HIGH RISK AREAS THAT CREATE LIABILITY FOR LABORATORIES

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This article reviews certain legal challenges facing providers of anatomic pathology, highlighting particular areas of risk and offering suggestions to reduce legal risk. Each fact situation is unique, however, and providers should consult their own legal counsel and advisors regarding their particular legal issues.

I. CURRENT TRENDS/RISK AREAS

The major claims areas for pathology practices and laboratories, both in terms of claims volume and the dollar amounts of recovery, are gynecological cytology, colon cancer, and breast cancer. The major risk areas for pathology practices and laboratories include missed/erroneous diagnoses, “process” errors such as mixed specimens, and the failure to adequately communicate results to attending physicians. Pathology providers also should be wary of vicarious liability for the acts or omissions of technical personnel, independent contractors, and consulting pathologists.

II. LIABILITY PLAN

Most pathology practices and pathology laboratories have detailed, comprehensive billing, fraud and abuse, and HIPAA compliance plans. However, many pathology practices and laboratories do not have an analogous plan in place regarding malpractice liability exposure. The lack of an effective liability plan increases the risk of a liability event and interferes with an effective response to a liability event. Note that an effective liability plan is not simply a quality assurance review program. Although a liability plan should encompass quality assurance, it is much broader.

A. Choice of Legal Entity

It is important to utilize legal entities that protect against individual liability, such as corporations and limited liability companies. The practice or laboratory must observe all corporate formalities to obtain this liability protection.

If the pathology practice or laboratory provides certain high risk services, consider providing these services through a separate legal entity, to protect the remaining assets of the practice or laboratory against liability for the high risk services. For the same reason, as a general matter, it is advisable to provide professional pathology services through one legal entity and technical pathology services through a different legal entity.
B. **Insurance Policies**

It is important to review the coverage terms of the insurance policies, paying particular attention to the identity of the insured individuals and entities, the description of covered services, exclusions from coverage, and limitations. Providers should ensure that the coverage terms are sufficient to cover all individuals who provide services, the legal entity of the pathology practice/laboratory, and all of the categories of services provided. It is important to consider whether there are any “gaps” in coverage, particularly with respect to lateral hires of pathologists and departed pathologists. Conversion from occurrence to claims made insurance, or vice-versa, can result in coverage “gaps”.

Appropriate coverage limits should be determined. Coverage limits are dependent upon the number of pathologists, the types of services provided, the geographic locations, and whether or not technical services are provided (particularly cytology services). Limits should be reviewed annually, particularly in light of the then current availability of coverage.

Pathology providers should have a proper understanding of the terms of insurance policies, particularly the insured’s responsibilities. It is advisable to prepare a summary sheet of key terms which relate to or impact operations.

A formal system for insurance-related trigger dates, particularly in a large practice with many insured individuals, can be useful. A computer “tickler” system can be utilized.

C. **Quality Assurance Protocols**

Obviously, careful and quality pathology services are the first defense against malpractice risk. Appropriate credentialing, review, training, and discipline of all levels of personnel (including pathologists) are essential. Contemporaneous documentation of these activities should be retained. With respect to individuals involved in the direct provision of pathology services, particular attention should be paid to appropriate licensure, prior claims history, and prior peer review or disciplinary actions.

In addition, providers should ensure that individuals do not provide services beyond the scope of their licensure or their skill levels. For example, be wary of pathologists performing services in complex areas of sub-specialization if they do not have fellowship training or special expertise in the area. It is better to refer certain services to consulting pathologists or laboratories if the pathology practice or laboratory’s own capabilities are not on par with the accepted standards of skill and expertise. CME should be reviewed periodically to ensure that pathologists obtain adequate information to keep their skills current.

Initial and periodic monitoring and auditing of outcomes, processes, personnel, facilities, etc. are critical and should be documented. Consider involving independent third parties to provide audits from time to time. Pathologists should be required to engage in periodic peer review audits of the services provided by all pathologists within the practice.

