

## An Overview of In-Office Pathology Models

# Available to GI Practices

BY GB PRATT & BRIT YOUNG, ESQ.

Over the past several years, gastroenterologists have increasingly considered in-office pathology for the clinical benefits and ancillary revenue opportunities. The variety of models available for in-office pathology has led to questions regarding the groups that qualify, necessary structures, and which model is most appropriate. This article provides an overview of the most common pathology models.

### GLOBAL PATHOLOGY

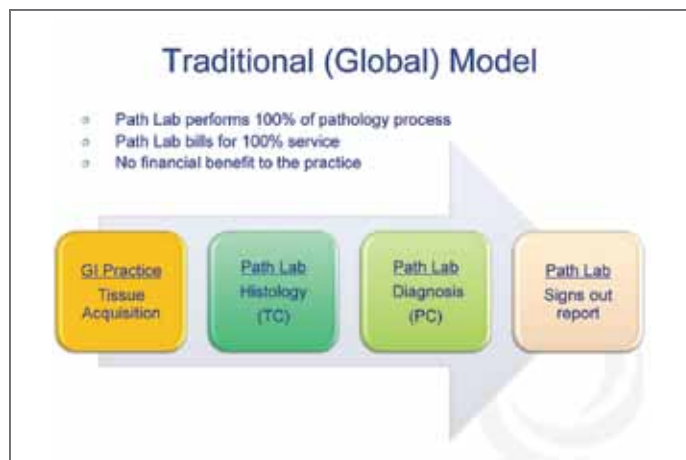
The traditional pathology model that a majority of GI practices still employ is the "global" model, in which the laboratory provides all of the pathology services (both technical and professional), and bills the payer for the entire charge. There is no financial benefit to a practice using the global model.



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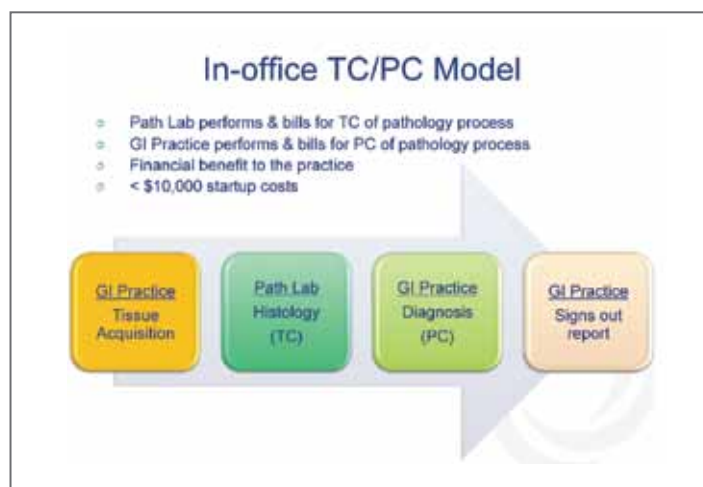
Over the past decade, many GI practices have shifted their global pathology service from hospitals to independent commercial laboratories to take advantage of the benefits that the commercial laboratories often provide over traditional sources, such as:

- **GI fellowship and subspecialty trained pathologists** to ensure pathologists have GI training and experience
- **GI focused histotechnicians** that process multiple sections of the biopsy to facilitate definitive diagnoses
- **Rapid turnaround time**, typically 24-48 hours
- **Electronic requisitions and EMR interfaces** to save time and ensure accuracy

### IN-OFFICE PROFESSIONAL COMPONENT, A.K.A. TC/PC

TC/PC refers to the in-office pathology model in which the referring physician practice sends its specimens to an outside laboratory for the processing of the specimens into slides. This outside lab then bills payers for the provision of this "technical component" (TC) of the pathology process.

After the specimens are processed, the resulting slides are then sent to a pathologist that is contracted to provide reading and interpretation services for the referring practice. The practice can then bill the payers for these services, known as the "professional component" (PC).



