Over the past several years, physicians who specialize in fields such as dermatology, gastroenterology, and urology have increasingly considered in-office pathology laboratories for the clinical benefits and ancillary revenue opportunities. The variety of models available for in-office pathology labs has led to questions regarding the groups that qualify, necessary structures, and which model is most appropriate. Through this article I hope to provide an overview of the most common in-office pathology models.

Defining the Pathology Process

Before one can delve into the different pathology models available to physician practices today, it is important that the pathology process is clearly defined. In traditional terms, when a physician performs a biopsy on a patient, that surgical specimen is sent to a pathology laboratory for interpretation.

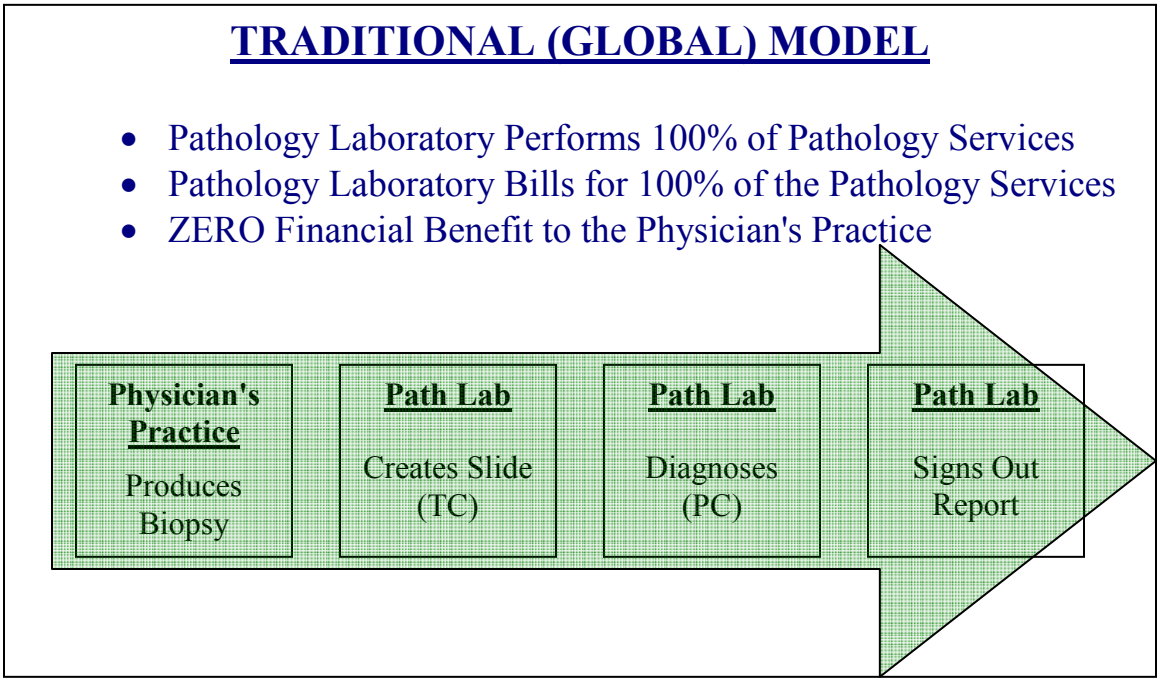
Once receiving the biopsy, the pathology laboratory has a licensed histotechnician(s) gross the specimen, process the tissue (usually a four to six hour process), embed the specimen into a cassette, cut the tissue, fixate the tissue to a slide, stain the slide, and finally coverslip the final product. This practice is called the Technical Component (TC) of pathology services.

After the slide is prepared, it is delivered to a pathologist along with a preliminary report that contains the patient's demographics, the type of biopsy that was taken (a shave, punch, excision, etc.), the part of the body from which the specimen was removed, the clinical description, and the gross description. The pathologist will interpret the slide and provide their diagnosis along with a microscopic description of their findings. Finally, these results are transcribed and an official report is generated. This practice is called the Professional Component (PC) of pathology services.