It is important to engage in a careful review of work flow and processes, to determine whether there are any areas of potential exposure. For example, are all tissues and specimens appropriately and clearly labeled? Does the necessary paperwork accompany all tissues and...
specimens? Are the items for each patient segregated, to avoid confusion or commingling? The McDougal case in Minnesota is an example of how a poor process led to a significant malpractice incident. In this case, specimens of two patients were not adequately identified and the paperwork for the patients was in a single folder. The pathologist reported malignancy for the wrong patient, resulting in a double mastectomy for a patient who did not have cancer.

It is advisable to implement standard reporting and communication procedures within the pathology practice or laboratory, to ensure that results are accurately and timely reported to attending physicians. Compliance with these procedures should be monitored and audited on a periodic basis. Many pathology malpractice cases involve situations where the plaintiff alleges that the pathologist failed to communicate the pathology results on a timely basis to the attending physician, particularly if a second review by another pathologist in the practice or an outside consulting pathologist resulted in a different diagnosis. Pathology malpractice cases also have focused upon the failure of a pathologist to take reasonable steps to ensure that the attending physician understands the pathology interpretation or advise the attending physician of additional diagnostic tests or services that should be performed.

D. Records and Specimen Retention

It is critical to ensure that appropriate retention policies are in place for patient records and specimens, as well as for documentation of compliance activities. Defense of a malpractice lawsuit is complicated if medical records and/or patient specimens cannot be located. HIPAA compliance policies dictate many aspects of the use and disclosure of patient information, but it is important to retain the originals of all patient records (if possible). If specimens must be sent out, the pathology laboratory’s policies should specify the manner in which the specimens will be transported and tracked, and identify the qualified custodians of the specimens.

In a malpractice lawsuit, the plaintiff may claim that the pathology practice or laboratory is at fault for not ensuring the quality of its services. Documentation of quality assurance and other compliance activities can assist in defending against such an accusation.

E. Contractual Review

It is advisable to review contractual agreements such as hospital contracts, managed care contracts, medical director agreement, and other service contracts to determine the pathology practice or laboratory’s liability obligations and responsibilities under the agreements. Pay particular attention to provisions which make the pathology provider “solely” responsible for all services or which require the pathology provider to insure against “all” acts or omissions. Both of these are difficult standards to meet. Any requirements to provide malpractice insurance should be subject to “standard policy limitations and exclusions”.

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Be wary of contractual indemnification provisions, which may not be covered by malpractice insurance. Such provisions should be reviewed by the insurance carrier to determine whether it will provide coverage. Alternative language would be: “Each party agrees to remain responsible for its own acts or omissions to the extent that it would be responsible under applicable law.”

Look for provisions that infer that the pathology practice or laboratory is responsible for individuals who are not part of the pathology practice’s workforce, such as hospital laboratory personnel. Be careful to avoid the assumption of legal responsibility for the acts or omissions of such personnel.

F. Reporting Process

An important part of a liability plan is the formal process for reporting liability risk concerns and liability events. This process should comply with the reporting requirements of applicable insurance policies, and include a step-by-step procedure for reporting. The specific reporting path(s) should be described. A checklist of the insurance policy reporting requirements should be utilized. Timely coordination with legal counsel should be included to avoid unintended “admissions” and to protect confidentiality, to the extent possible.

It is important for the reporting policies emphasize the importance of timely reporting of all potential liability concerns and events. The policies should include a prohibition against penalties for reporting. There should also be penalties for non-compliance with the reporting protocols. Formal training of all personnel regarding the importance of reporting and the process for reporting also is important.

A critical element of the reporting process is prompt notification to attending physicians of any errors or modifications in professional interpretations or test results. A strong element of many malpractice cases is the failure of the pathologist to alert the attending physician that the initial diagnosis was in error, with the consequence of further harm of the patient as a result of a delay in treatment.

III. OTHER STRATEGIES

It is critical to promote a strong “culture” of quality services, with emphasis on timely and careful diagnosis. Communication with ordering clinicians is another critical component of quality-oriented pathology practice. Open communication within the pathology practice or laboratory also is key, and should be consistently highlighted at all levels.

