

ESTABLISHMENT OF IN-HOUSE HISTOLOGY LABORATORIES

Jane Pine Wood, Esq.
McDonald Hopkins LLC
956 Main Street
Dennis, MA 02638
508.385.5227 (direct dial)
508.385.4355 (facsimile)
jwood@mcdonaldhopkins.com

In light of the government scrutiny and regulatory initiatives to limit pod laboratories, many referring physician practices, such as urologists and gastroenterologists, are pursuing the establishment of an in-house histology laboratory. These practices often contract with their local pathology practices for assistance in establishing the laboratory and providing professional interpretations. The principle legal and business considerations associated with these arrangements are outlined below.

A. Financial Expenditures

Obviously, there are significant financial expenditures involved in the establishment and operation of a histology laboratory. Not only must the referring practice make space available for the laboratory, but it also must invest in equipment, personnel, and supplies. In order to provide quality services, the practice must continue to invest in new equipment and in education and training for laboratory staff. The failure to do so not only can have an adverse impact upon patient care, but also can increase the practice's malpractice risk from the histology services that it provides.

B. Licensure and Certification

The practice must ensure that its histology laboratory is in full compliance with all applicable federal and state license and certification requirements, including but not limited to CLIA certification, state laboratory licenses, etc. This requires not only time and effort, but also financial expenditures. The failure to maintain proper licenses and certifications places the urology practice at risk for administrative penalties, the disallowance of payment for the pathology services, and increased malpractice liability.

CMS takes the position that CLIA certification is not required for technical component histology processing, although CLIA certification is required for other types of technical component services, such as cytology and IHC services. This is relevant to the application of the Medicare anti-markup rule, discussed below.

C. Malpractice Liability

Malpractice liability is a significant issue involved in the establishment of a histology laboratory. Because the practice will be the actual provider of the technical component pathology services, it will have full legal liability for the services. In the event of a malpractice action, the referring practice likely will be held to the standard of care of a hospital or pathology laboratory, which is a high standard of care.

Furthermore, the individual physicians in the referring practice who are responsible for the supervision of the pathology services will bear legal liability for their supervisory services. Under the new Medicare anti-markup rules, discussed below, one of the practice physicians likely will be designated as the “supervising” physician (this is different than the CLIA medical director), which could increase the malpractice exposure for this physician. In a malpractice action, the plaintiff’s legal counsel may argue that the applicable liability standard is the quality of supervision provided by a board certified pathologist, and any supervising physician must be prepared to fulfill this standard of care.

The referring practice also should confirm that its malpractice insurance covers not only the provision of the pathology services, but also the supervision of the laboratory personnel. This could entail additional insurance premiums and/or an endorsement or supplement to the policy.

D. Fraud and Abuse Compliance

In order to refer specimens of its Medicare and Medicaid patients to its own anatomic laboratory, the practice must comply fully with the in-office ancillary service exception of the Stark law. An important requirement of this exception is that the revenues from the practice’s technical component services cannot be allocated among the referring doctors based upon referral volume.

The applicable Stark law exception requires that the technical component services be provided by or under the supervision of one of the referring practice’s physicians, or an independent contractor of the referring practice. In light of both the location and the supervision requirements of the Stark law prohibition, the most reasonable location for the laboratory is in the practice’s offices (i.e., where the practice’s physicians see patients). If the practice has more than one office location, it is acceptable for the laboratory to be housed in one of the office locations.

It is permissible for the referring practice to contract with a pathology practice to provide consulting services with respect to the establishment and management of the ongoing operations of the referring practice’s laboratory, provided that (a) the consulting and management arrangements comply with the Stark law exception for personal service contracts or the Stark law exception for fair market value compensation, (b) the arrangements comply with the safe harbor under the Medicare and Medicaid anti-kickback law for personal services contracts, and (c) the referring practice remains responsible for its supervision obligations under the in office ancillary service exception. It also is possible for the referring practice to contract with the pathology practice as an independent contractor to provide the required supervision of the performance of the technical component services. Both Stark law exceptions and the anti-kickback safe harbor require that the compensation paid to the pathology practice for the consulting and management services, as well as the supervision services, reflect fair market value, and the compensation cannot vary based upon the value or volume of referrals between the parties.

E. Medicare Anti-Markup Rule

Pursuant to the new Medicare anti-markup rule, if the referring practice bills for the professional or technical component of a diagnostic test that was ordered by the practice and the diagnostic test is performed or supervised by a physician who does not “share a practice” with the billing/referring practice, the Medicare payment to the practice for the technical or professional component of the diagnostic test may not exceed the lowest of the following amounts:

1. The performing supplier’s net charge to the practice;
2. The practice’s actual charge to the Medicare program; or
3. The Medicare fee schedule amount for the service that would be allowed if the performing supplier billed the service directly to the Medicare program.

With respect to the technical component, the “performing supplier” is the physician who supervised the technical component, and that the “performing supplier” for the professional component is the physician who performed the professional component. CMS has indicated that the performing supplier’s net charge will be regarded as the amount paid to the supervising or performing physician, but does not include any amounts paid directly to the technician who furnished the technical component. In addition, the regulations specify that the net charge must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing/referring practice.

