use, fall risk prevention, mental acuity aptitude, social network infrastructure, genetics, preventative services, and current health status. Critically evaluating this data provides a more thorough understanding of the patient and affords the clinician an opportunity to tailor health recommendations to the individual. This

data is also submitted to the patient's insurance company where it is aggregated with other data for a better understanding of the population's health. If the patient is found to be lacking in an area that could be detrimental to their health, the insurance company often partners with the physician to mitigate potential poor health outcomes. Furthermore, the collected clinical data helps satisfy MIPS, HEDIS, and other clinical quality programs that pay significant bonuses for high quality care.

Specifically at St. Joseph's/Candler, this opportunity of repurposing ambulatory care pharmacy job descriptions aligned with current ambulatory care pharmacy practice, doctoral pharmacy curriculum, and reduced intensity for monitoring. At SJ/C pharmacists managed anticoagulation clinic given changes in medical therapy options in evidence based guideline recommendations. This shift allowed St. Joseph's/Candler to redeploy the clinical pharmacists into physician offices where their services would increase revenue, expand capacity, improve health outcomes, and educate patients.

Challenges

The greatest significant challenge in implementing a clinical pharmacist program was to develop the concept and then sell it to administration. Because the concept was so new, very few leaders within the healthcare system had a reference point from which to understand the program's concept. The clinical pharmacists were eager to try the endeavor and were confident it would be a success clinically. Administration, however, was skeptical of the financial impact of the program and did not want to add significant cost to the physician practices without offsetting revenue. Ultimately, administration relented with heavy oversight after initial success was captured at one practice with one pharmacist one day per week. Administration had to be assured the program was break-even and grew organically at a measured pace. Another challenge was assuring patient buy-in; which was needed for programmatic success. At the time of concept, it was not known if patients would allow anyone but their primary care physician to treat or recommend treatment. This has since been resolved.

More recently, the greatest challenge has been maximizing the pharmacists time. Because of the demands of the physician office, it is not always possible for existing clerical staff to call and schedule

patients for AWVs with the clinical pharmacist. Therefore, this task has oftentimes fallen on the clinical pharmacist themselves. This is poor use of the pharmacist's time, yet a necessity. To address this issue, an "ATC" (air traffic controller), essentially a dedicated member of the clerical staff, has been hired to mine reports for eligible patients. Once it is determined that the patient is eligible for an AWV or another service (i.e. transition of care from a hospital), the patient is called by the ATC and scheduled with the clinical pharmacist. The ATC works in a central location and serves multiple clinics where clinical pharmacists operate.

Next steps

The program continues to grow organically where the requisite patient volume can support at least six AWVs per clinical pharmacist day. The program initially evolved from one clinic, where proof of concept was established, to now five locations. Growth is not only achieved by expanding to other offices but also accomplished by adding additional days of service to existing offices. Several offices have enough demand that a clinical pharmacist operates in the clinic five days a week.

An additional partnership for growth is also available. St. Joseph's/Candler has partnered with a local School of Pharmacy to deploy their pharmacy professors within the clinics. This provides additional AWVs and data collection to the health system at zero cost other than providing a practice site for pharmacists to precept student pharmacists. The school of pharmacy benefits by using real-world data and experiences for research and education. This partnership has recently been implemented in a second clinic, a faculty transition from our HCA competitor, which speaks to St. Joseph's/Candler's community relationship and commitment to quality patient care. St. Joseph's/Candler looks to organically expand this service as warranted and available.

As the pharmacist's contribution to quality metrics and insurance company qualities bonuses are better understood and demonstrated, there is also a push to further expand the clinical pharmacist's services. These offerings can be in the form of extra billable services including: transitions of care and chronic care management, and focused implementation on Medicare Advantage plans care gaps. These services can fill gaps in the pharmacist's schedule due to no-shows or irregular demand. While these

services are revenue producing, they are not as profitable or as easily implementable as Medicare's Annual Wellness Visits. The use of clinical pharmacists in implementing quality care that is indirectly reimbursed through third-party payer quality programs is also being explored when there is availability. An example of this is promoting an antimicrobial stewardship, or defining a performance improvement initiative, which consists of pharmacist audit of prescribing patterns, providing data and feedback to prescribers, and collaboratively develop infectious disease protocols that can be easily accessed by all the clinic's prescribers. This is largely beneficial to all prescribers within St. Joseph's/Candler outpatient groups given that evidence based medical therapy recommendations for infectious diseases encourage use of regional specific antibiograms. Antimicrobial stewardship programs are significant population health issues that will continue to garner national attention in the healthcare industry.

