



Advancing Excellence

Professional Relations Manual

12th Edition
2003



Practice Management Committee
College of American Pathologists

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College of American Pathologists 2003 Practice Management Committee

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Library of Congress Control Number: 2003108274
ISBN: 0-930304-83-7



Advancing Excellence

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Introduction

“A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.”*

To enable pathologists to obtain this objective, the College of American Pathologists *Professional Relations Manual* proposes guidelines for the development of contractual and professional relationships. These guidelines are intended solely to aid individual pathologists in determining the environment in which their medical judgment and skills may best be exercised in the interest of the patient. The ultimate decision as to which environment best serves this goal in each case must, of course, be made by the individual pathologist.

Section I of this manual offers voluntary guidelines for professional practice in pathology. The guidelines recognize evolving patterns of medical care and changing concepts of ethical relationships. Voluntary guidelines concerning professional conduct and relationships to the medical community, to the nonmedical community, and to patients are included.

Section II offers suggestions to assist pathologists in establishing a desirable contractual basis for their practice. The guidelines reflect experience with agreements between pathologists and institutions, interpathologist and pathologist/medical staff relationships, and the relationships between pathologists and independent laboratories. While each of these settings presents unique contractual problems, the same principles of professional conduct and sound business judgment can be applied to all.

The forms of agreement employed by pathologists vary greatly. One should not expect a model contract to cover all situations. These guidelines provide only the broad base upon which modifications should be made to meet individual needs and situations.

Upon request, sample contracts are available to CAP members as a supplement to this manual. They illustrate the general form and content of representative contracts, but they should not be used without appropriate adaptation to changing laws and regulations and to the local situation. (To obtain sample contracts, call CAP Customer Service at 1-800-323-4040, option 1#.)

Pathologists also may wish to discuss specific details of an individual contract with members of the CAP Practice Management Committee, other experienced pathologists, and/or an attorney expert in professional contract law.

* American Medical Association Principles of Medical Ethics. In: Council on Ethical and Judicial Affairs. *Code of Medical Ethics. Current Opinions and Annotations*. 2002-2003 ed. Chicago, Ill: AMA Press; 2002.

Guiding Principles

This edition of the *Professional Relations Manual* is prepared at a time when socioeconomic forces are changing dynamically. Regardless of these changes, the pathologist as a physician should be guided by the ethics of medicine.

Pathologists should strive constantly to provide high-quality laboratory services at a reasonable cost. In addition to ensuring efficiency of management within the laboratory, the pathologist should be concerned with the ever-increasing total cost of illness. The hospital and laboratory should meet the needs of the patient rather than the convenience of the personnel. Medical costs may be reduced through increased outpatient and preadmission testing, improved scheduling of laboratory work to provide greater efficiency in reporting results, and educational efforts with clinicians to curtail overutilization of laboratory services. Pathologists should employ skillful medical and managerial techniques to satisfy the concerns of the patient, the government, and other payers, while containing the cost of medical care. Pathologists should also recognize their responsibility as guardians of the quality of patient care and should strive to have the laboratory provide accurate and reliable test results to meet the needs of both physician and patient.

Section I: Professional Practices

Preface

In this section of the *Professional Relations Manual*, the College of American Pathologists strives to provide the pathologist with voluntary guidelines for professional practices, which recognize evolving patterns of medical care, developing standards of professional conduct, and changing concepts of ethical relationships.

Advances in medical science and proliferation of technology continue to enlarge the pathologist's scope as a practitioner and consultant. Meanwhile, increasing legislative, regulatory, managed care, and public constraints must be met. It is the goal of the CAP to aid pathologists in organizing their practice to provide the most meaningful participation in patient care.

I. Guidelines and Responsibilities for Professional Practice

A. Principles of Medical Ethics of the American Medical Association

Preamble: The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

Adopted June 1957; revised June 1980; revised June 2001.

B. Professional Responsibilities and Conduct of a Pathologist

Physicians practice medicine in many ways. In all of these, there is a fundamental relationship between patients and physicians. Medical specialization merely adds unique and additional opportunities to affect patient care in settings as diverse as the operating room, the intensive care unit, the clinical laboratory, and the office. The practice of pathology therefore has its particular relationships to patients, hospitals, other institutions, payers, and regulatory agencies. These guidelines are intended to address pathology's unique role in the practice of medicine.

1. Professional Relationships

Most pathologists practice in association with a clinical laboratory, either as directors or associates. Their practice brings them into contact with patients' physicians more frequently than with patients themselves. Laboratory findings are generally conveyed to the practitioner requesting the service, although, where permitted by law, they may be provided directly to the patient. However, departure from usual reporting procedures may be justified by the specific needs of the patient and good professional practice.

Reports should be released to third parties only when required by law or upon receipt of a specific written release from the patient. Laboratory personnel should be carefully schooled in these principles in order to help maintain the patient's privacy. The release of reports to the patient should occur only after the attending physician has been consulted, unless the patient has ordered the test in accordance with the governing law. Exceptions to the foregoing are the occasions when a clinician specifically requests a pathologist (preferably in writing) to explain findings to a patient, or when laboratory findings of public health import are required by law to be reported to public authority (eg, sexually transmitted and other infectious diseases).

When pathologists act as clinical consultants, they may examine the patient's record before preparing a report in which findings are documented and recommendations for further work-up and therapy are proposed. The patient may, of course, be billed for this professional service. An operating room consultation certainly falls into this category. It generally is more accurate to use the term "consultation," rather than "frozen section," for this service, as the pathologist is responsible for deciding whether or not the diagnosis can be made without microscopic examination. Findings and recommendations should be documented for timely incorporation in the patient's medical record.

The examination of surgically removed tissue is also a clinical consultation. Local custom and common sense should govern the propriety of going beyond the findings of fact and diagnosis in pathology reports.

In many states, nonphysician practitioners are legally authorized to practice under laws similar to those governing Doctors of Medicine. In such states, pathologists should exercise their own individual judgment concerning the circumstances and the manner in which their services are made available to these practitioners. They should be guided by state law and their independent assessment of what is in the best interest of the patient.

2. Requests for Expert Consultation on Pathologic Material

Pathologists may encounter situations in which their experience is limited or in which they do not feel qualified to make a definitive diagnosis. In these situations, the pathologist should obtain a consultation with a qualified colleague. By doing so, the pathologist will have acted in the best interest of the patient. If a clinician or patient requests that a consultation or second opinion be obtained, the pathologist should cooperate.

Whenever possible, the pathologist should select the consultant. The pathologist is best qualified to know who is the most appropriate consultant for the specific problem. Moreover, the pathologist can be held liable for a consultant's erroneous diagnosis (vicarious liability).

When sending a case to a consultant, do not issue a final report. Instead, issue a provisional report, with or without a provisional diagnosis, depending on the urgency of the situation. Discuss the differential diagnosis, your provisional diagnosis (if any), and the reasons for seeking an expert opinion. Clearly state that a final report will be issued with a final diagnosis when the consultant's report is received. This approach is designed to prevent potentially inappropriate therapy from being initiated prior to arriving at a definitive final diagnosis.

A copy of the provisional pathology report and other relevant clinical data should be sent with the referred material so the consultant will be in possession of all necessary facts. The referred materials should be sent with a cover letter requesting the consultation, identifying each item sent, and setting forth any conditions. For example, the pathologist might request that if there appears to be a substantial difference of opinion, the consultant discuss the matter with the original pathologist prior to issuing a report. Further, the pathologist might request that if the consultant seeks a further opinion, the consultant first contact the original pathologist.

The consultant's opinion should be in writing. The consultant should always send a copy of the report to the original pathologist. It also may be appropriate, when practical, for the consultant to discuss the matter with the original pathologist before issuing a report. Arrangements should be made between the original pathologist and the consultant for the timely return of any referred material, unless return is unnecessary. Return of the materials should be noted in the pathologist's records.

From time to time, a consulting pathologist may wish to seek a third opinion on referenced material. In these situations, the consulting pathologist should notify the original pathologist. Moreover, the consulting pathologist should make arrangements to have the diagnosis and report of the third reviewer sent to both the referring consultant pathologist

and the original pathologist. Arrangements should also be made for the referred material to be returned to the original pathologist.

3. Requests for Surgical Pathology and Cytopathology Materials by Another Physician, Another Institution, or an Attorney

Pathologists may, from time to time, receive requests for slides, blocks, or tissue. The request may come from another health care provider in cases where the patient is seeing a new physician or has sought a second opinion. Alternatively, a request may come from an attorney, in connection with possible malpractice litigation against a clinician or the pathologist. When the pathologist is responding to a request for review of patient slides or other patient materials, it is preferable to obtain consent from the patient permitting release of these materials. Each laboratory must, of course, establish its own policy for responding to requests for materials. However, there are a number of considerations that should be taken into account.

First, if a request for materials is made by a physician who is not known to the laboratory, or if there is doubt about the purpose of the request, the pathologist should contact the requesting physician's office to verify that the request is for medical reasons, or to clarify the nature of the request. Even if the requester is well known to the laboratory, it may be useful to discuss precisely what sorts of materials are needed. The laboratory should insist upon a written request so it will have documentation in its files.

If a written request for materials is made by or on behalf of an attorney, it is possible that malpractice litigation, either against the pathologist or a clinician, may be under consideration. Accordingly, the pathologist should notify their professional liability carrier. Insurance company risk-management personnel can then review the situation and assist in formulating a response.

In both medical and legal contexts, the pathologist should discuss the reason for the request with the person who made it. The pathologist should attempt to identify the specific report and slides needed, and determine whether recuts will suffice or whether the requester is insisting on original slides. This process will also allow the pathologist to determine whether or not the requester should reimburse for the costs incurred in providing materials, for example, in making recuts.

For several reasons, it is advisable to send recuts—rather than original slides—if the pathologist determines that recuts are comparable to the original materials. First, the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the CAP's Laboratory Accreditation Program each require the retention of slides, blocks, and reports for specific periods of time. (See Appendix A for CAP retention policy.) Moreover, some states may impose their own requirements for the retention of laboratory materials.

Second, retaining original materials is important if a malpractice case is brought. The originals will permit a defense expert to review the same materials that were relied on for the original diagnosis, and will enable the pathologist to base a defense on those materials. Further, having the originals will avoid the awkward situation that can arise if the originals have been furnished in response to a request from a plaintiff's attorney, and then a similar request is received from an attorney for a defendant clinician. Inability to produce the

original materials at trial may expose the pathologist to insinuations by the plaintiff's attorney that there has been loss or destruction of evidence.