A referring practice that provides technical component pathology services in its own in-house laboratory can avoid the anti-markup rule by satisfying either of two alternative standards for “sharing a practice.” One alternative (“Alternative 1”) focuses on whether the supervising physician furnishes at least 75% of his or her professional services through the billing/referring practice. The other alternative (“Alternative 2”) focuses on where the diagnostic test is performed and supervised.

Under Alternative 1, a supervising physician is deemed to share a practice with the referring practice if the supervising physician furnishes substantially all (at least 75%) of his or her professional services through the referring practice. CMS has announced that supervision of histology processing need not be performed by a pathologist (because CLIA certification is not required for histology processing, as noted above), but could be performed by any physician within the medical practice. Therefore, if a referring practice has an in-house laboratory, a physician within that practice could be designated as the supervising physician for purposes of the anti-markup rule. Assuming the physician provides at least 75% of his or her services through the referring practice, the practice will avoid the application of the anti-markup rule with respect to all of its technical component services.

Under Alternative 2, a supervising physician will be deemed to share a practice with the billing/referring practice if the supervising physician is an owner, employee, or independent contractor of the practice, and the on-site supervision of the technical component by the supervising physician occurs in an office where the ordering physician provides services, presumably during all times when diagnostic tests are performed. This Alternative 2 may be difficult for multi-office practices to meet, although most practices should be able to comply with Alternative 1 to avoid the application of the Medicare anti-markup restriction.

F. Payor Issues

If the referring practice's operations comply with the Stark law in-office ancillary services exception, then the practice can submit claims for its technical component of anatomic pathology services to the Medicare and Medicaid programs as well as non-government payors (assuming the payors do not require designated laboratories to provide these services). The practice also should confirm that its major payors will reimburse the practice for the pathology services. Increasingly, payors are refusing to reimburse for diagnostic services provided by a referring physician practice. Instead, such payors will only reimburse for diagnostic services provided by a hospital or an independent freestanding diagnostic provider. Many national payors contract exclusively with selected laboratories for all pathology services.

Even if the referring practice's major payors currently reimburse for pathology services provided in its histology laboratory, the practice should be prepared for a change in the payors' policies, and the potential loss of the practice's investment in the histology laboratory.

Another payor issue that should not be overlooked is the increased billing risk for submitting claims for pathology services, particularly with respect to claims submitted to the Medicare and Medicaid programs. Most non-pathology practices (and their billing agents) do not have experience in billing for pathology services. Errors in claims submission for these services could increase the overpayment exposure of the referring practice.

G. Professional Interpretations

If the pathology practice will bill payors directly for its services, the referring practice will not be responsible for payment for these services. This is the preferred approach from a compliance and malpractice standpoint, and avoids the issues discussed below.

If the referring practice wishes to bill government payors for the professional interpretations, the practice will need to comply fully with an applicable Stark exception. Besides paying the pathology provider fair market value for the professional pathology interpretations, compliance with the Stark law typically will require the interpreting pathologist to provide the professional interpretations in the offices of the referring practice. The new anti-markup restrictions also will require the services to be performed by a pathologist who meets Alternative 1 (the 75% of his or her practice test) or Alternative 2 (interpretations provided in the offices of the ordering physician) if the referring practice wishes to obtain the full Medicare allowable payment for the interpretations.

The new rules will cause some problems for multi-location practices. For example, if a referring practice has five locations, and the pathologist provides professional interpretations in only one location, and if the pathologist does not meet the first “sharing a practice” test (the 75% test), then the anti-markup rule will apply with respect to any interpretations performed by the pathologist that were ordered by practice physicians who do not practice in the building in which the pathologist is providing his or her professional interpretations. If the practice physicians do not rotate through the office where the pathologist performs his or her professional interpretations, then the professional interpretations ordered by the physicians in the other four offices will be subject to the anti-markup rule. A second alternative is for the pathologist to move from building-to-building, interpreting in each location only specimens ordered by the physicians who practice in that location.

The referring practice will be responsible as well for supplying a microscope and office space to the pathologist, as well as transcription services.

If the referring practice wishes to bill for the professional pathology interpretations, the practice also incurs the professional liability associated with these services. In virtually all such arrangements, the referring practice must purchase additional malpractice insurance to protect the practice in the event of acts or omissions by the pathologist. It is important to note that a pathologist’s professional liability insurance covers only the pathologist, and not the referring practice. Compliance with the Stark law requires the referring practice to take full responsibility for the professional pathology interpretations, which must be reported out under the name of the referring practice. If the referring practice attempts to disclaim responsibility for the professional interpretations, it will be destroying its compliance with the Stark law. Similarly, the pathology practice should insure that its malpractice insurance also covers the pathologist(s) when services are being rendered on behalf of the referring practice.

Prior to commencing to bill for the professional pathology services, the referring physician practice must enroll the interpreting pathologist(s) under the practice’s managed care contracts as well as its Medicare and Medicaid group numbers.