Global Pathology

The traditional pathology model that the majority of physician's practices still employ is the “global” model, in which the laboratory provides all of the pathology services (both

the technical component - preparing the slide and the professional component - providing the diagnosis), and bills the payor for the entire charge. There is no financial benefit to the physician's practice for using the global model.



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

• Subspecialty trained pathologists to ensure that they have focused training, experience, and expertise in your specific discipline;

• Licensed histotechnologists who process multiple sections of the biopsy to facilitate definitive diagnoses;

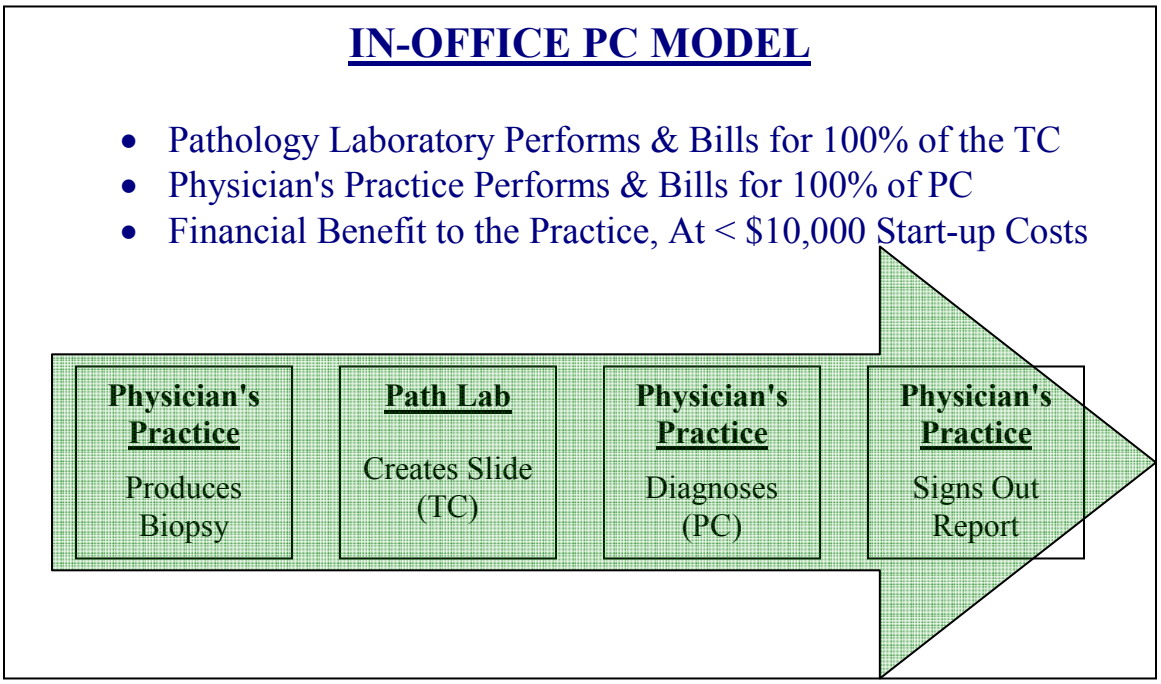
• Rapid turnaround time, typically 24-48 hours;

• Customizable requisitions, reports, as well as electronic reporting to save time and ensure accuracy;

• In-house couriers and account executives who guarantee that each physician's practice is provided the exclusive attention that it deserves.

In-Office Professional Component Model

The In-Office PC Model is the most frequently used model for physician's practices that employ an in-office pathology laboratory. This model entails the referring physician's practice sending its specimens to an outside laboratory for the processing of the specimens into slides. This independent lab then bills payors for the provision of the "technical component" of the pathology process. After the specimens are processed, the resulting slides are then sent to a pathologist who is contracted to provide reading and interpretation services for the referring practice. The practice can then bill the payors for these services, known as the "professional component".



Because the same pathologist performs the professional pathology services in the practice's office, this model provides significant clinical benefits and enhanced patient care, including:

• A pathologist with specialized training 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.