Because the same pathologist performs the professional pathology services in the practice's office, the TC/PC model provides significant clinical benefits and enhanced

patient care, including:

- **A pathologist specialized in the field of the practice**
- **The same pathologist for every specimen, with open lines of communication with the referring physicians**
- **A standard diagnostic lexicon between the pathologist and the referring physicians**

**“Under the TC/PC model, the pathologist becomes a member of the endoscopy team; improving communication and enhancing quality and patient safety.”**

*– Dr. William Dupree, Director of Pathology for EndoChoice, Inc.*

In order for the referring physician practice to perform the PC, a pathologist joins the group, either as an employee or an independent contractor. The pathologist can be compensated via salary, a set dollar amount per billable specimen, or in some states, as a percentage of receivables. Average compensation for the pathologist nationally amounts to 50% of the PC reimbursement or approximately \$20 per specimen. Likewise, because it is contributing to the episode of care by providing the equipment and the overhead (including malpractice insurance), the practice can realize the remaining revenue from the PC reimbursement (usually \$20/specimen).

**“With very minimal investment, the TC/PC model provides the opportunity for a significant source of ancillary revenue along with the clinical benefit of having a pathologist join the group practice.”**

*– Dr. Nidhir Sheth, Gastroenterology Associates of South Jersey*

It is important to note, however, that laboratory services are considered “Designated Health Services,” so if the practice wishes to bill government payers, it must comply fully with Stark Law, as well as the CMS Anti-Markup Rules. Practices performing the TC/PC model typically use the Stark “In-Office Ancillary Services Exception” (IOASE) to comply with Stark Law. In order to satisfy the IOASE and the current Anti-Markup Rule, the professional component is usually performed at the site where the referring physician regularly provides his full range of patient care services (i.e., the referring physician’s practice office, not the ASC where he is only performing procedures). Also, in order to satisfy the IOASE, the PC must be billed by the

group practice of the referring physician.

In addition to the federal requirements mentioned above, it is also important for practices to be cognizant of their state laws. State self-referral laws tend to apply to all payers (not just government payers), and can have more stringent requirements than the federal laws. Also, state fee-splitting laws may limit the available relationship and compensation structures for the pathologist.

Under the TC/PC arrangement, the practice must provide the following for the pathologist:

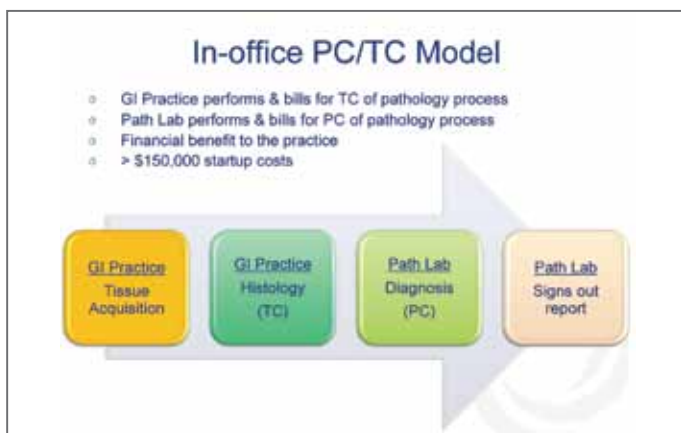
- Space for the pathologist to perform the professional component services
- Adequate malpractice insurance
- Necessary equipment, including a microscope, a slide storage unit, and a computer for the Lab Information System (LIS)
- Lab Information System (the laboratory providing the technical component usually will provide a remote instance of their LIS)

Additionally, the practice must take steps to prepare its in-office pathology lab, including: obtaining an unwaived CLIA certificate, enrolling the pathologist under the practice’s payer contracts, undergoing an inspection by state laboratory authorities, and entering into a work agreement with the pathologist.

In addition to the clinical benefits described above, these relatively minor start-up costs make TC/PC a very attractive in-office pathology model for the small to mid-sized practice.

### **IN-OFFICE TECHNICAL COMPONENT, A.K.A. PC/TC**

PC/TC is the reverse of the TC/PC model, in that the referring physician practice performs the technical component (i.e., slide processing) in its own histology laboratory, and bills the payer for the TC. The processed slide is sent to an outside pathologist to perform and bill the professional component.