If recuts are not comparable, or if irreplaceable items, such as cytology smears, are requested, the laboratory should offer to make the original materials available for inspection and review by the plaintiff's experts on the laboratory's premises. If the pathologist subsequently receives a subpoena to provide the original materials, the professional liability carrier should be notified. The court can be requested to restrict review of these materials to the laboratory's premises. If the court orders the release of the original materials, the pathologist will then be under the protection of the court, should these materials be lost or destroyed.

Before any materials are sent, or before another physician is permitted to examine such materials, the pathologist should review the original materials, any recuts, and the original report. This procedure enables the pathologist to determine whether the recuts are comparable, and whether an error might have been made at the time of the original diagnosis. If significant unexpected findings are made on review, such findings should be reported to the attending physician and to the liability insurance carrier. They should be recorded in a supplemental pathology report.

When laboratory materials are sent out of the laboratory, whether for medical or legal purposes, it is good practice to send a cover letter. The letter should describe the request and explain that the materials are being furnished in response to that request. It should identify with specificity the materials transmitted. (See Appendix B.)

The letter should identify the person in the laboratory to whom inquiries or other correspondence should be sent. The letter should specify a date by which the materials are to be returned, as well as any packaging requirements. In addition, it should include any other conditions under which the materials are provided. For medically motivated requests, for example, it can ask for a copy of any report issued by any reviewing physician. This report can be placed in the laboratory's quality assurance files and used for quality assurance purposes. Other possible conditions include a request that the reviewing physician consult with the original pathologist before issuing a report or before seeking a third opinion. These conditions allow the pathologist to point out relevant medical considerations that may not be evident from the original materials transmitted, and thus help to clarify the situation.

It is advisable to have a system for tracking materials that are sent out of the laboratory. Shortly before the specified return date, laboratory personnel can contact the person to whom the materials have been sent. If necessary, any packaging requirements can be discussed at that time. If the materials are not returned on time, there can be follow-up calls or letters. When the materials are returned, they should be examined to make sure that they are the same as those sent out. Receipt of the materials should be noted in the laboratory's records.

Much of the foregoing discussion applies to both medical and legal requests for materials. Additional considerations arise, however, when the request comes from an attorney. Even if the request is in the form of a letter, the laboratory should, as noted above, contact its professional liability carrier. The company's risk managers can assist the laboratory in ascertaining the purpose of the request, deciding what materials are necessary, and otherwise determining how to proceed.

In this connection, the pathologist should understand that an attorney cannot compel production of laboratory materials without a subpoena. Thus, letter requests from an

attorney can be handled much like requests from a physician in terms of discussing the scope of the request and any conditions that the laboratory imposes on production. If the laboratory is reasonable, many attorneys will try to cooperate and work out the issues without resorting to a subpoena.

Subpoenas are issued by an attorney and are generally not ruled upon in advance by any court. Accordingly, even if a subpoena is issued, the laboratory has some recourse. Initially, the attorney who issued the subpoena should be contacted by a representative of the laboratory to try to work out an accommodation. Sometimes, an accommodation cannot be worked out; for example, the attorney may insist upon originals, when recuts would be adequate. In these situations, a motion to quash or limit the subpoena can be filed by the attorney for the laboratory. The court will then determine the extent to which the subpoena should be enforced, if at all. The mere threat of a motion to quash will cause many attorneys to be more conciliatory. If the requesting attorney is really unreasonable, the court may well rule for the laboratory.

The principal point to remember in responding to all requests for materials is to act reasonably. A reasonable approach will succeed with most physicians who request materials for medical reasons. It will often succeed with attorneys. If an attorney remains inflexible, the fact that the laboratory has attempted to be reasonable will stand it in good stead if a motion to quash or limit has to be filed.

4. Professional Fees and Billing for Laboratory Services

The College of American Pathologists is dedicated to the principle that high-quality service should be provided to the patient at a reasonable fee. The containment of health care costs is an important objective and should serve as a continual stimulus to all laboratory directors to review the efficiency of their own laboratories, with the goal of cost control. However, the quality of laboratory work should never be compromised. Pathologists should become familiar with third-party insurer billing requirements as well as state and federal laws governing reimbursement.

Medicare requires outpatient clinical diagnostic laboratory tests to be billed directly to Medicare by the person or entity that performed or supervised the tests, unless an exception applies (for example, in some circumstances a laboratory may bill for tests referred to another laboratory). It is no longer permissible under Medicare for an independent laboratory to bill the referring physician for these tests. Instead, bills should be sent directly to Medicare. Several BlueShield plans and some state laws have adopted the same “direct billing” requirement.

Pathology practices should have policies and procedures to ensure that all claims submitted to Medicare, Medicaid, and all other third-party payers are accurate and correctly identify the service(s) performed by the practice. This includes ensuring that the CPT (Current Procedural Terminology) or HCPCS (Healthcare Common Procedural Coding System) code accurately describes the specimen received and the service performed. The practice should select only the code(s) that most accurately describe the services performed. Improper coding can expose the pathologist to allegations of having made false claims. Additional information on correct coding for pathology services can be obtained by calling the CAP Government and Professional Affairs staff (800-392-9994).

The Medicare program also prohibits physicians from making Medicare and Medicaid referrals to a clinical laboratory in which the physician (or an immediate family member of such physician) has a financial relationship, unless certain specific exceptions apply. The Medicare program broadly defines “financial relationship” as an ownership or investment interest in the laboratory, or a compensation arrangement between the physician (or an immediate family member) and the laboratory. A compensation arrangement is defined as any arrangement involving any remuneration between a physician (or immediate family member) and an entity. Remuneration includes any remuneration, directly or indirectly, in cash or in kind. The pathologist should consult a competent attorney if there is any question about a possible violation of the Medicare prohibition on physician self-referrals.

The pathologist should not divide fees for laboratory services with a referring physician directly or by means of any subterfuge. The giving of “free” or unreasonably discounted laboratory services for a certain volume of work referred may be a subterfuge for the division of fees and is prohibited by statute in many states. In addition, the Medicare and Medicaid antikickback statute provides stiff criminal and/or civil penalties for soliciting or receiving kickbacks (in cash or in kind) in return for referral of patients for goods or services reimbursable by Medicare, Medicaid, or other federal programs. Judicial interpretation of the scope of the Medicare anti-fraud-and-abuse statute is evolving. The pathologist should carefully evaluate business relationships and seek advice of competent legal counsel to avoid allegations of kickbacks and fee splitting.

The rental of office or laboratory space on a percentage basis from a medical group could lead to overutilization and may be a subterfuge for the splitting of fees or illegal kickbacks. These problems can be avoided if rental charges for a pathologist’s laboratory space are based solely upon the fair market value of the space to be occupied.

When a clinician procures the specimen, or when collection costs are negligible or absent, fees may be appropriately reduced without the stigma of “kickbacks” or fee splitting, because such discounts are justified by accepted business practices. Such discounts are justified by lower billing, handling, and collection costs.

Medicare regulations do not require identical laboratory charges to hospital inpatients, outpatients, or referred work from physician offices; but they do require that hospitals report revenue from inpatients, outpatients, and referred work in a manner that permits the Part A fiscal intermediary to accurately identify hospital expenses. Hospital cost reporting rules remain in effect despite the adoption of the DRG (diagnosis related groups) prospective payment system. Medicare continues to collect inpatient cost information for comparison to DRG payments.

There is no requirement that inpatient and outpatient charges be the same, and there may be good reasons why they should differ. For example, the cost of maintaining a 24-hour, 365-day service for inpatients may not be appropriate for outpatients, for whom services are often available only on weekdays. In addition, the considerable costs of peer and utilization review and the educational structure of an institution, including house staff, conferences, rounds, and autopsies, may not be appropriate for outpatients, who do not benefit from these expensive but necessary accoutrements of inpatient care. Indeed, competitive pressures and reasonableness may require that outpatient fees reflect the lesser cost of what is offered and available to them.

Some pathologists have provided services to physicians and members of their immediate families as a professional courtesy to their clinical colleagues. Similarly, pathologists may receive medical and surgical attention from clinicians. All professional courtesy practices, including the collection of coinsurance and deductibles, should conform to institutional and medical staff policies, applicable laws, and third-party payer requirements. Discounts and routine waiver of coinsurance may implicate the Medicare antikickback statute if the physician receiving the benefit also refers to the pathologist. Routine waiver of coinsurance amounts may also be inconsistent with private insurer procedures and may implicate health care fraud and abuse statutes. Pathologists are well advised to have discount and waiver policies reviewed by competent legal counsel.

5. Solicitation of Appointments

A pathologist is free to solicit or accept a position occupied by another pathologist without first consulting the incumbent. However, both the pathologist seeking a position and the incumbent may benefit from an early consultation. The incumbent may disclose unreasonable limitations upon a pathologist's position or other problems that might not be immediately apparent.

Administrators, boards of trustees, staff and executive committees, and clinical colleagues have been known occasionally to impose unreasonable conditions that may not be readily apparent. The advice of an incumbent may enable the pathologist seeking a position to address the problem constructively. When an interim pathologist or *locum tenens* is the "immediate" incumbent, it may be advisable to contact the pathologist who previously held the permanent position.

6. Contractual Relationships

The advantages and disadvantages of the many varieties of contractual relationships for pathologists are discussed in depth in Section II of this manual and will not be repeated here. The CAP believes that contracts should not interfere with or impair the exercise of medical judgment, or otherwise interfere with the provision of quality of medical care. With good will, a variety of different agreements can be beneficial for the patient, the pathologist, and the institution. The agreement should ensure that patients receive quality pathology services, and that the pathologist is practicing under conditions that permit such services.

The CAP, through its Practice Management Committee and the CAP Division of Membership and Advocacy staff, will provide consultation on contract issues. The successful and harmonious practice of pathology in an institution requires agreement on many items unique to our specialty. A pathologist, to be maximally effective, needs to have meaningful input into decisions affecting this environment (eg, quality of supplies and equipment). The demands on a pathologist's time for educational and committee activities, and in the evaluation of medical care in the institution, may be recognized in the contract. In this context, the mechanism for the compensation of a pathologist for the performance of autopsies should be stated. This is necessary because of the important contribution of the autopsy to medical care. The costs of an autopsy should be recognized, and a mechanism for compensation established.

Section II of this manual discusses pathologist contracts in more detail. CAP members can request sample contracts through the CAP Web site, www.cap.org, or by calling Customer Service at 1-800-323-4040, option 1#. Pathologists can also seek the advice and

counsel of senior pathologists in the community and of the College of American Pathologists Practice Management Committee, as appropriate. Pathologists are also well advised to use the services of a competent attorney.