Finally, the program will continue to be monitored monthly for profitability and effectiveness. Program leadership, whether it is through health system administration, medical group administration, physician representation, patient focus groups, or pharmacy management frequently reviews metrics of the program. Protocols and procedures are continually refined and updated in response from feedback from various stakeholders. This continual improvement ensures program longevity and effectiveness.

Part V: Addendum: Other Factors

Billing

Traditional Medicare offers three preventative health visits: the Initial Preventative Physician Examination ("IPPE"), which is sometimes referred to as the "Welcome to Medicare" preventative visit, and two types of Medicare Annual Wellness Visits. These visits are provided as an "initial AWV" or "subsequent AWV." Traditional Medicare does not provide beneficiaries with a yearly physical although some commercial and Medicare Advantage plans may.

The initial AWV is billed as a "G0438" and a subsequent AWV is billed as a "G0439". Patients do not pay any coinsurance, co-pay, or deductible for the AWV. An AWV can be provided on the same

day as another Evaluation & Management ("E/M") visit by utilizing the "-25 modifier" when billing. Co-pays, co-insurance, and deductibles would apply to this E/M visit but not to the AWV component.

AWVs can be billed if the patient is:

1. Not within the first 12 months of the Medicare Part B coverage period, and
2. If it has been at least 12 months since the patient's IPPE exam or previous AWV.

The previous notwithstanding, some commercial or Medicare Advantage plans allow for an AWV on a calendar year basis. The "initial AVW" is the first time a patient receives an AWV regardless of the time period for the patient. The "subsequent AWV" are all AWVs after the initial AWV.

While clinical pharmacists are eligible service providers for AWVs, they do not serve as the billing provider for these encounters. This was affirmed by a March 25th, 2014 letter to the American Academy of Family Physicians by CMS Administrator Marilyn Tavennar, BSN, MHA, that a physician may bill Medicare for a Part B covered service provided by a pharmacist in a practice. Thus, AWV billing codes are generally sent out under the Medicare participating physician providing direct supervision of the service. Specifically, while the clinical pharmacist performs the lion's share of the AWV and face-to-face encounter with the patient, the physician ultimately reviews and signs the clinical note. Therefore the service is billed under the physician's name and National Provider Identifier ("NPI") number. There is no requirement that the physician or supervising provider must sign off on all clinical pharmacist notes.

Because the service is being billed largely as "incident-to" there are nine rules that must be satisfied, including:

1. Patient must be seen first by the physician for an E/M visit,
2. Physician must have provided authorization for the service in the medical record (usually done by standard referral process or referenced standing order),
3. The physician must continue to see the patient at a frequency that reflects his/her active participation in the management of the course of treatment,
4. The service is furnished in a physician office or through an approve telemedicine vehicle,
5. The service must be medically appropriate,
6. The service must be within the clinical pharmacist's scope of practice as dictated by the state's Pharmacy Practice Act,
7. The service must be provided in accordance with state law,
8. A physician or Medicare Part B approved practitioner be on the premises, and

9. The pharmacist providing the incident-to service must be an employee, leased, or contracted to the physician (or health system) or Medicare Part B provider.

Other factors

Currently, other alternatives exist for providing Annual Wellness Visits, including through Registered Nurses, Nurse Practitioners, and other licensed personnel. For varied reasons, largely including patient perception of care and opportunity cost considering the level of care that is provided by pharmacists comparative to other supportive licensed personnel, ambulatory care pharmacists are a unique fit for completing AWVs and complementing other professionals within the medical clinic. Therefore, no major changes are being explored at the moment; rather the program undergoes continual small refinements to ensure success.

In conclusion, the program of using clinical pharmacists in primary care offices to bolster care, improve access, assist physicians, and obtain an at-or-above financial break-even point has been a success.

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