Pathology practices and laboratories should understand their limitations, in terms of skills, volume capabilities, technology, etc. and should avoid exceeding these limitations.

It is important to understand the expectations of attending physicians and patients, so that pathology practices and laboratories can make reasonable efforts to meet these expectations. Many malpractice lawsuits are a result of the failure of the pathology practice to meet patients’ expectations. If the expectations are unreasonable, it also is advisable to document the reasons why the expectations are unreasonable and take steps to educate the attending physician and/or patient.
IV. MARKETING YOUR LABORATORY SERVICES: HOW TO STAY COMPLIANT IN A COMPETITIVE MARKETPLACE

The marketing of laboratory services is very competitive, raising the compliance stakes with respect to marketing techniques to secure new clients and retain existing clients. Any benefits provided to referral sources, however, must be carefully considered in light of applicable federal and state fraud and abuse regulations, many of which carry criminal penalties in addition to substantial civil monetary fines. The most relevant federal restrictions are the following:

- The Medicare and Medicaid anti-kickback law prohibits the knowing and willful solicitation, offer, payment or receipt of any remuneration, whether direct or indirect, in cash or in kind, to induce or in return for referrals for items or service covered by the Medicare, Medicaid or other government health program. Violations are punishable by civil monetary penalties, criminal penalties, and exclusion from the Medicare and Medicaid programs.

- The Stark law prohibits a physician from making a referral for certain designated health services (including clinical laboratory and anatomic pathology services) for which payment may be made under the Medicare or Medicaid program, if the physician (or an immediate family member) has a financial relationship with the entity that provides the designated health services. The Stark law contains limited exceptions. The penalties include civil monetary penalties and exclusion from the Medicare and Medicaid programs.

It is important to review the guidance provided by the Office of the Inspector General (“OIG”) with respect to the marketing of laboratory services and is most often in the form of Fraud Alerts, Bulletins, and Advisory Opinions (http://oig.hhs.gov):

- **Provision of Free Goods and Services (OIG letters dated July 1, 1997 and July 3, 1997)** – In these two letters, the OIG wrote about the provision of computers to referral sources of laboratory services. If referral source is free to use it for a variety of purposes in addition to receiving test results, the computer may constitute an illegal inducement. The OIG also explained that the analysis would be equally applicable to fax machines, consulting services, or gifts given to referral sources, either for free or at a cost below fair market value.

- **Free Prostate Biopsy Needles (OIG letter dated August 4, 1997)** – The OIG explained that biopsy needles have a clear independent value to physicians, and that the cost of the needles may already be included in the practice expense portion of the Medicare payment made to the physician. Under these circumstances, an obvious inference is that the biopsy needles are being provided to the physicians by the pathology laboratories in exchange for referrals.

- **Free Services Performed by Laboratories (OIG letter dated October 2, 1997)** – The OIG explained that a kickback violation could occur if a phlebotomist placed in a referral source’s office or facility by the laboratory performs clerical or medical functions not directly related to the collection or processing of
laboratory specimens. This letter also described as suspect a situation where clinical laboratories provide a variety of chart review and infection control services for nursing homes free of charge.

- Arrangements for the Provision of Clinical Laboratory Services (Fraud Alert dated October 1994) – This fraud alert describes the following arrangements as suspect under the Medicare and Medicaid anti kickback law: the provision, without charge, of a phlebotomist in a physician’s office who performs additional tasks that are normally the responsibility of the physician’s office staff; below-market laboratory pricing for renal dialysis centers; free pickup and disposal of biohazardous waste products unrelated to the collection of specimens for the outside laboratory; the provision of computers or fax machines without charge, unless such equipment is integral to and exclusively used for the performance of the outside laboratory’s work; and provision of free laboratory testing for referring health care providers, their families and their employees.