7. Competitive Practice and Conflict of Interest

Participation in community affairs—medical and nonmedical—is important. Under many circumstances, pathologists may best fulfill their responsibilities to the community by making their services available to others besides hospital patients. They should consider teaching, consulting, and practicing pathology outside the hospital, provided that such activities do not conflict with the best interests of patients at their institution. The CAP therefore recommends that the term “full-time” not be used in pathologist-hospital contracts. Moreover, a contractual reference to providing pathology services at an institution on a “full-time” basis may cause the pathologist to be determined to be an employee of the hospital by the Internal Revenue Service. A reference to providing “needed services” is preferable. Needed service is that degree of service and medical supervision which will meet the needs of patients to the satisfaction of the medical staff.

Some hospital administrators and boards of directors may look upon a department of pathology as a profit center, from which funds may be generated to support the non-revenue-producing areas of an institution or to reduce deficits incurred by other patient care departments. The search for additional revenue has intensified with the recent decline in inpatient utilization and restrictions on payment for inpatient services. This has led to a desire by hospitals to have all outpatient laboratory work done in the hospital laboratory, and to consider work done in a pathologists’ private laboratory as not in the interest of the hospital and therefore a “conflict of interest.” This problem may confront a pathologist who practices both in a hospital and in a private laboratory.

To forestall charges of conflict of interest, pathologists should carefully consider all activity outside of the hospital. Contractual agreements can be negotiated in a way that allows the pathologist to practice outside of the hospital.

Double billing by a pathologist should be avoided. A pathologist who does some hospital work in a private laboratory should pay careful attention to third-party insurer billing requirements. For example, Medicare requires that clinical laboratory tests performed by independent laboratories for hospital patients be billed to the hospital. If there is doubt about billing requirements, competent advice should be sought from knowledgeable consultants.

8. Marketing Laboratory Services

Pathologist-directors of laboratories may want to inform their clinical colleagues of the scope of services available, fee schedules, and the range of reference values. Many pathologists find that this is most effectively done by dignified announcements, usually by direct mail, or by employing professional service representatives. It is generally more effective to present the information in an educational manner, stressing service, quality control, and professional consultation. Such material may include a fee schedule and other relevant information.

9. Practice Qualifications and Responsibilities

Pathologists should be trained and currently competent in those areas of pathology practice in which they hold themselves to be expert. Such practice may range from a very limited, highly developed subspecialty to that of director of the department of pathology in a community hospital. In the latter instance, the pathologist may be best characterized as a “generalist” in pathology. As generalists, they will be widely involved in both anatomic pathology and in directing a clinical laboratory, supervising highly qualified technical personnel, and utilizing instruments ranging from the simplest to very sophisticated computerized systems. They should stay abreast of new developments and anticipate the ever-changing needs of their clinical colleagues. They may maintain this competence and understanding of new developments by consulting with other pathologists, their clinical colleagues, and other scientists, as well as by reading and attending scientific meetings sponsored by local and state pathology societies and national and international societies. Pathologists are encouraged not only to attend such activities, but whenever possible to actively participate as educators.

10. Confidentiality of Patient Information

The principle of the confidentiality of patient information is a cornerstone of the physician-patient relationship. Modern concepts of the patient’s right to privacy and confidentiality have evolved from the Hippocratic Oath and the law. The principle of confidentiality is therefore an ethical and legal responsibility of pathologists. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishes privacy standards for protecting patients’ health information. Pathologists must develop and implement policies and procedures to govern how the clinical laboratory and its employees and other agents use and disclose protected health information. HIPAA privacy requirements are discussed in detail in the next section.

The “American Medical Association Principles of Medical Ethics” state, “A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.”

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has accreditation standards that require organizational policies and procedures that assure the patient’s personal privacy and protect the confidentiality of patient information.

Information generated within departments of pathology is often the most sensitive and personal to be found in a patient’s chart. The reason is the great specificity of that information and the attendant diagnoses. Yet, even when one might expect the patient’s right to confidentiality would be outweighed by the right of others to know for public health reasons, state statutes vary and federal guidelines are vague. The situation with respect to human immunodeficiency virus (HIV) and AIDS is particularly complex. Pathologists should be aware of state laws and other rules that govern confidentiality of patient information in the states in which they practice.

Pathologists should strive to impress upon their professional, clerical, and technical staffs their responsibility to treat patient information in the most confidential manner. Except for official communications, such information should be kept within the laboratory. Of course, much information generated in pathology departments, having once left the confines of the laboratory in written or electronic form, is out of the control of

laboratorians. Therefore, it is important that each department of pathology have a written statement regarding the confidentiality of patient information. Each department also should have a written policy concerning the release of patient information. The policy should specifically address release of information to attending and consulting physicians, other hospital departments and committees, insurance companies, attorneys, and federal and state auditing entities.

11. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was approved by Congress based on the concern that health care delivery and billing is rapidly being accomplished through electronic means, and that safeguards are needed to protect patients' health information. HIPAA is intended to reduce the costs and administrative burdens of health care by making possible the standardized electronic transmission of certain administrative and financial transactions that currently are carried out by paper. The goal of HIPAA is to promote the free flow of health information in order to provide high-quality health care services, while also assuring that individuals' health information is appropriately protected.

The following points are provided as a brief guide to the major provisions of the privacy component of HIPAA. These materials do not constitute legal advice and are for educational purposes only. The information provided is based on current federal law as of September 2002. It is subject to change based on changes in federal law, the effect of state law, or subsequent interpretive advice. The complete Privacy Rule and other compliance information can be found at <http://www.hhs.gov/ocr/hipaa/>.

Who Must Comply?

As a pathologist, you must comply with HIPAA standards if you, a billing company, or any other third party acting on your behalf transmit patient-identified health information electronically for billing, coding, insurance benefits coordination, claim status, health plan enrollment and eligibility, referral authorization, or submission of health claims attachments.

If you, or anyone acting on your behalf, do not submit billing or coding transactions electronically, you are exempt from the HIPAA privacy standards.

When Do I Have to Comply?

The Privacy Rule compliance date was April 14, 2003.

Designate a HIPAA Privacy Official

You or your employer must designate a privacy official, who assumes responsibility for the development and implementation of Privacy Rule policies and procedures. In larger pathology groups or laboratories, the privacy official position could be a substantial task; in smaller practices, the privacy official may be one of many roles fulfilled by an individual, such as the office manager.

Train Your Workforce

All members of the workforce must be trained on the organizational policies and procedures with respect to protected health information. Each new member of the workforce must be

trained within a reasonable period after being hired. You must document that the training has been provided. (See Part 164.530 of the Privacy Rule.)

Prepare Your Policies and Procedures Governing Use and Disclosure of Information

A laboratory must develop and implement policies and procedures to govern how the laboratory and its employees and other agents use and disclose “protected health information (PHI).” The general rule is that a pathologist or laboratory may not use or disclose protected health information except as specifically permitted or required in the privacy regulations.

Depending upon the purpose of the use or disclosure, the privacy regulations permit the use or disclosure of protected health information under the following circumstances: (1) with consent; (2) with authorization; (3) after providing the patient with the opportunity to object prior to use or disclosure; (4) after providing the patient with the opportunity to object prior to a second use or disclosure; and, in some circumstances, (5) without any permission whatsoever. (See Part 164.502 of the Privacy Rule). A detailed memo on this topic, written by the College’s legal counsel, is available at the “HIPAA Resources” portion of the CAP Web site, www.cap.org.

These written approaches should communicate how you intend to comply with the rules. It would be an error to have written procedures that are not followed, such as claiming to use advanced technologies—encryption or private networks for e-mail, for example—and not having those technologies in place.

Draft or Update Your Notice of Privacy Practices

A *direct treatment provider* is required to make a good faith effort to obtain a patient’s written acknowledgment of receipt of the provider’s Notice of Privacy Practices. Pathologists who do not have direct patient contact are *indirect treatment providers* and are exempt from obtaining written acknowledgement from the patient.

The pathology practice should have a Notice of Privacy Practices document. This is an important document. It states how you will protect, use, and disclose patients’ protected health information. (See Part 164.520 of the Privacy Rule.)

Identify Your Business Associates

The HIPAA Privacy Rule requires you to enter into written agreements with your “business associates.” These business associate agreements ensure that a business associate will provide the same privacy protections to patients’ protected health information as you would. A business associate is a person or entity that has access to patients’ protected health information as a result of providing services to you.

For example, a pathologist’s or laboratory’s billing service clearly will be a business associate of the pathologist or laboratory. Similarly, an attorney, accountant, or consultant who provides services to a pathologist or laboratory may be a business associate of the pathologist or laboratory if such individuals have access to patient information in the course of providing their services.

In addition, in certain circumstances, a pathologist or laboratory may be the business associate of another “covered entity.” For example, when a pathologist provides medical direction services for a hospital’s laboratory, the pathologist is providing services to the

hospital and will have access to information about the hospital's patients. In these circumstances, the pathologist likely will be a business associate to the hospital. Also, the Privacy Rule has defined private accrediting bodies, such as the CAP Laboratory Accreditation Program, to be a business associate of the accredited laboratory.

Therefore, each pathologist and laboratory must determine which of the people or entities providing services to the pathologist or laboratory will need to sign a business associate contract. In addition, the pathologist or laboratory must identify which hospitals, laboratories, or other covered entities to which the pathologist or laboratory provides services will ask the pathologist or laboratory to sign such a contract. A sample business associate contract can be found at <http://www.hhs.gov/ocr/hipaa/contractprov.html>.

A detailed memo on this topic written by the College's legal counsel is available in the HIPAA Resources portion of the CAP Web site, www.cap.org.

Establish Safeguards

The privacy regulations require pathologists to establish certain safeguards to protect the privacy of protected health information they maintain. These safeguards, which incorporate administrative, technical, and physical safeguards, are likely to overlap with the safeguards that will be required under the HIPAA security regulations. For example, administrative safeguards may include the performance of periodic audits to analyze the effectiveness of privacy protections that are in place. Technical safeguards may include the use of password protection on computer systems, so those who do not need access to test results and other private information will not be able to access that information. Physical safeguards may include the backing-up of computer systems or the preparation of a disaster emergency plan in order to protect the integrity of patient information.

Communications Consistent With CLIA

HIPAA, to be consistent with CLIA, allows for the communication of test results to the patient, as allowed by CLIA. CLIA permits labs to provide test results only to "authorized persons," as defined primarily by state law, which, in most cases, is the ordering physician, not the patient. If state law does allow for test results to be communicated directly to the patient, and the results are sent by fax or e-mail, reasonable security measures should be followed.