Though the TC reimbursement is typically higher than reimbursement for the PC (approximately 60% vs. 40% of

the overall reimbursement, respectively), the out-of-pocket start-up costs for a practice wishing to build its own histology lab can be significant (\$150,000— \$300,000), and managing the required non-physician technicians can become an administrative burden.

Additionally, performing only the TC in-office does not provide the clinical benefits of having the in-office pathologist with the TC/PC model.

It is also important to note that the PC/TC model has the same legal and regulatory considerations described above for the TC/PC model. In addition, state regulatory requirements relating to the provision of in-office TC laboratory services may be more stringent than with PC services due to the technical nature of the histology services and the handling of unprocessed human tissue and chemicals.

### PHYSICIAN-OWNED LABORATORY

A large practice may find it makes economic sense to build its own laboratory where both the professional component and the technical component are performed. Due to the significant start-up costs of this model (\$150,000– \$300,000), it is typically only recommended for practices that perform more than 8,000 procedures per year.

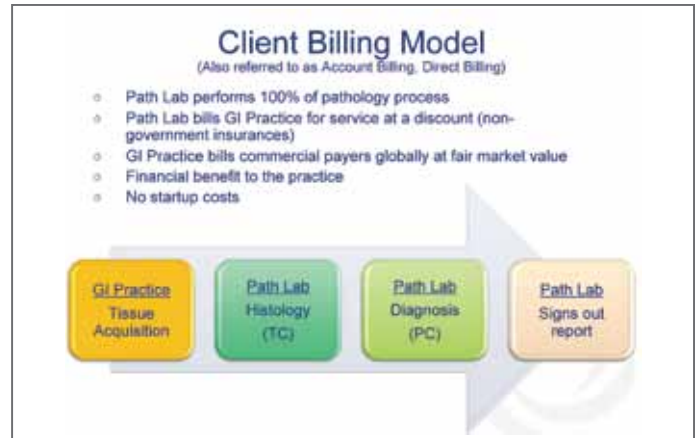
Practices building a physician-owned laboratory must comply with the same Stark Law and Anti-Markup Rule restrictions described above. However, they generally have the resources and specimen volume to hire a full-time pathologist to perform services. If this is the case, subject to applicable state law, the services may be performed by such pathologists in a building separate from where the referring physicians perform their patient care services, as long as it is space leased full-time by the practice.



### CLIENT BILLING

An additional model that does not require the practice to perform either the technical component or the professional component is known as client billing (also known as account billing or direct billing). In client billing, the physician practice purchases the technical component and/or professional component at a discount from the laboratory and

re-bills the services directly to the payer. In this arrangement, though no pathology services are provided by the referring physician practice, the practice realizes revenues in exchange for assuming the laboratory's billing, administration and collection risk costs.



Client billing arrangements are only allowed for private payers because federal restrictions governing the government health plans generally do not allow for any markup for services. Also, in order not to violate the federal Anti-Kickback laws, the fee the laboratory charges the practice must be at least at fair market value and reasonable in light of the services the practice is performing.

It is also important to note that many states prohibit client billing, and some that do permit it require disclosure to the patient and/or payer.

### SUMMARY

In-office pathology is becoming increasingly popular as practices look to improve patient care and increase ancillary revenues. As described above, the right model for your practice will depend on your practice's size, location, payer mix and available space.

*It is important to note that the legal environment surrounding each of the in-office pathology models described above is highly technical and changes frequently. This article is an attempt to provide a high-level overview of the current in-office pathology options available, but is not a comprehensive analysis of the legal requirements for your practice. Please seek advice from a health care attorney prior to an investment in in-office pathology.*

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Prior to joining EndoChoice, Mr. Pratt has served as CEO, vice president and director at leading medical service and electronic medical record companies focused on health care integration platforms linking hospital and physician practices on services such as pathology and imaging.

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Mr. Young has represented companies in all stages of growth from organization to IPO. In such capacity, Mr. Young has negotiated and documented dozens of transactions, with a focus on mergers and acquisitions, and venture capital, private equity and debt financings. Mr. Young also has extensive experience in Stark Law and compliance.

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