The Stark self-referral law contains an exception for non-monetary compensation. This exception permits a laboratory to provide certain non-monetary compensation to referring physicians, and avoid violation of the Stark law. The Stark limit is adjusted for inflation every year, and currently is $380.00 annually per physician. It is important to note that this exception covers only non-monetary compensation provided to a physician, and does not include cash, cash equivalence, or gift certificates.

In addition, in commentary to the Stark II regulations, the government provided guidance with respect to the provision of free supplies by laboratories for the collection of specimens. The government explained that low cost supplies used solely to collect specimens for the laboratory may be provided without charge to a physician. However, higher cost items used by the physician to perform the underlying surgical procedure, such as biopsy needles and snares, could violate the law.

Free Meals and Other Non-Monetary Compensation – Boxed lunches, dinner meals, coffee mugs, and other small items or gifts are commonly provided by laboratories to referring physicians. These are subject to the Stark $380.00 per physician non-monetary compensation limit. For example, in a physician office with five physicians, up to $1,900.00 worth of free meals may be provided annually, presuming no other monetary compensation is provided to any of the physicians during the year. It is prudent for the laboratory to maintain a detailed log of all such meals provided during the year, the cost of the meals, the date the meals were provided, and the physicians for whom the meals were provided.
It is important to note that the annual non-monetary compensation limit would cover all non-monetary items provided to physicians, including free coffee mugs, pens, and other incidental supplies, in addition to meals. Gift certificates to restaurants and other vendor gift certificates are strictly prohibited and the provision of these items would violate the Stark law.

**Pap Results and Reminders** – The provision of Pap results cards and annual appointment reminder cards poses difficult compliance issues. If a laboratory bears the expense of printing Pap result cards or reminder cards with the name and address of the referring clinician and/or if the laboratory bears the postage expense involved in sending these cards, the government would likely view such activities to violate the federal fraud and abuse laws. This is because the laboratory is picking up an expense on behalf of the referral source. However, there is much less concern if a laboratory sends its own notice (referencing only the laboratory) informing the patients of the results of the laboratory testing performed by the laboratory. Therefore, while bearing the expense of a Pap results card with the clinician’s name on the card would be problematic from a compliance standpoint, the compliance risks are substantially reduced if the laboratory sends its own results card providing the results of its testing to the patients. Similarly, there are relatively minimal compliance risks if a laboratory sends a reminder card to patients for whom it has provided testing in the past, reminding the patients to contact their clinicians (who should remain unnamed on the card) to schedule their annual examinations.

**Speculums, Biopsy Needles and Snares** – Disposal speculums are clearer compliance risk. As explained above, the commentary to the Stark II regulations clearly explains that laboratories may only provide low cost items that are used solely for collection purposes. The government commentary explains that the items “must be used solely to collect, transport, process or store specimens for the laboratory …, such as cups used for urine collections or vials used to hold and transport blood to the [laboratory] … [The government] does not regard specialized equipment such as disposal or reusable aspiration and injection needles and snares as solely collection or storage devices. Instead, these items are also surgical tools that are routinely used as part of a surgical or medical procedure.” Speculums are used as part of the pelvic examination, for which the clinician submits a claim for his or her services. The speculum is not used solely for the collection or transportation of the specimen that will be sent to the laboratory. Therefore, the provision of disposal speculums without charge by a laboratory to a clinician would appear to be a violation of the Stark law, subjecting both the laboratory and the clinician to the significant penalties for violation of the Stark law.

Similarly, the provision of biopsy needles and snares without charge would violate the Stark law. The text quoted above from the Stark II regulatory preamble clearly refers to biopsy needles and snares as surgical devices that are used by the clinician for the underlying surgical or medical procedure, and are not items or devices that can be provided without charge to the physician. An advisory opinion on the provision of certain supplies is expected from the Office of the Inspector General in the next few months.

It is important to keep in mind that violation of the Stark law or the Medicare and Medicaid anti-kickback law subjects both parties to civil and criminal penalties, so the clinician is equally at risk with the laboratory. Laboratories also should consider any applicable state fraud and abuse laws.