Compliance Resources

There are a number of valuable sources of information on the Internet. The College's "HIPAA Resources" section of [cap.org](http://www.cap.org) provides information and links to other HIPAA compliance resources. The US Department of Health and Human Services Office for Civil Rights has a number of compliance aids available at <http://www.hhs.gov/ocr/hipaa/>.

II. Guidelines as a Member of the Medical Community

Pathologists are physicians who are involved in all aspects of patient care, including prevention, diagnosis, treatment, and monitoring of disease. They often serve as an intellectual and practical bridge between the basic sciences and the clinical practice of medicine. They counsel their colleagues in the appropriate utilization of the medical laboratory and in the clinical correlation of laboratory results. To remain abreast of new scientific and medical developments, and to maintain communication with clinical colleagues, are continuing challenges to pathology. This chapter therefore is devoted to a discussion of the organization and medical administrative aspects of the practice of pathology and the relationships among pathologists, their clinical colleagues, and organized medicine.

A. Relationships to Hospitals

1. *Relationships to a Hospital Medical Staff and Executive Committee*

The pathology service in a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) must be directed by a physician or a doctoral scientist who is qualified to assume professional, scientific, consultative, organizational, administrative, and educational responsibilities, both for the facilities and for the services provided. When a pathologist is not the director, a pathologist is retained as required for the provision of anatomic pathology services and for input into the medical aspects of clinical pathology. The director of the pathology service must be a member of the medical staff and generally is a pathologist certified by the American Board of Pathology or its equivalent. It is also required that the director of pathology services should establish an effective working relationship with the medical staff, the hospital administration, and other departments or services.

Principles of continuous quality improvement and quality management are becoming increasingly incorporated into every aspect of the delivery of health care. There is an important interface between pathology laboratory services and patient management. Therefore, the pathologist has an opportunity to assist the governing body and administrative officials, as well as members of the medical staff, in the implementation of plans that improve patient outcomes and ensure effective utilization of resources.

Medical Staff Appointment and Qualifications

Each pathologist is required to apply for and obtain an appointment to the medical staff of the hospital in a manner similar to all other physicians. The pathologist is subject to the bylaws and rules and regulations of the medical staff. A pathologist-director is responsible to the executive committee and, through the committee, to the medical staff for the professional standards and administration of the department of pathology. The Joint Commission on Accreditation of Healthcare Organizations requires delineation of practice privileges for each member of the medical staff and their periodic review and update of privileges. A sample privilege delineation form and guidelines for delineation of clinical privileges in pathology are discussed in greater detail in Appendix C.

Practice Privileges

The majority of pathologists practice both anatomic and clinical pathology, for which they usually are certified by the American Board of Pathology. Subspecialty certification may be available for those with special interests.

A pathologist certified by the American Board of Pathology in Clinical Pathology or having equivalent qualifications may be granted privileges in clinical pathology and all its subspecialties (eg, clinical chemistry, clinical microbiology, immunohematology/blood banking, radioisotopic pathology, hematology/hematopathology, and clinical microscopy).

A pathologist certified by the American Board of Pathology in Anatomic Pathology or having equivalent qualifications may be granted privileges in surgical pathology (including dermatopathology, oral pathology, and ophthalmic pathology), autopsy pathology, and cytopathology.

Privileges for pathologists with qualifications for special biopsy techniques (needle or surgical), chemotherapy, in vivo nuclear medicine, or other special diagnostic or therapeutic procedures should be considered by the medical staff on an individual basis.

The privileges of the pathologist, like those of any other consulting physician, must delineate the patient care activities in which the pathologist may be engaged. These activities may, at times, require patient interview and physical examination. Documentation of consultative opinion by a written entry into the medical record is appropriate, and standards regarding the completion of medical records are applicable to the pathologist.

National Practitioner Data Bank

The Health Care Quality Improvement Act of 1986 (42 USC ss11000 et seq) established a central data bank that serves as a nationwide repository for information related to disciplinary actions, licensure status, and malpractice claims experience of physicians. The National Practitioner Data Bank has been operational for several years. Four types of actions must be reported to the National Practitioner Data Bank. Each person or entity, including an insurance company, which makes payment on behalf of a physician as a result of a medical malpractice claim or judgement, must report the amount of payment and other related information. Each Board of Medical Examiners must report to the data bank any disciplinary action based on reasons related to professional competence or professional conduct. Hospitals and other health care entities must report to their State Board of Medical Examiners when adverse actions are taken against a physician's clinical privileges (eg, termination or reduction lasting for more than 30 days) based on the physician's professional competence or conduct. The State Board must then report these adverse actions to the data bank. Lastly, professional societies of physicians that engage in professional review activity through a formal peer review process for the purpose of furthering quality must report adverse membership actions to the data bank.

Physicians can request a copy of their National Practitioner Data Bank file. If a physician has never received notification of a report being filed, there should be no adverse information in the data bank. Each hospital must request information from the data bank when a physician applies for medical staff membership or clinical privileges, and every 2 years while the physician is on its medical staff. State licensing boards and other health care entities may also request information. An attorney or plaintiff who has filed a professional liability action

against a hospital may query the data bank for information regarding a physician who is named in the action against the hospital. Information will be disclosed to plaintiffs only upon submission of evidence that the hospital failed to request information from the data bank.

The National Practitioner Data Bank mails copies of reports of malpractice payments or adverse actions to the physician. The physician has 60 days from the date that the report was mailed to dispute the information. It is noteworthy that not all actions affecting clinical privileges are reportable. For example, termination of medical staff membership as a result of contract termination due to inability to agree on appropriate compensation is not a reportable event because it is not related to professional competence or conduct and is not the result of a professional review activity.

Committee Appointments

Pathologists should accept assignment to medical staff committees and should make known any special talents or interests which might prove to be of service to the medical staff. The burden of committee appointments frequently is heavy for the relatively small number of pathologists in most hospitals. This is an indication of the importance of the department of pathology in maintaining and improving the professional standards of the medical staff, and accordingly should be welcomed. Pathologists can be of particular service on mortality, quality assurance, infection, utilization review, tissue, transfusion, and education committees.

Because of the relationship of the department of pathology to all other services, it is desirable for a pathologist-director to be a member of the executive committee so the pathologist may contribute to the development and implementation of staff policies relative to the continued improvement of patient care. All members of the medical staff should be concerned with the maintenance of high standards of medical practice. The pathologist, however, should not be considered a police officer for the institution. This is particularly the case where the structuring of quality assurance programs and committees are concerned. These activities are medical staff functions. Although not the sole responsible agent, the pathologist should be a willing participant. The criteria for case review should be developed and confirmed by the medical staff, thus allowing all persons affected to be involved in the decisions made. Operative findings and the pathology report should be considered in those cases that warrant evaluation of the surgical procedure performed.

Service Responsibilities

The internal day-to-day operation of the department of pathology is the responsibility of the director, within the limits established by the medical staff bylaws and rules and hospital administrative policies. The role of the laboratory manager who is commonly an employee of the hospital should be clearly defined. Any policy that will affect other departments or medical staff members should, however, first be reviewed and approved by the appropriate medical staff committee or hospital administration before implementation. Failure to follow the principle of providing advance notice and obtaining medical staff approval is likely to result in rapid deterioration of rapport with the medical staff.

As more focus is placed upon quality assurance and quality improvement, it is important to be aware of recommendations that may be promulgated by authoritative groups and that may be viewed as representing standards of practice. Publications, such as

the *Quality Improvement Manual in Anatomic Pathology, Second Edition* (College of American Pathologists, 2002); *Autopsy Performance & Reporting, Second Edition* (College of American Pathologists, 2003); and CAP Q-Probes reports, are examples. In general, the following principles apply.

Surgical pathology reports should be accurate, complete, and available within appropriate time frames. When a delay is inevitable, the attending physician should be notified and a preliminary report may be issued. Intraoperative consultations, including any oral communications and the results of frozen section interpretations, should be documented verbatim in the written final surgical pathology report. Copies of the report should be provided for the chart, the surgeon, the referring physician, and departmental files. Each institution, in conjunction with the pathologist and appropriate medical staff departments, should develop a written policy that addresses which specimens do not need to be submitted to the pathology department and which specimens may be exempt from a requirement for microscopic examination. The policy should be individualized for each institution and should take into account the diagnostic needs of the medical staff, the likelihood of significant findings in otherwise unremarkable specimens given the clinical situation, the reliability of procedures to ensure proper handling of specimens in surgery, and potential medicolegal implications. (See Appendix L.)

Autopsies are a valuable medical education tool. When practical, the attending physician should be encouraged to attend the autopsy. A written preliminary report of the gross autopsy findings should be issued promptly. The CAP's Laboratory Accreditation Program (LAP) requires preliminary reports to be issued within 2 working days, so that the attending physician may complete the death certificate. The LAP requires the final report to be completed within 30 working days for routine cases, and 3 months for cases requiring specialized testing and/or specialist consultation.

Written reports of clinical laboratory results should be available in a timely manner. Pathologists should be available at any time to clinicians who may wish to consult them on the appropriateness and interpretation of laboratory tests. The consultation service should be considered of major importance and of prime significance to the quality of patient care. All consultations should be handled expeditiously. The pathologist should provide the medical staff and each nursing unit with a manual or other source of readily retrievable information describing the manner of preparation of the patient, the specimen required, and the range of reference values for each clinical laboratory test. This manual should be kept up-to-date and reviewed as a whole at least annually.

Educational Responsibilities

Pathologists should play a leading role in the educational program of the medical staff. Clinico-pathologic conferences, grand rounds, tumor conferences, and departmental meetings should be considered as opportunities to emphasize the place of clinical pathology in patient care, in addition to presenting an array of gross surgical pathology and microscopic findings. The pathologist may invite other laboratory personnel to a conference to contribute their special knowledge. A pathologist-director should prepare a carefully integrated and coordinated program of instruction for hospital residents featuring formal conferences and laboratory experience, as well as individual teaching, discussion, and evaluation.

If there is a laboratory personnel training program, pathologists can assist in the recruitment of suitable students. As the medical advisor, the pathologist should hold ultimate responsibility for the quality of the educational programs, although the day-to-day operation of the school may be delegated to the program director, who may be an associate pathologist or a medical technologist. Pathologists should participate in the instruction of students both in the laboratory and by giving formal lectures.

The pathologist should participate in the continuing medical education program for medical technicians and technologists as both a medical advisor and a participant in formal and informal programs.

Medicolegal Responsibilities

A pathologist-director should ensure that the department and its associates meet all applicable federal, state, and local licensure or accreditation requirements. The director should be certain that all associates have adequate professional liability and other insurance coverage.