In order for the referring physician's practice to perform and bill for the PC, a pathologist must join the group as a "bonna fide" employee. The pathologist can be compensated via salary or a set dollar amount per billable specimen. Average compensation for the pathologist (fair market value) nationally amounts to 50% of the PC reimbursement rate or approximately $20 per specimen. Likewise, because it is contributing to the episode of care by providing the equipment and the overhead (often including malpractice insurance), the practice can realize the remaining revenue from the PC reimbursement (usually $20-$30 per specimen).

It is important to note, however, that laboratory services are considered “Designated Health Services.” This means that in order for a physician's practice to obtain a CLIA license and bill both government and non-government payors, it must fully comply with a number of state and federal regulations. Some of these regulations include the Stark Law, Fee-Splitting Prohibitions, the Patient Brokering Act, Self-Referral Laws, as well as CMS Anti-Markup Rules. Practices performing the in-office PC model must make sure to follow the Stark “In-Office Ancillary Services Exception” (IOASE) to comply with most of these regulations. In order to satisfy the IOASE and the current Medicare Anti-Markup Rule, the professional component must be performed at the site where the referring physician regularly provides their full range of patient care services (i.e., the referring physician’s practice office, not the surgery center where they perform procedures).

Under this in-office professional component arrangement, the physician's practice must provide the following for the pathologist:

• Space for the pathologist to perform the professional component services (mainly consisting of a desk and office chair);

• Necessary equipment, including a microscope, a slide storage unit, and a computer for the Lab Information System (LIS);

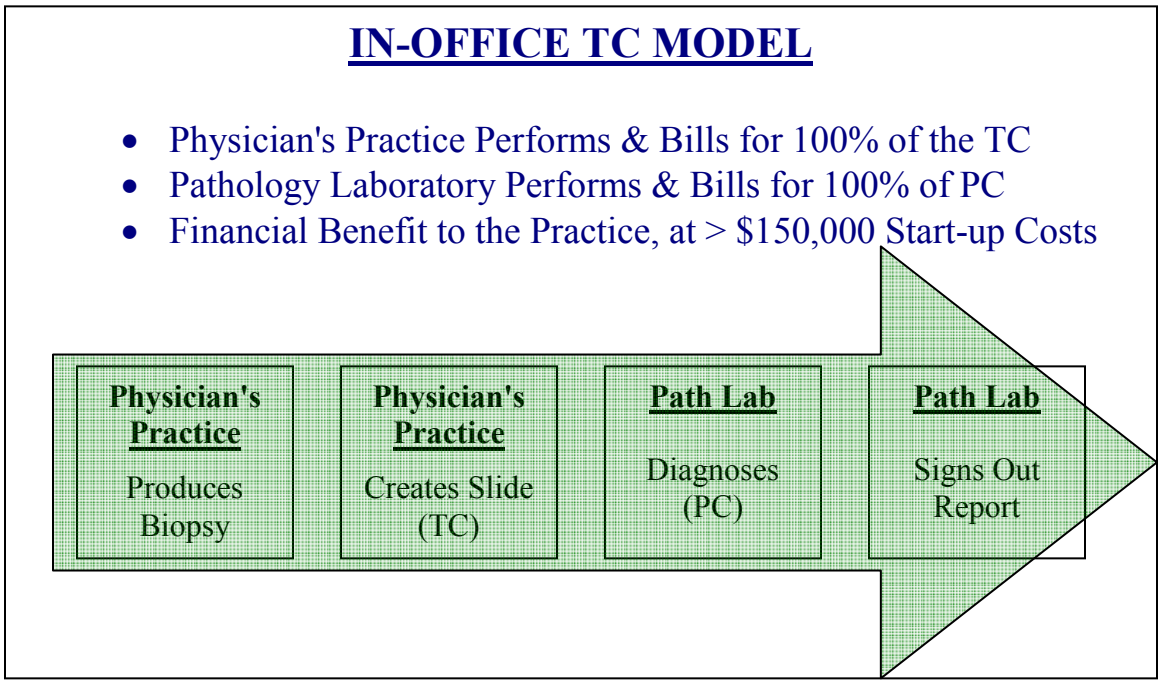
• A Lab Information System (although the laboratory providing the technical component usually will provide remote access to their LIS).

