

(Part II)

Gastroenterology Practice 2016 and Beyond: Survival Guide for Ancillary Income

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With the “draconian” cuts imposed by the Centers for Medicare & Medicaid Services for endoscopic procedures effective 2016, gastroenterologists are presented with a significant challenge to fiscal stability and potentially the viability of their practice. In addition to the financial cuts, there are innumerable other factors, such as involvement or exclusion in accountable care organizations or networks, which may direct or exclude patient access to their practices with significant consequent effects.

With this in mind, a group of nationally known, private practice experts developed this treatise to help guide their peers via their success in developing alternative revenue streams, which they have found highly successful in their practices.

In the first part of this two-part series, published in the winter 2016 issue of *EndoEconomics*, we had excellent guidance from Drs. Steve Morris, Reed Hogan and Jim Leavitt regarding opportunities for developing lines of

service revenue through anesthesia services, radiologic imaging and in-house pharmacies. In this continuation, Drs. Harry Sarles, myself and Klaus Mergener discuss other opportunities for revenue streams by developing programmatic hemorrhoidal banding, research- and pathology-related lines of service. This discussion is not meant to be applicable to every practice, but will hopefully encourage gastroenterologists to explore some options that may fit their practice. With challenging times upon us, gastroenterologists should

evaluate every option to leverage and potentially monetize the value of their practices.

Hemorrhoid Banding

By Harry Sarles Jr., MD, FACC

Diversification is a strategically important concept that is paramount to the survival of today's GI practices, and should be a part of a practice's business plan. Reimbursements for the services of gastroenterologists have been declining since the 1980s. Successful practices have been diversifying since the 1990s by adding ambulatory surgery centers (ASC), pathology labs, anesthesia companies and infusion services, each of which has been very helpful to our practices. One of the newer service offerings being offered in GI practices is hemorrhoid treatment.

Though there are many treatment options available, hemorrhoid banding is now the preferred treatment for the non-surgical management of symptomatic internal hemorrhoids. The procedure is known to be safe, effective and easily adaptable to the skill set of the gastroenterologist.¹ Most GI fellowship programs do not spend a significant amount of time training us to care for anorectal problems, but a company such as CRH Medical (CRH O'Regan System) will provide this training through physician-to-physician procedural instruction at your office in order to help incorporate these procedures into your daily practice.

The addition of hemorrhoidal banding to my practice has allowed me to provide more comprehensive care to existing patients and attract new patients, ultimately allowing me to provide a higher quality of care as well as create a new revenue stream.

Most patients have three columns of hemorrhoids that require treatment, and we typically treat one column per session at two-week intervals in order to keep complications to a minimum. Symptomatic relief has

been reported in as high as 99% of patients, and the vast majority of the complications (1%) are easily cared for by the gastroenterologist.² No patient prep is required; the procedure is easily performed in the office or ASC setting, and is well reimbursed, providing more benefit to your practice per hour than colonoscopy.³

Anoscopy has also become a routine part of my physical exam in the office for any patient complaining of anorectal issues. The anoscope has been shown to be superior to the flexible endoscope for examining the anorectum, and it is a quick, painless and inexpensive procedure that is easily performed in the office setting.⁴ While most patients will attribute any anorectal complaint to "hemorrhoids," the use of anoscopy, along with a good anorectal examination, has allowed us to better identify the causes of the patients' problems. They may include hemorrhoids but also other entities that need to be addressed in order to achieve optimal patient outcomes. These techniques and treatment algorithms are presented alongside the hemorrhoid banding training provided by CRH Medical.

The addition of nonsurgical hemorrhoid and anorectal care to my practice has provided great benefits to both my patients in my practice, and I recommend that all GIs consider doing the same.

Clinical Research

By David Johnson, MD, MACG, FASGE, FACP

Although traditionally thought to be the purview of academic health centers, clinical trials to evaluate new drugs, tests and devices are being performed more and more in private medical practices or other healthcare organizations with little or no academic affiliation. A well-developed clinical trial program can improve the finances of a practice or healthcare facility by providing an

income stream not directly related to traditional patient care activities. Since this income stream comes through a contract with a for-profit company and not from a government program or healthcare insurance company, it provides a diversification for the revenue of the entity. So, is clinical research as part of a private medical practice something you should pursue? Here are seven points to consider, with some caveats.

1. Decide if you have the practice "culture" amenable to clinical research. Is there an intellectual interest in performing these studies? Since they may involve treatments or testing with randomization, the local investigator must be willing to have the patient treatment plan directed by the protocol, not the treating care provider.