Multiple Testing Sites Within the Hospital

Clinicians and other health care personnel sometimes provide diagnostic services or operate diagnostic instruments in a hospital location convenient for patient management, such as at the bedside, on patient floors, and in surgical suites. In instances of decentralized laboratory testing, or “point-of-care” testing, the pathologist must ensure that both the quality assurance and policy and procedure requirements of accrediting agencies are met.

Similarly, clinicians or other scientists may offer special diagnostic services ancillary to research activities. Specialized laboratories frequently require duplication of space, equipment, and personnel, thus increasing the cost of medical care. The pathologist can reduce or eliminate the need for such special laboratories by ensuring that all reasonable needs of the medical staff are met. One approach may be to appoint clinicians as consultants to the department of pathology. Their expertise can enhance patient care without duplication of facilities. When research procedures are demonstrated to be practical and meaningful to patient care, they should be offered by the department of pathology. However, when the most reasonable use of resources determines that special testing be provided in other settings that are not directed by a pathologist, then the pathologist may offer to review or assist with quality assurance activities and provide consultation to verify that there is compliance with regulations relevant to facilities that perform clinical laboratory procedures. Medical staff and institutional policy should require that all specialized laboratories providing patient services meet the same accreditation and standards as are required of the pathology laboratory.

Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88; 42 USC. ss 263a) introduce additional factors that must be considered when there are multiple testing sites in the hospital. CLIA '88 regulations require each laboratory location to apply for a separate CLIA certificate. There is an exception for laboratories within a hospital that are located at the same street address and are under “common direction.” These laboratories have the option of applying for a single certificate or multiple certificates for each laboratory. Therefore, separate research laboratories and point-of-care laboratories must have a separate CLIA certificate unless they are under common direction

from the hospital's central laboratory. If there is a single director responsible for all laboratories in the hospital, the director has the option of obtaining a single certificate or separate certificates. CLIA '88 regulations allow one individual to direct up to five separate laboratories. (A listing of the laboratory director's responsibilities under CLIA '88 regulations is available at <http://www.phppo.cdc.gov/clia/regs2/toc.asp>.)

2. Relationship to Hospital Administration

Because pathologists spend significant time at the hospital, they often have frequent contact and a close working relationship with hospital personnel, including administrative staff. Pathologists occupy a critical administrative position in the hospital. Involvement in medical staff activities often gives them positions on the executive, infection, utilization review, and other committees. Therefore, pathologists are often in a unique position to advise the hospital administration on important, medical staff issues.

The pathologist-medical director should develop support from the hospital supervisory staff, especially the laboratory manager or chief technologist. The pathologist-medical director should provide material assistance in regard to administrative issues, such as budget preparation, personnel standards, and staffing requirements for the clinical and anatomic laboratory.

3. Suggested Rules and Regulations for the Laboratory (See Appendix D)

Written rules and regulations are necessary for the efficient operation of every pathology department. They may be general or detailed, depending on local circumstances and need. As a minimum, they should establish a departmental table of organization and broadly define relationships between the department and the medical staff, administration, other hospital departments, and hospital administration. They also should deal with intradepartmental personnel relationships and specify the duties, responsibilities, and authority of each member of the staff—professional, technical, and clerical. Rules and regulations should not be developed unilaterally by the pathologist, but should follow consultation with laboratory personnel at all levels and with appropriate medical staff committees and other hospital departments. All rules affecting nonprofessional personnel should conform to hospital policies. Rules affecting pathologists should conform to the bylaws and rules and regulations of the medical staff. Deviations from established rules and regulations should rarely be necessary and may indicate the need for revision. New employees should be given a copy of the rules, regulations, and policies of the pathology department and the hospital, and should be required to sign a document indicating they have read and understood these documents. Copies should also be filed with the administration and the medical staff executive committee.

Laboratories must comply with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, effective March 6, 1992, and any subsequent revisions. This regulation applies to all employees who have occupational exposure to blood or other potentially infectious materials. Employers of such persons are required to develop a written exposure control plan; implement training and information on the exposure control plan; establish recordkeeping systems; implement engineering and work practice controls; provide personal protective equipment; implement housekeeping procedures;

provide hepatitis B vaccination, post-exposure evaluation, and follow-up; and display warning labels and signs indicating hazardous and infectious materials.

Appendix D contains an outline for rules and regulations for a hospital laboratory. Regulations implementing the Clinical Laboratory Improvement Amendments of 1988, the checklist of the College's Laboratory Accreditation Program, the requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), NCCLS standards and guidelines, Centers for Disease Control and Prevention (CDC) guidelines, and OSHA standards should be consulted. State laboratory licensing laws and regulations also should be consulted when clinical laboratory rules and regulations are developed.

Some of these organizations' clinical laboratory standards are available at the following Web sites:

- www.cap.org
- www.cdc.gov
- www.cms.hhs.gov/clia
- www.nccls.org
- www.osha.gov

4. *Techniques of Communication in the Hospital*

The pathologist should have a good working relationship with the hospital administration and the medical staff. The needs of the medical staff must be considered within the financial constraints of the hospital. The pathologist should stimulate development of new services and techniques that enhance the quality and efficiency of care in the hospital.

This dual relationship with hospital administration and medical staff requires tact and diplomacy if the pathologist is to be respected and trusted by both groups. It is important to develop and maintain lines of communication at all levels. Informal contacts with fellow physicians and hospital administrators frequently can result in candid discussions of means for improving and expanding patient care.

A wide variety of communication techniques have been utilized by pathologists. In addition to serving as a committee member, laboratory administrator, and educator, a pathologist will find that informal conversation in the medical staff lounge will be beneficial. The medical staff newsletter and a periodic laboratory newsletter provide forums in which to discuss new procedures and changes in laboratory policies.

Daily or frequent rounds of patient areas can reveal problems of which the pathologist would otherwise be unaware, thus discovering problems at their early stages. Rounds also permit informal teaching of clerical personnel, which will enhance their interest and thereby improve patient care. Regular rounds in the laboratory are a means of assessing the needs and problems of the personnel. An open exchange can frequently result in steps to improve services or simplify existing systems.

One of the most efficient and effective techniques is an open-door policy. A warm welcome and a candid discussion are conducive to developing rapport. A more formal means of communication with the various departments, medical staff, and administration is through written policies, procedures, and memoranda. When a change in policy or procedure involves other hospital departments, it is advisable to write a preliminary

procedural change and submit it to the appropriate departments for review and comment, prior to implementation. Laboratory procedure manuals provide an important avenue of communication.

In some institutions, a laboratory liaison or advisory committee of the medical staff is developed to formalize communication between the pathologist and staff members. This committee, preferably chaired by a pathologist, should meet periodically to discuss changes in procedures, future plans, problems, and means of improving laboratory service.

5. Informed Consent in the Practice of Pathology

Pathologists must obtain a patient's informed consent for a medical procedure far less frequently than other physicians. Nevertheless, pathologists occasionally must obtain such consent from a patient. State laws do not uniformly require that consent for performance of a medical procedure be in writing, but this is strongly advised. To be considered "informed," consent must include the following elements.

- The patient must be an adult or an emancipated minor.
- The patient must be mentally capable of giving consent.
- The medical procedure must be clearly identified, preferably in both medical and lay terminology.
- The physician engaged to perform this procedure must be clearly identified.
- All complications that might reasonably be associated with a procedure, including the risk of failure, must be described in a manner understandable to the patient and in sufficient detail, so the patient may weigh the benefit-risk ratio.
- Possible alternatives must be described in sufficient detail, so the patient may also take these into consideration.
- The patient's signature should be witnessed.

If the patient is a minor or lacks the capacity to give informed consent, consent should be obtained from a close family member, eg, a spouse, parent, adult child, or legal guardian. If the patient does not speak English well enough to understand the information provided, the physician obtaining informed consent should obtain an appropriate interpreter. Failure to obtain valid consent for any medical procedure involving touching of the patient may, except in an emergency, be regarded by the courts as a "battery." Blanket consent forms are unacceptable to many courts and should be avoided. The risk of liability is reduced if the consent form clearly indicates that the physician has explained the procedure to the patient, and the patient's signature has been witnessed. The task of obtaining consent should not be delegated to paramedical personnel.

Pathologists are unlikely to be involved in emergency circumstances in which the patient is incapable of giving consent. In an emergency, pathologists should perform any necessary medical procedure and document why it was necessary.

Pathologists should obtain consent when they perform bone marrow and fine-needle aspirations, or any time they inject a patient with a foreign substance, such as a dye, drug, or isotope. Consent may also be needed when the pathologist provides apheresis services.

In recent years, a number of transfusion recipients have sued physicians and blood banks for illnesses, including AIDS, acquired as a result of receiving blood or blood components. It is therefore extremely important that, except in emergency situations, physicians obtain patients' informed consent prior to administering blood or blood components. Whether the pathologist or the clinician should be responsible for obtaining the patient's consent is a matter of local custom and arrangement. When obtaining informed consent, physicians must warn patients of the risks of a transfusion, including allergic, febrile, and hemolytic reactions, as well as transmission of infectious diseases, and should indicate the benefits to be obtained from the transfusion. Pathologists associated with blood procurement facilities must be familiar with and assure compliance with all donor procedures and regulations as required by the Food and Drug Administration (FDA).

Pathologists must follow state law when determining who can grant permission for performance of an autopsy. (See Appendix E for sample consent form.) Legal counsel should review the consent form to ensure compliance with applicable laws and regulations. Items that should be explained in obtaining informed consent for the autopsy include the extent of the autopsy examination and site of autopsy performance. Assuring the family and others of the respect and dignity afforded the body and the confidentiality of any information acquired is important. Pathologists should provide policies on partial or complete retention of body parts and the use of tissue or organs for transplantation. When the autopsy service is provided at the request of the family of the deceased, the pathologist who performs the autopsy may bill the family of the deceased for the professional service. The financial responsibility of the family requesting the autopsy should be discussed, when appropriate, before permission for the autopsy is secured. (See Appendix K, "Payment and Performance of the Autopsy Service.")

It should be noted that the rules governing informed consent for HIV testing are determined by state law and will therefore vary from jurisdiction to jurisdiction. Pathologists should determine whether there are any controlling statutory or regulatory requirements in the states in which they practice. Similarly, pathologists should be aware of any applicable judicial decisions. Pathologists should consult with a knowledgeable attorney.