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 payor contracts, undergoing an inspection by state and/or federal 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 an In-Office Professional Component Pathology Laboratory a very attractive model for a small to mid-sized physician's practice.

In-Office Technical Component Model

The In-Office Technical Component Model is the reverse of the In-Office Professional Component Model; in that the referring physician's practice performs the technical component (i.e., slide processing) in its own histology laboratory, and bills the payor for the TC, while the processed slide is sent to an independent pathologist to perform and bill the professional component.



Though the TC is reimbursed at a higher reimbursement rate than the PC (approximately 60% vs. 40% of the overall compensation, respectively), the out-of-pocket start-up costs for a practice wishing to build its own histology lab can be significant (usually between

$150,000 and $300,000 - depending on the discipline). The required equipment to run an in-office histopathology lab includes (with quoted prices represented as approximations from a 2010 cost analysis); a grossing station ($2,500), a tissue processor ($30,000), an embedding center ($15,000), a microtome ($12,000), a flotation waterbath ($1,000), an automatic stainer ($30,000), a coverslipper ($25,000), a standard refrigerator ($1,000), and a table top lab oven ($500). An immunohistochemistry stainer ($125,000) may also be necessary, but most vendors will provide these at a significant discount if you sign a reagent usage contract, where you agree to exclusively use their reagents and products.

Besides the high out-of-pocket initial investment, another draw back to the in-office TC model is the time commitment and day-to-day management of the required non-physician technicians and histotechnologists, which can become an administrative burden. Additionally, performing only the technical component in-office does not provide the same clinical benefits as having an on-site pathologist, as with the in-office PC model.

It is also important to note that the in-office TC model has the same legal and regulatory considerations described above for the in-office PC model. This means that the lab must be on-site, where the physician sees patients, and therefore requires considerably more in-office space to be dedicated and built-out; including significant countertop space, fire-safe storage cabinets for chemicals, and high-powered exhaust fume hoods.

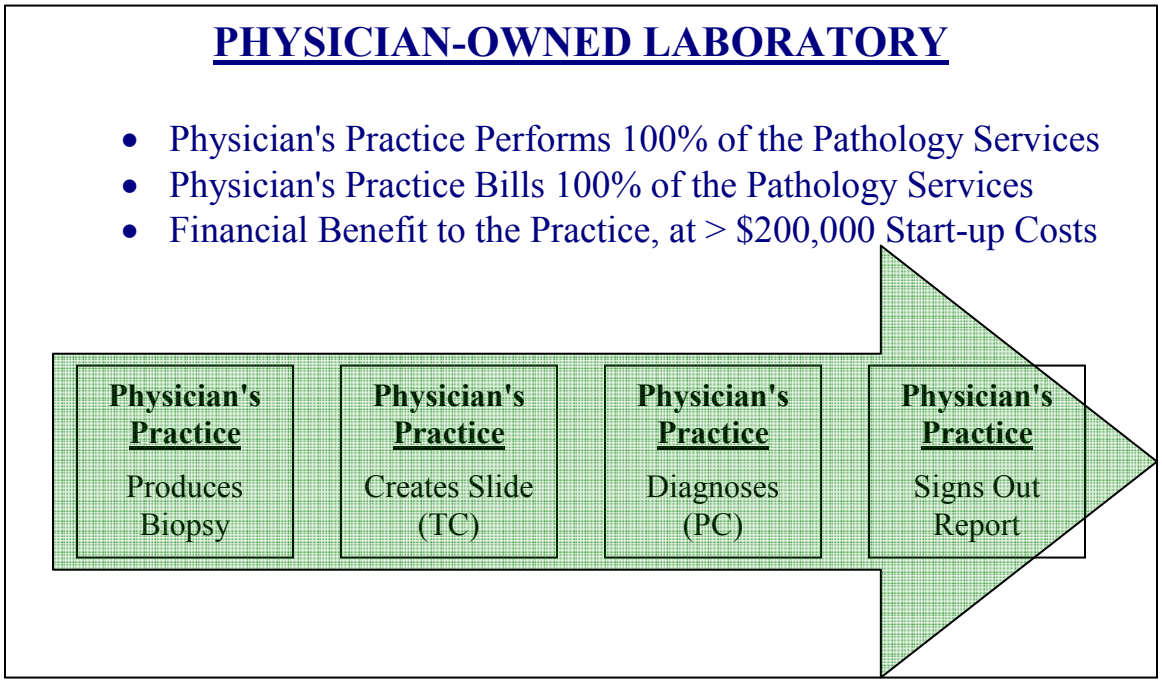
The final element to consider when deciding whether an in-office technical lab is a viable alternative for a practice is sensual; in sound, sight, and smell. Pathology laboratory end-users (referring physicians and patients) typically do not visit the lab where they send their specimens; so they are not aware of the excessive noises caused by high-powered exhaust fans that are constantly running, the paraffin wax that becomes embedded in all lab fixtures, the Hematoxylin and Eosin stains that inherently discolor the counters and floor tiles, or the smells that are emitted, and eventually become rooted in the drywall and ceiling tiles of the building, from the required chemicals such as Flex Alcohol, Xylene, and Buffered Formalin. One must remember that an in-office TC lab is "in-office" where patients visit and may be dismayed by the noises and odors inherent in a TC laboratory.

