

## **Office-Based Laboratories: Navigating The Pitfalls to Reap The Rewards**

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Adding ancillary services, as a means to improve practice profitability and increase physician and patient satisfaction, continues to gain momentum among physician practices across the country. Given national data on the growing pressures faced by physician practices, it is not surprising that physicians and their office administrators are looking for ways to increase profitability, assert more control over the patient care process and differentiate themselves from the competing physician group down the street. Numerous studies tracking physician job satisfaction find that physicians are experiencing greater dissatisfaction with their jobs than ever before; with many citing a lack of control over process as a key contributor to their unhappiness.

Laboratory testing has historically been an area where lack of control has frustrated physicians. Lost patient samples, delays in results, inconclusive test results can lead to physician and patient frustration and in some cases, lapses in the quality of patient care. Greater control over laboratory testing, as well as its potential to deliver a source of new revenue, makes opening an office-based lab an opportunity for physician practices. Done well, an office-based laboratory that goes beyond the simple waived pregnancy and glucose dipsticks can offer numerous benefits for physicians and their patients; but the complexities of opening and then managing an office-based lab can also pose a significant threat to the practice if unanticipated problems arise.

*What is the Road Map?*

A wrong turn can occur as early as the decision to add an office-based lab. Careful analysis of the practice's patient base, historic test volume, and payer mix are crucial first steps that cannot be overlooked in the decision phase. There are critical thresholds of testing volume and expected reimbursement that are clear indicators of whether an office-based lab will have a positive benefit on the practice. Often, because a practice interested in starting a lab has no previous claims experience, they lack the expertise to effectively analyze their potential reimbursement and revenue landscapes. And while there are generic analyses readily available based on volume, many physicians find that once their lab is running, the previous generic analyses do not end up mirroring their real-world experiences.

*The basics can make or break the whole plan*

A thorough feasibility analysis is needed to determine equipment needs, space and staff planning and how this new service will fit into the current practice workflow. Identifying which instruments to purchase and how to configure a lab for effective space utilization can be a challenge to physicians and administrators who lack previous lab experience. Like any product, research can be done and support from manufacturers or consultants can be helpful, but physicians must use their own knowledge to identify what are the precise features they need to service their unique patient population. Often new instruments are launched with many more bells and whistles than an office-based lab could economically use. Physicians must take a critical look at technology and match the instrument capabilities to their patient mix to appropriately identify the specific list of equipment needed for their lab. A review of recommendations for equipment from manufacturers or consultants must take into consideration that the manufacturer or individual has something to gain when you buy from them. Their job is done once they have the sale. You will be left to make the instrument work for the practice.

Staffing is the next major hurdle in planning for the lab. The phlebotomist and laboratory technologist are the central figures in the lab. The phlebotomist is the critical person to draw blood and keep samples flowing to the technologist. The phlebotomist is also the face of the lab and can make or break patient satisfaction. For the technologist, the job description not only requires clinical expertise but also business acumen for precise ordering of supplies (and therefore managing the lab’s profitability), effective decision-making regarding lab operations and the ability to identify problems and solutions before they can negatively impact the lab or the practice. In a sense, the lab tech is the air traffic controller as well as the pilot. He or she must watch out for hazards and perform the key function – the testing. With availability of lab techs low, screening can be made more difficult when there are few candidates to choose from. But without a strong technologist to work closely with the physicians, tasks such as problem identification and cost management can quickly derail an office-based lab’s success.

*Key traits to look for in hiring a medical technologist in an office-based laboratory*

Technical competency	Ability to identify problems and potential solutions	Laboratory financial management experience	Policy development knowledge and experience	
Problem-solving skills	Collaborative with physician director	Supply ordering and management expertise	Previous experience with inspections and compliance management	

*All Systems Go Until You Stall on the Launch Pad*

Once a good roadmap is completed, it seems setting up and operating the lab should be straightforward. Get the instruments and supplies and then, send in the patients. Were it so easy, you might find a lab in every physician office. Getting through the planning process is an important hurdle, but progress in the time period following planning to lab set-up and operation can be delayed for many legitimate reasons including: instrument set-up and calibration issues, development of standard operating procedures, regulatory inspections and preparations for accurate test coding and billing.