2. Develop the necessary infrastructure. This involves having clinical coordinators as well as personnel dedicated to the regulatory monitoring and reporting process. This is not simply another collateral duty imposed on a member of your office staff. There are certifications of competency for clinical coordinators, and this is highly encouraged. Holding these credentials is very attractive to research organizations evaluating your site for potential clinical trial participation.

3. Understand the "rules." The oversight of patient participation in a clinical trial has liability implications, rule of law implications and ethics concerns. The dedication to attention to developing the necessary infrastructure and culture of "attention to detail" is critical. This is not simply another collateral duty imposed on a member of your office staff. Clinical competency and regulatory process understanding are essential for all involved in the program. Additionally, there is ever-increasing scrutiny placed on clinicians who assume the role of principle investigator (PI) in regard to conflicts of interest and oversight responsibilities monitoring progress of the study and patient safety.

A new, additional responsibility is the FDA's Physician Payments Sunshine Act which requires any sponsor of a clinical trial to post the income a PI receives on a publically accessible website even though much of that revenue will be used to support the infrastructure needed to run a clinical trial.

4. Develop a business case for your level of clinical trial involvement. It is also necessary to have the appropriate staff as well as certain equipment and space, all of which vary depending on the nature of the clinical trial. A mistake to avoid is to perform such activities by adding the new responsibilities of clinical trials to old responsibilities of clinical care. This practice is not a good formula for the business success of the new venture. You must do a great job and foster a great reputation among clinical research organizations and sponsoring companies when making your debut into clinical research. Remember: Good news spreads slowly but bad news spreads quickly. A bad performance can knock you out of the business quickly. Do not overextend or overcommit.

5. Do not select all trials presented to you by sponsors. The target patients should be reflected by your practice setting. Selecting a trial for disease states that are naturally common to your patient population avoids unproductive recruiting searches.

6. Develop a database of patients with key disease states you anticipate will be areas of forthcoming trials. In our practice, we have done this with hepatitis C, non-alcoholic liver disease and inflammatory bowel disease patients. When a sponsor comes, we can not only demonstrate the number of potential patients, but also have a means to rapidly recruit to studies, which frequently have competitive enrollments. Sites that are able to enroll more are frequently

given this preference by the sponsors if enrollment by other sites lags.

7. Market your practice. Mention to pharmaceutical representatives that you are in this business and have them pass your name to their companies. In addition, promote your practice, patient population, expertise and experience to contract research organizations.

Do your due diligence

The development of a clinical trials program can be personally, intellectually and financially rewarding if it is developed properly. You will not only provide your patients and community with care they may not otherwise receive, but you will also keep yourself on the leading edge of change and development in your field. If done well, a clinical trials program can provide a very meaningful alternate revenue stream to your standard practice. Just make sure you do it well.

Pathology Options

By Klaus Mergener, MD, PhD, MBA, FACP, FACP

Busy endoscopy centers generate large numbers of biopsy and polypectomy specimens for histologic evaluation. The tissue is initially fixed in formalin and then prepared for reading by embedding it in paraffin, cutting and mounting it onto slides and finally staining it with a variety of solutions. This work is referred to as the "technical component" (TC) of the pathology service. Slides are then examined and interpreted by a pathologist. This represents the "professional component" (PC) of the service.

Traditionally, GI practices have sent tissue specimens to an external laboratory at a local hospital or a national lab company for processing and interpretation. The external pathology company then generates

a report back to the practice and bills insurers and patients independently for both the TC and the PC.

In recent years, many GI practices have explored the option of insourcing pathology services (either TC, PC or both) in order to better control quality and turnaround times, but also to capture additional revenue in an era of continued cost increases and reimbursement cuts. Others have engaged in a practice termed "client billing."

The following review explains these different models and provides practical tips for interested GI practices to consider.

Insourcing the TC

The TC of the pathology service (i.e., getting polyp tissue and biopsies ready for professional interpretation) can be performed as a semi-automated process in a 300-400 sq. ft. laboratory. Equipment required includes a processor, embedding center, microtome, stainer and cover-slipper. The initial financial investment is modest, and should always include obtaining the assistance of an experienced consultant to build the lab and help navigate the many legal and regulatory issues. Some payers now require accreditation of in-office pathology laboratories,⁵ and the related costs need to be factored into the overall expense of creating the lab.

Operational expenses will include rent, utilities, supplies, maintenance and repair costs as well as salary and benefits for one or more histopathology technicians. Building a small, de novo histopathology laboratory and getting it ready for operations can usually be accomplished with outlays of under \$500,000.

The upfront investment necessary to build the lab will only make sense if a GI practice is large enough to generate

a sufficient enough number of tissue specimens to recoup its investment and reach profitability in a reasonable amount of time. As a general rule of thumb for determining the feasibility of TC insourcing, an annual volume of at least 5,000-6,000 specimens is desirable. These specimens must be available to be processed in the practice's own laboratory (i.e., not tied to payer contracts that mandate processing of tissue by a specific external laboratory).