Physician-Owned Laboratory

An extremely large practice may find it makes economic sense to build its own In-House Global Pathology Laboratory where both the technical component and the professional component are performed. Due to the significant start-up costs of this model ($200,000 – $350,000), it is typically only recommended for practices that perform more than 10,000 procedures per year.

Practices building a physician-owned global 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.

Patient care is escalated in this model and the physician's practice can bill out 100% of all pathology services. High reward often includes some risk, and with this model a physician's practice is open to extended liability. Typically during a malpractice claim a plaintiff will bring suit against their physician, the pathology laboratory, and the diagnosing pathologist (with each party bringing their respective insurance policy limits to a mediation table). In the Physician-Owned Laboratory model, one must understand that they are the sole proprietor of all three branches, which increases their liability in the case of a malpractice claim.



Client Billing

An additional, but an infrequently used, 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's practice purchases the technical component and/or professional component at a discount from the laboratory and re-bills the services directly to the payor. In this arrangement, though no pathology services are provided by the referring physician's 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 on services that they don't specifically render. 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 payor.

The conundrum that exists in client billing is that the rules and regulations that a laboratory and a physician's practice has to abide by are separate and somewhat contradictory of each other. As part of a pathology laboratory's Medicare Agreement, the lab is contractually obligated to adhere to an "across-the-board" billing philosophy. Here, the lab cannot charge a non-Federal health care plan, provider, or non-indigent patient the "lesser-of-cost-or-charges" than they charge a Federal health care plan (Medicare or Medicaid). The premise behind this is that if a "usual" discount is able to be offered to a non-Federal provider then the Federal provider must be offered that same discounted rate. For example, if a laboratory charged a physician's practice, or any other third party payor, a flat fee of $20 for the technical component, the maximum they would be legally allowed to charge Medicare for all future 88305-TC's (the CPT billing code for surgical pathology) would be $20. Billing them anything more would be in violation of their CMS contract.

So the problem exists where a physician's practice is legally allowed to purchase the technical component at a discount and mark-up the component when billing it to a non-Federal third party payor; yet regulations are in place where labs cannot legally sell the component at a discounted rate; leaving this model at an impasse.

Unfortunately for law-abiding laboratories in this industry, many smaller competitive labs do still sell physician's practices the technical and/or professional component at discounted rates. So while this model is officially prohibited, it is none-the-less an option and an everyday happening for many physician's practices that can find an independent laboratory to partake.

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 a practice will depend on the specific practice's size, location, payor 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. It is strongly urged for anyone progressing in this arena to seek advice from a health care attorney prior to any investment in in-office pathology.

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Wes Moschetto, Owner and President of iPathology, LLC
Wes Moschetto has over 10 years experience building and managing both independent pathology laboratories and physician owned in-office pathology laboratories. Mr. Moschetto is the head of a pathology practice management firm that advises, builds, and manages, laboratories to ensure optimum performance in clinical care as well as ancillary returns on the practice's investment.