### *Instrument Calibration and Transition to Operation*

Chemistry analyzers and other instruments require precision for set-up, calibration and verification testing process. Getting more than one piece of equipment up and running and then creating connectivity among the instruments and the laboratory information system doesn't always go smoothly. Once the instruments are in the office, along with the lab tech to run them, each day that they are not being used for testing costs money and drains practice profitability. Conversely, a smooth transition to operation, where things run like clockwork, can begin the process of paying back the practice's upfront investments.

### *Passing the Inspection*

Inspections are a critical component of laboratory operations. Inspectors do not give you credit for being a new lab or special consideration for your learning curve. Documentation needs to be thorough, policies must be written and available and staff must demonstrate they have the knowledge required to effectively run the lab. Documentation polices and procedures and smooth operations are all requisite to obtain a regulatory sign-off. When a lab fails an inspection, that idle lab drains profits and physician time.

### *Getting Your Billing and Compliance Plans in Place Before You Begin*

The final step in opening the lab is ensuring that the physicians and office staff are well-trained and prepared to begin the process of coding and billing for the new laboratory services. Mistakes in coding and billing are a significant risk to physician practices. Such errors can result in a loss of revenue but also have implications for fraud and abuse if coding and billing are not done properly. Thus, the financial repercussions could quickly escalate from lost revenue to penalties and fines. Many office-based labs get into trouble in this area. More often than not, it is a case of misinformation or lack of clarity on policies and procedures among staff. But, obviously the implications and threat to the practice could be disastrous. Drafting policies from scratch is a time-consuming process, especially if the service is new to the practice, and sufficient time must be devoted to this task in order to have the lab run smoothly and be in compliance with state and federal mandates regarding patient care, testing and referrals.

Compliance monitoring is critical to success. Changes in reimbursement guidelines, new payer policies, new fee schedules or medical necessity guidelines are difficult to keep up with, but must be followed in order to ensure revenue is appropriately billed and collected.

### *Realizing the Value*

Once the lab is up and running, a constant vigilance is required to keep a watchful eye on the operations. But, once open, the benefits of having an office-based lab can grow exponentially.

Fears of inaccurate results, lost samples or delayed test results can be better managed in an office-based lab. With tighter control over the testing process, physicians usually report increased satisfaction with lab services and improvements in clinical decision-making. A well-run lab can support physicians' needs for the right information at the right time.

Patient satisfaction is also a benefit of the office-based lab. With no need to go elsewhere for testing, patient compliance and satisfaction usually go up. And, with fewer complaints about missing or lost lab results, practices have one less emotional issue to address for their patients.

The financial impact of an office-based lab can be significant. Run poorly, labs can be difficult to manage and costly. However, when running with precision, office-based labs can be an important source of revenue for practices, providing additional income or capital for growth. The potential income will be determined by volume, payer mix and the operational costs of the lab and should be evaluated prior to building the lab. Ongoing management of supplies, staffing, maintenance and repairs, and coding and billing practices is integral to ensuring the lab remains profitable. Overstocking of reagents and high maintenance costs are often the key areas subject to financial waste in an office-based lab.

The complexity of the lab costs and the management of those costs is usually the number one reason physician practices turn to outside consultants for support. But, it is more difficult to correct problems than set the lab up correctly in the first place. And, it is often the initial steps such as feasibility analysis, equipment and personnel selection and billing policies that are most challenging for labs to initiate and maintain. For practices with sufficient volume, an office-based lab is a smart way to switch from outsourcing testing to handling it within the practice. But, as with all investments, understanding the intricacies of each issue or seeking outside counsel to provide guidance if you do not have relevant experience, is requisite when considering or operating a physician-office laboratory. Having an office-based lab is a valuable asset, and physician practices will do well if they give the lab the same commitment, interest and investments that they do any other growth area for their practice or other business endeavors. A well-run office-based laboratory has the potential to be the most important ancillary service in the practice.