Insourcing the PC

The pathologist interpreting the tissue specimens can be employed by the practice or work as an independent contractor. In a single-specialty GI practice, this work is highly focused (only involving GI specimens) and usually comes without any on-call requirements, making employment an attractive proposition to many pathologists. Issues such as backup staffing for vacations and absence due to illness need to be considered and favor larger volume practices, which may generate work for more than one pathologist.

An important regulatory issue to consider is the Medicare anti-markup rule and site-of-service requirement for the PC. In short, in order for the GI practice to bill Medicare for the PC and realize a profit from this service, pathologists need to perform at least 75% of their professional services for the GI practice or perform their work "in the office of the billing physician." A more detailed discussion of this important regulation is beyond the scope of this review and can be found elsewhere.⁶

Legal framework

While the federal Stark law generally prohibits physicians from referring patients to entities with which they have a financial relationship, such referrals are permissible under certain

circumstances under the in-office ancillary services exception (IOASE) to the Stark law.⁷ Recent concerns about inappropriate overutilization of such self-referred services have led to a number of challenges to the IOASE on both a federal and a state level. However, proponents of in-office labs have argued that evidence for such inappropriate overuse is scant and contradicted by a recent study,⁸ and that the IOASE instead improves patient care and efficiencies by integrating necessary medical services in a single office. At the time of this writing, proposals to limit the scope of this exception have not been adopted.

Reimbursement for pathology services

Table 1 shows commonly used Current Procedural Terminology (CPT) codes for GI pathology services and their 2015 Medicare reimbursement rates. Medicare payments for the TC of the most commonly reported code for GI pathology work (CPT 88305) were reduced by 52% in 2013 and many commercial payers have since followed suit on this payment reduction. While operating a histopathology lab can still be a profitable proposition, GI practices need to perform a detailed analysis of the payment rates for their major payers and expect the rate of return for newly built pathology labs to be lower compared to previous years.

Notes about quality

The insourcing of pathology services greatly improves the GI practice's ability to take control of turnaround times and the quality of the service. Many practices now guarantee a 1-2 day turnaround on pathology specimens and create a single report to the patient, including the endoscopy findings, pathology results and their interpretation. A single bill can be generated for the entire service.

When hiring pathologists, an effort can be made to find providers with subspecialty training in GI pathology. Pathologists often participate in the GI practice's journal clubs, peer review meetings and quality assurance projects, thereby facilitating the dialogue with their gastroenterology colleagues about complex clinical cases. While it is difficult to quantify the effect of this approach, we believe that having well-trained GI pathologists as an integral part of the GI team has resulted in substantial improvement in the quality of the service we provide to our patients.

Client billing

Some GI practices that do not want to consider insourcing of pathology may instead choose to pursue another model known as client billing. With this model, the GI practice purchases pathology services at a discounted

Table 1. 2016 Medicare payment rates (national average) for commonly used GI pathology CPT codes

CPT	Descriptor	Global Payment	Professional Component	Technical Component
88305	Surgical pathology, level IV (gross and microscopic examination)	\$74.11	\$39.74	\$34.37
88312	Special stains (microorganisms)	\$98.82	\$28.29	\$70.53
88313	Special stains (e.g. iron)	\$69.10	\$12.53	\$56.57
88342	Immunohistochemistry	\$107.41	\$37.24	\$70.18

rate from an independent laboratory or pathology group. The GI practice then bills insurers and patients for this pathology work at the full rate, thereby realizing a profit in exchange for assuming the costs of specimen collection, billing and related administrative services.


The advantages of client billing include the practice's ability to partake in the pathology reimbursement without having to assume the cost and the risk of insourcing this service. Practices that do not generate large volumes of specimens may find this option particularly attractive. However, Medicare rules prohibit client billing, and several states have passed disclosure laws and anti-markup rules that need to be reviewed to determine whether client billing is an option in a specific commercial market. A list of states with direct billing and anti-markup laws can be found online.⁹

Take-home messages

Here are three key take-home messages:

- Insourcing the TC and/or PC of pathology services provides gastroenterologists with an opportunity for ancillary revenue. It is still feasible for medium- and large-sized practices even after recent reimbursement cuts.
- A detailed review by regulatory and legal consultants is necessary before internalizing TC/PC or pur-

suing other models such as client billing arrangements.

- In an era of bundled payments, GI practices are well advised to internalize and thus control the operations and related quality and costs of all services that are integral to the performance of GI endoscopy, including the pathology evaluation of tissue specimens. 

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