Informed consent may need to be obtained from a patient prior to performing an HIV test. Generally, the responsibility for obtaining a patient's informed consent falls on the patient's attending physician, rather than the laboratory or pathologist performing the test. However, the pathologist should have the ordering physician document that informed consent has been obtained, and that it is broad enough to include the laboratory. This can be accomplished by including on the laboratory test request form a box that the ordering physician can check to indicate that the physician has complied with applicable state law, and the patient has consented to be tested. The availability of or, in some states, the necessity for pre-test and post-test counseling, as well as positive test confirmation, should also be considered in the testing process.

The laboratory should maintain a policy and procedure manual that includes a list of the persons who will be informed of the patient's test results and the circumstances and manner in which such disclosure will be made. State law may require that certain other individuals or entities be informed of positive HIV test results. As other specific tests become indicative of HIV infection or AIDS, requirements for specific informed consent for these tests should be considered.

6. Confidentiality of AIDS-related Information

State law generally will determine whether HIV test results and other sensitive AIDS-related information is given the same degree of protection as other medical information, or whether special precautions regarding recordkeeping and disclosure are required. In some states, HIV test results may be recorded in a patient's written or electronic medical record only in a manner that does not permit disclosure to persons who might otherwise review the record but are not authorized to receive AIDS-related information.

If state law does not require specific confidentiality precautions for AIDS-related information, the general duty of confidentiality towards patients' medical information still exists. This duty may be heightened in the AIDS context. Therefore, where HIV test results and other AIDS-related information may be maintained in a patient's hospital chart or the electronic record, the laboratory should consider adopting policies and procedures that protect the confidentiality of the information. It is recommended that policies and procedures ensure that laboratory personnel and hospital staff receive written instructions and in-service training sensitizing them to the confidential nature of all medical information and the risks of inappropriate disclosure.

The decisions as to whether HIV or other AIDS-related tests should be performed as part of an autopsy, and whether the results of such tests should be included in the autopsy report, are medical decisions that should be made by the pathologist performing the autopsy, in accordance with the pathologist's best medical judgment or as dictated by state law. Once an HIV or other AIDS-related test has been performed, the results of the test generally should be entered in the autopsy report and should be based on medical rather than confidentiality concerns. If the autopsy was performed at the request of the medical examiner's office, and if state law requires that the autopsy report be made a matter of public record, then the pathologist may choose to include AIDS-related information only if it is relevant in determining the decedent's cause of death.

Hospital autopsy reports should be treated in the same manner as other medical records, and precautions should be taken to protect the confidentiality of autopsy reports.

State law generally will determine whether the pathologist must report positive HIV or AIDS test results to public health or other authorities, and whether certain at-risk third parties, eg, spouses or other sexual partners of the decedent, must be informed. The pathologist should also report to any tissue or organ procurement agency that received tissue from an HIV-infected decedent.

7. Disposal and Release of Tissue and Bodies

All surgically removed tissue, foreign bodies, and calculi should be appropriately preserved, labeled, and retained in the laboratory according to legal or accrediting agency regulation. When the patient is discharged from the hospital, it may reasonably be assumed that the patient does not desire to keep these items. Most specimens may be disposed of in accordance with local custom and regulations. Certain specimens with medicolegal implications, such as bullets and other foreign bodies, should be retained as specified by law and stored in a manner that preserves the evidentiary chain. Such specimens should be released to the patient, the patient's representative, or authorized legal authorities only upon written request, as specified by local law and custom. A witnessed receipt should be

obtained. Pathologists should seek legal counsel in these matters lest they commit a misdemeanor by improperly destroying or withholding evidence.

In some hospitals, no special provision is made for consent to dispose of amputated limbs, and they are treated like all other surgical specimens. Some religious faiths require burial of amputated limbs. Pathologists must take this into account when considering disposing of an amputated limb.

Although most states have some form of legislation dealing with the disposal of various stages of the products of conception, there is no universal agreement on the exact definition of such terms as fetus, stillborn, and viability. Where existing state legislation and regulation is vague or incomplete, hospital administration may need to adopt its own definitions and instructions regarding disposal of fetuses. Policies should include consideration of family wishes and religious beliefs. Appropriate records should be kept of all permits and disposal forms to comply with existing law and to protect both the pathologist and the institution from liability.

In some institutions, pathologists may be called upon by administration or parents to dispose of stillborn infants. This is usually effected by cremation and/or through cooperation with a local funeral director. A disposal request and permit, signed by both parents, should be obtained, where possible; and a stillbirth certificate should be filed with the local authorities, as required by law, indicating disposal rather than burial of the body. In some states, the pathologist may sign in the space provided for the funeral director if no funeral director is involved. Birth and death certificates must be prepared and filed for any postnatal infant death.

Larger institutions, which serve as recipients of bodies under the Uniform Anatomical Gift Act, may also be required to dispose of adult bodies, following completion of dissection or other studies. Such disposal may be carried out in a similar manner, with the pathologist or other responsible individual signing in lieu of the funeral director. In most jurisdictions, it may also be necessary to obtain a burial or removal permit from the local registrar. This should be maintained permanently in the pathology or medical records department of the institution. The specific jurisdictional requirements for the handling of such cases should be obtained from the state office of vital statistics.

8. Uniform Anatomical Gift Act

Since the development of a model Uniform Anatomical Gift Act in 1968, all 50 states and the District of Columbia have enacted laws that are reasonably similar and follow the model act in all major respects. These laws have removed some legal barriers to donation of bodies for autopsy or anatomical studies, and donation of organs for transplantation, therapy, and research. However, pathologists may still face exposure for harvesting organs without documentation of the decedent's wishes or without permission from the next of kin.

The Uniform Anatomical Gift Act is based on the belief that an individual should be able to control the disposition of their own body after death, and that the individual's wishes should not be frustrated by any next of kin. However, the decedent's wishes on this issue may not be clear. The uniform provisions of the act also ensure that a gift made in one state or jurisdiction will be valid when death occurs in another. The provisions may vary from state to state, especially because the act was altered in 1987. A copy of local law

should be obtained, reviewed, and retained. The Uniform Anatomical Gift Act is described in more detail in Appendix F.

9. Organ Procurement and Transplantation

The federal government has become involved in organ transplantation because of the need to coordinate organ procurement activities. The National Organ Transplantation Act of 1984 created a task force which recommended federal legislation to establish certification standards for organ procurement agencies and to encourage organ donations. Congress enacted organ procurement legislation in 1986. The Secretary of Health and Human Services (HHS) adopted final regulations in 1988.

These regulations require hospitals to establish protocols for identifying potential organ donors and to notify the family of the option to donate organs or to decline to donate. “Potential donors” are defined as persons who die in circumstances that are generally acceptable for donation of at least one organ. Pathologists are urged to comply with applicable policies and may be requested to perform an autopsy to determine acceptability of the donation.

10. Preservation of Specimens and Records

The necessity of preserving pathologic specimens and records is well accepted. Premature disposal may have unfortunate medicolegal consequences, while excessive retention may result in encroachment upon valuable laboratory or office space.

Factors to be considered in establishing policy include local and national laboratory accreditation and licensing laws, the state’s statute of limitations, the nature of the institution, requirements of the medical staff, research needs, local custom, and personal preference. Some pathologists may wish to give consideration to microfilming reports to accommodate their storage needs. In no event should specimens and records be destroyed earlier than the retention times required by applicable federal and state regulations.

CLIA ’88 minimum periods for retaining pathologic material and reports are available at <http://www.phppo.cdc.gov/clia/regs2/toc.asp>. The CAP policy on retaining material and reports is included in Appendix A. The most stringent applicable law or regulation should be followed. Approval of the medical staff and administration should be sought for all recommended policies.

11. The Pathologist and the Rural Hospital

The pathologist’s role in relation to a rural hospital is a challenging blend of professional endeavor, both in the form of direct service as a consultant and as an educator. A pathologist has an opportunity and responsibility to take a leadership role in striving to ensure that high-quality medical care is available in the rural community.

The most dynamic and visible role that today’s pathologist plays in a rural hospital is that of a professional consultant who guides the medical staff and laboratory personnel in efficient and cost-effective utilization of all aspects of laboratory services. To accomplish this, the pathologist may find it necessary to promote an awareness by the medical staff, hospital personnel, and administration of the wide spectrum of pathology services and how these services may best be used.

The amount and nature of direct or personal professional service rendered by the pathologist depends, in large measure, on the sophistication of the rural institution and its medical staff. Surgical and cytological diagnosis and consultation should be readily available either at the pathologist's "home base" or "on site," depending on the hospital's size and the demands of its medical staff. Likewise, interpretation of bone marrow specimens and other needle aspirations should be available. Frozen section diagnosis may be provided on a schedule that is mutually agreeable to pathologist and the medical staff. If this service is to be provided, the pathologist should ensure that the hospital is properly equipped to process frozen specimens on site. Arrangements should also be made for autopsy service for those cases for which it is medically or legally indicated.

In the hospital laboratory, the consulting pathologist should strive to ensure that the test results are of consistently high quality. The pathologist should review quality control data and proficiency test results on a regular basis and recommend appropriate corrective measures when indicated. Participation in the College's various quality assurance programs, including Q-Probes and Q-Tracks, can provide a convenient vehicle for monitoring quality. The pathologist should also periodically review requisitions and reports for proper reporting of test results.

The consultant-pathologist should review and date procedure manuals on a regular basis, not less than annually. The pathologist should be alert for undocumented modifications to prescribed procedures and should be consulted prior to the establishment of new procedures or modification of existing protocols. The pathologist is also in a position to advise which procedures should be performed in the hospital's laboratory and which should be sent to a reference laboratory. In making these recommendations, the pathologist should take into account the demands of the medical staff, competence of technical personnel, frequency, and cost effectiveness. Advice on appropriate instrumentation should take into account the level of service required by the medical staff, the competence of personnel, and cost of equipment service and repair.

The pathologist can assist in establishing laboratory personnel qualifications that are adequate for the needs of the rural hospital and consistent with relevant accrediting agencies and state and federal laws and regulations. Familiarity with qualifications of existing personnel and review of the qualifications of prospective laboratory personnel are important considerations.

The pathologist has important educational responsibilities in a rural setting. The pathologist should develop and participate in programs to train and to monitor the effectiveness of laboratory personnel. The pathologist should initiate education programs for the medical staff and hospital personnel, including clinico-pathologic conferences and conferences on laboratory-related problems. The pathologist's relationship to the medical staff will vary widely from hospital to hospital due to the nature of the medical staff, the size of the hospital, and geographic limitations. The opportunity for consultation and communication should be available either in person or by telephone at any hour. Upon request, the consultant-pathologist should serve on medical staff committees and participate in regular medical staff meetings.

B. Relationships to Public Health

Pathologists have an important role in maintaining and promoting the public health. State and federal public health measures are often implemented through local and state public health departments. The following section discusses the areas of principal concern to pathologists.

1. Clinical Laboratory Licensure and Accreditation

On February 28, 1992, the Secretary of Health and Human Services (HHS) published the final rules implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). The CLIA '88 regulations set forth a single set of requirements that apply to almost all laboratory testing of human specimens. The regulations establish federal standards for personnel, quality control, and test management. The regulations also establish application procedures and fees for CLIA certification. The federal government has extensive authority to sanction clinical laboratories that do not meet federal requirements.

Under CLIA '88, all clinical laboratories, regardless of location, size, or type of laboratory, must meet standards based on the complexity of the tests that they perform. Four levels of testing complexity are defined in the regulation: waived, moderate complexity, high complexity, and "provider performed microscopy procedures." Laboratories performing moderate- and/or high-complexity testing or "provider performed microscopy procedures" must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category. The major differences in regulatory requirements between moderate- and high-complexity testing are in the quality control and personnel standards. CLIA requirements for laboratory director responsibilities are available at <http://www.phppo.cdc.gov/clia/regs2/toc.asp>. The major difference in regulatory requirements for the "provider performed microscopy" category is that routine inspection is not required. Tests included in this category must be performed for the physician's own patient during the patient's visit.

The statute requires the CLIA program to be financed by user fees. Laboratories must pay all costs involved in issuing certificates, conducting special studies mandated by CLIA '88, developing and conducting surveyor training, and the costs of the biennial on-site inspections. Follow-up visits, complaint investigations, and validation inspections of laboratories that are privately accredited or located in states with licensure programs approved by the Centers for Medicare and Medicaid Services (CMS) are included in the fees charged to the laboratory. Fees are based on laboratory test volume and number of test specialties. Test volume, for purposes of determining fee amounts, excludes tests performed for quality control and proficiency testing. For chemistry profiles and panels, each individual test is counted separately.

Many states have passed medical laboratory licensing laws, which govern the operation of both hospital and independent laboratories. State licensure laws are usually administered by the health department and often require not only licensure of the laboratory, but also of its director and personnel. Requirements vary from state to state, but in most instances, laboratories are required to pay a licensure fee, submit an annual report and list of tests performed, participate in a proficiency testing program, and open their doors to inspection. Laboratories in these states must comply with CLIA '88 standards and state requirements,

unless the state program is approved by the Centers for Medicare and Medicaid Services (CMS) for a state exemption from CLIA requirements. Results of the College's Surveys Program are reported to the appropriate health department upon request, or as required by law, and often can be used to substitute for the state proficiency testing program.

2. Infectious Diseases

In most jurisdictions, pathologists also have a legal responsibility to report certain infections to the local health department. State and local law should be consulted. Some state health departments offer a diagnostic and consultative service in microbiology and serology. This takes the form of definitive identification of mycobacteria and a variety of unusual bacteria, fungi, and viruses. Biologic studies, both serologic and by tissue culture, are frequently available. It is usually required that certain clinical information be submitted with the specimen. Pathologists should readily cooperate in this regard. The Centers for Disease Control and Prevention (CDC) serves as a referral laboratory for all state health departments.

3. Licensure of Pathologists and Laboratory Personnel

Medical practice acts in each state govern the licensure of physicians. State medical boards are usually responsible for administering the licensure process and disciplining physicians. The practice of telemedicine and the transportation of biopsy specimens across state lines for primary diagnosis have raised the issue of whether physicians located outside the state where the patient has presented for primary diagnosis must be licensed in the patient's state. Many state medical boards interpret their medical practice act to require physicians rendering primary diagnosis and/or treatment to have full unrestricted licenses to practice medicine in the state where the patient is located. Most medical boards allow consultations (as opposed to primary diagnosis or treatment) between out-of-state physicians and in-state physicians if the consulting physician is licensed by another state and does not have an office in the state. Some states, however, take the position that any physician who receives a specimen from a patient in a state should be licensed to practice medicine in the state in which the patient resides. Pathologists should check with the appropriate state medical board to determine the licensure requirements when specimens or images are transported or transmitted across state lines for primary diagnosis.

The College supports the right of each state to regulate the practice of medicine and takes the position that a pathologist who issues a pathology diagnosis that is contained in the patient's medical record should have a full unrestricted license to practice medicine from the state in which the patient presents for diagnosis. (See Appendix N, "Licensure Requirements for Interstate Diagnosis, Including Interstate Telemedicine Practice.")

Only a minority of states require licensure of clinical laboratory personnel, although bills to accomplish this are repeatedly introduced in many legislatures.

4. Other Relationships

The National Regulatory Commission establishes standards for the use of radioactive material. Many states require licensure for the use of radioactive material, and some have organized tumor, maternal, and child health registries administered by the state health department. Pathologists should be familiar with these federal and state requirements.

The state health department frequently plays an advisory role in the promotion of a variety of health-related legislative proposals. Pathologists should be ready to provide their expertise to state health departments on public health issues.

C. Relationships to Academic Medicine

All pathologists, whether practicing in academic settings or in community settings, have common scientific interests. The work of each group is complementary to the other. Pathologists in universities and medical schools can provide specialized consultation and can make available the technical resources of their institutions. They can also offer continuing education programs in their specialty. Community pathologists are an important source of referral of cases and can provide pathology material and other assistance to medical teaching programs. It is important that good relations be maintained between the groups in order that the contributions of each can be best utilized.

Academic pathologists have primary responsibilities in the teaching of medical students, residents, and others. They may not always appreciate the contributions that can be made to this work by pathologists in private practice. The latter often are involved in the organization of teaching programs in their hospitals and are knowledgeable in ways to utilize patients and pathology materials in medical education. Community pathologists should apprise academic pathologists of the availability of their teaching resources and of their willingness to participate in academic instructional programs. In turn, academic pathologists should make efforts to identify community pathology teaching resources and faculty, and utilize them in medical school teaching.

D. Relationships to Organized Medicine

Pathologists should consider becoming active contributing members of organized medicine. Pathologists should appreciate the problems of their clinical colleagues and help with their solution. Clinicians should be made aware of the problems, pressures, and unique demands of the practice of pathology. All pathologists should consider participating actively in the affairs of county, state, and national medical and pathology organizations.

1. County and State Medical Societies and the American Medical Association

The county medical society is the fundamental unit of organized medicine. At this level, physicians can participate most effectively in assisting their peers with the design and implementation of medical and health care programs in the community. Programs relating to emergency medical services, public health, school health, availability of care, quality of care, professional liability insurance, and the public's attitude toward the profession can be effectively acted upon at this level. The county society has a key role in assuring a smooth working relationship between physicians, hospitals, allied health professionals, and the general community. The patient who seeks medical care or who has a grievance with a physician should be encouraged to turn to the county society. The county society can be of vital assistance to the physician when dealing with third-party payers and may accept responsibility for the coordination and implementation of some governmental programs. Representatives elected from the county medical societies, in turn, elect the leadership of the state medical association.

The state medical association is part of the federation that makes up the American Medical Association. The state association provides physicians with information and a policy-setting mechanism for issues related to continuing medical education, licensure, relicensure, ethics, the legal aspects of medical practice, governmental regulatory measures, and third-party payers. The state medical association represents its members before the governor, legislature, administrative agencies, and other professional and nonprofessional opinion-setting groups. It often offers insurance benefits to members.

The American Medical Association is a federation of state and territorial medical associations that provides a wide range of benefits and services to physicians and the public. The AMA develops and promotes policies on medical education, continuing education, hospital accreditation, health legislation, federal regulation, and public health education. It provides various scientific and socioeconomic publications and offers a variety of insurance programs. The AMA is a prime resource for the legal, ethical, and managerial aspects of medical practice.

2. *Specialty Societies*

Local pathology societies provide a forum for the discussion of interesting cases and problems. The communication established by these groups frequently lead to the solution of local problems.

State pathology societies monitor legislation and regulations affecting pathologists and laboratories. They usually maintain active liaison with the state medical society and public health agencies. In addition to these activities, the state society usually provides for scientific and socioeconomic exchanges at the regional level.

All pathologists, whatever their type of practice, should consider joining and becoming active in one or more of the national pathology organizations. The publications and meetings of these organizations offer pathologists useful information in a well-synthesized and organized form. National organizations attract outstanding physicians and scientists to their meetings and thus provide an opportunity for the pathologist to become aware of new and important developments and to continue to grow in this specialty.

The College of American Pathologists encourages pathology residents to become actively involved in the CAP Residents Forum and to serve as a resident member of CAP committees. Appointment to the Residents Forum is at the discretion of each state pathology society. Involvement in the CAP provides pathologists-in-training with a direct voice in organized pathology, promotes the involvement of young leaders in College activities, and establishes a network for pathology residents.

Practicing pathologists have good reason to be active members of the College of American Pathologists, since the College represents the socioeconomic and scientific interests of all pathology. Pathology residents should also consider joining and becoming active in local, state, and other national pathology organizations. Pathologists who are interested in serving on a College committee should send a letter of interest and a CV to the Director of Governance Services. Through its committees, governors, and officers, the College has a significant impact on governmental and regulatory agencies. In addition, it provides pathologists with invaluable tools for laboratory administration and management through quality control services and standards (eg, Laboratory Accreditation Program, Surveys Program, Path*Focus* Program), educational programs (eg, pathology practice

management seminars, CAP national meetings), and publications (eg, *STATLINE*, *CAP Today*).

The CAP Publications Catalog provides a complete listing of current publications available from the College. Contact the CAP Customer Service Department (800-323-4040, option 1#) to obtain a current catalog.

E. Relationships to Physician Office Laboratories

Pathologists have seen a shift of laboratory testing from hospital inpatients to outpatients and to the physician's office. This trend has been the result of government legislation and regulation as well as the development of new technology. The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) extend federal regulation to all clinical laboratories (including physician office laboratories) performing tests on human specimens for diagnosis, prevention, or treatment of disease. Because of these changes, new opportunities exist for the pathologist as a consultant to the physician's office.

Consulting in this area requires knowledge of instrumentation, personnel training, and service needs that are unique to the physician office laboratory (POL) setting. Many of the functions performed for a hospital laboratory are required for an office laboratory. The pathologist's background and experience provide the tools needed for the proper management of a clinical laboratory, regardless of its location. The pathologist can provide valuable advice on CLIA compliance, QC systems, procedures, and PT program selection and requirements.

In addition to CLIA requirements, some states have regulations pertaining to clinical testing in the physician office setting. The pathologist-consultant can provide invaluable information on how to comply with the standards. COLA has been established to provide a voluntary accreditation program for physician office laboratories. COLA is an independent organization formed in 1988 as a result of the joint efforts of the College of American Pathologists, the American Academy of Family Physicians, and the American College of Physicians. These organizations and the American Medical Association and the American Osteopathic Association are also represented on the COLA board of directors.

Pathologists can expand their consultant roles through the use of medical technologists. Technologists can assist the pathologist in the consultant function and can help physician office employees prepare procedure manuals, evaluate equipment problems, and conduct continuing education programs.

Pathologist consultation with physician office laboratories will help assure quality laboratory services. Various forms of compensation for providing consultative services are available. Compensation agreements can be any of the types discussed in Section II of this manual.

III. Guidelines for Relating to the Nonmedical Community

The College encourages pathologists to participate in community affairs, both medical and nonmedical. Not only will the community benefit from the pathologist's special skills and interests, but also such involvement is a demonstration of the pathologist's commitment to the well-being of the public and the community. County health departments or medical societies may invite pathologists to participate in local medical projects such as immunizations or Pap smear drives. Agreeing to participate in such programs helps the public understand the importance of pathology in health and wellness. In addition, pathologists may seek involvement in nonmedical community affairs through cultural, political, and religious organizations; service clubs; and local charities.

A. Relationships to Patients

Pathologists' understanding of and empathy for the patient's needs and apprehensions will improve the interaction and rapport between patients and pathologists. Pathologists should be available to communicate with patients about their personal health concerns in a language that the patient understands.

In hospitals and other health care settings, the pathologist may improve rapport and understanding by talking directly with the patient, the patient's family, and in many instances, the patient and attending physician together. Pathologists should be able to explain their role as members of the health care team. When pathologists interact directly with patients, it is essential that the pathologist coordinate patient communication with the attending physicians. By talking directly to the patient and the family, the pathologist can explain, educate, and facilitate interpretation of both anatomic and clinical pathology results.

Pathologists should also instruct, counsel, and train other laboratory personnel about the necessity of excellent patient relations. A helpful guideline is to treat the patient as you would wish yourself or a member of your family to be treated under similar circumstances.

As medicine in general has become more decentralized, and patients have become more accountable for their own health care, home testing and direct access to laboratory testing have become available in parts of the country. Pathologists should review the applicable law in their state before providing patients direct access to laboratory services. The College believes that patients are best served when laboratory tests are ordered by a qualified physician who directs the course of diagnostic and therapeutic care of the patient, and that a physician should determine which clinical and anatomic laboratory services are appropriate. Pathologists who wish to offer direct patient access to laboratory testing are referred to the College policy concerning this issue. (See Appendix G.) Pathologists who offer this form of patient service should consider the implications for informed consent, patient counseling, and continuity of care.

B. Relationships to the General Public

The College, through the Council on Public Affairs, has developed programs to improve the public's understanding of the pathologist's role in providing health care services. All pathologists can make it their business to help the public understand what pathologists do. This can be done by becoming a CAP Spokesperson, responding to media inquiries,

speaking to local community groups or high schools about health issues, and organizing laboratory tours. The College has developed brochures and videos to help its members speak to the public about health and wellness issues and to help the public better understand the role pathologists play in their everyday health care. The College has a training and support program for CAP members who want to become official spokespersons or ambassadors for the profession to their communities. For more information, contact the Division of Communication Services at 800-323-4040, ext 7538.

C. Relationships to the News Media

A good rapport between pathologists and the local news media helps the public appreciate the role of pathology in medical practice. With this increased awareness and understanding, the public is more likely to be receptive to pathologist-proposed initiatives in such areas as health care economics, governmental regulations, and other concerns of the specialty. The College has an established Spokespersons Network composed of pathologists from all over the country. Each Spokesperson is media trained and speaks on behalf of pathology. This program encourages proactive involvement with the media. More information about the Spokespersons Network can be obtained by calling 1-800-323-4040, ext 7538, or by e-mail to media@cap.org.

In addition to members of the Spokespersons Network, the College encourages all pathologists to become acquainted with the reporters and editors who cover health care in the print and broadcast media in their communities and to be available to speak with them when they call with questions. These contacts should include health and medical reporters, science editors, assignment editors, and city editors. If you need help identifying any of your local media representatives, please contact the CAP communications department for assistance at media@cap.org.

It is important to note that when CAP members and spokespersons address the medical community, the public, or the media, they speak as individuals representing the profession. The only pathologist who is authorized to speak for the College of American Pathologists is the College president or the president's designee. Unless you have been asked by the president to speak on behalf of the College, be certain that the reporter understands that you are expressing your own professional opinion, not that of the College.

If you are contacted for an interview by your local media outlet or by the CAP Communications Department, consider the following points.

- You don't have to take a call the moment it comes in. You don't have to answer questions unprepared. The reporter understands that you are a busy professional. Find out as much as you can about what the reporter wants to discuss with you and what kind of deadline the reporter has. Reporters will probably understand if you are tied up at the moment and need some time to prepare. A reporter will usually agree to arrange a later time to reschedule the interview. Once you've established a time for the interview, call or e-mail the CAP Communications Department for assistance. A reporter who wants to "ambush" you without any warning is probably not a reporter with whom you want to work. Be certain to return the call at the promised time.
- Assistance is available from the College's Communications Department (800-323-4040, ext 7538 or 7439). Staff may be able to quickly provide you with current

background information about your topic and may have information about the reporter or news outlet that contacted you. If you would like, College Communications staff can contact the reporter for you and get more information, which may help you field the interview.

- Rather than let the reporter set the agenda for the interview, you can determine in advance the single message you want to communicate and how it best can be presented. Consider in advance what questions are likely to be asked. You should not blatantly ignore or evade a reporter's questions, but you can tie the interview together by working your theme into answers to the reporter's questions.
- Determine your single overriding communications objective (SOCO). Write down the single message that you want to communicate. This is the key point—the thing you want your audience to remember if they take nothing else away from your interview. Keep it in front of you, especially during the telephone interview.
- Repeating your important point will make it stand out from everything else that is said during the interview. Draw attention to it by using phrases such as: “I think it is very important to remember...”; “As mentioned earlier, it is important...”; “Let me emphasize...”

In developing your SOCO, remember that the following overall themes should be conveyed to your audience as a backdrop to everything you say: “The pathologist is concerned about the health and welfare of the public.” “The pathologist is a highly specialized physician who diagnoses diseases and provides critical information necessary for treatment.”

- Do not present only the pathologist's point of view. Emphasize how your expertise, research, or perspective may *benefit* the reporter's *viewers* or *listeners*. Give real life examples or consider analogies to help the audience understand your point. Throughout the interview, the audience is asking themselves: So what? Who cares? What's in it for me? Your message should answer these questions.
- Be sure you identify yourself as a pathologist. Be sure the public knows that this important information is coming from a pathologist. For example, “As a pathologist, I am especially aware of the importance of women having annual Pap tests.”
- Be personable rather than using one-word responses to questions. Amplify your answer to assist the reporter in getting the story. Use anecdotes and metaphors to make your point. For example:

“For my own piece of mind, I make sure that my own (wife; daughter; mother) has her Pap test taken by a doctor she trusts, and that the test is read in a CAP-accredited laboratory.”

“If a woman is careful about where her silk blouse is dry-cleaned, why wouldn't she be equally concerned about where her Pap test is read?”
- Show consideration and respect for the reporter and the reporter's objectives. Take the time to explain technicalities or even the basics of your subject. The better the

reporter understands the subject, the better they can communicate it to the audience.

- Identify anything you say as either fact or opinion. Fact is fact; your opinions are your own. Be careful to separate fact from opinion when talking to reporters.
- Try not to repeat a negative. If a reporter asks, “Why are so many Pap tests misread?”, don’t answer by saying, “It’s not true that many Pap tests are misread.” A better answer would be:

“No diagnostic procedure for detecting any kind of cancer or precancerous abnormality is more effective than the Pap test. Since its introduction after World War II, the death rate from cervical cancer has decreased by more than 70%.”
- Correct misinformation. If reporters include misleading or erroneous information in their questions, correct the misinformation before you answer the question.
- Tell the truth and don’t exaggerate. Nothing will destroy an individual’s or an institution’s credibility quicker than to be caught in a lie. You, the College, and pathology are much better off acknowledging an uncomfortable truth than “stonewalling” or hiding something.
- Never speculate or guess. If you don’t know the answer, say so. Offer to find out and make arrangements to get back to the reporter when you have the information.
- Avoid excessive or complicated medical terminology. The more easily the reporter is able to understand you, the greater the likelihood that you will not be misunderstood or misquoted. Furthermore, using nontechnical language makes an audience much more comfortable with and trusting of you (eg, “A young mother-of-two saw her doctor...”; rather than, “A 25-year-old female presented with...”).
- Avoid discussing hypothetical situations. Be wary if a reporter starts a question with “what if...” or “let’s suppose...”. You can decline to respond to questions about hypothetical situations. Instead, go back to your message.
- Avoid commenting on subjects outside your area of expertise. If you are not an expert on the subject, say so. You can offer to find the expert.
- Never go off the record. If you don’t want to see it in print, don’t say it. Give a reporter information you are willing to stand behind. Although most reporters will respect off-the-record remarks, they are under no legal obligation to do so. Always assume the microphone and cameras are on.
- Keep your word. If you told the reporter that you would call back with further information by a certain date or time, do it. If you can’t get the information in time, let the reporter know when you will be able to provide with the information.
- Never assume you will hear or see the reporter’s story before it appears. As a professional, the reporter is under no obligation to show you copy or tapes. If scientific or technical data are involved, you might suggest that the reporter check the facts with you for accuracy.

- Debrief the College after the interview. Let the College’s media and special events specialist know how the interview went from your perspective, what questions were asked, and how you answered them. If you need to follow-up with the reporter to provide additional information or to find out when your interview will be aired or printed, College staff may be able to do it for you.
- Take a bow. Congratulate yourself for being one of the people who is helping the public to understand the role pathology plays in meeting health and wellness needs. Your active involvement in service to our lay and medical communities is required for your personal success and the survival of our profession.

For background information and other assistance, contact the College’s Communications Department at 800-323-4040, ext 7439 or 7538.

D. Relationships to Government Representatives

One of the major influences shaping the practice of pathology has been the increasing role played by government agencies in regulating medical services. Local, state, and federal governments all contribute money to pay for public health programs. Thus, government at all levels considers itself responsible for assuring the appropriateness of the services for which it pays. No one in the medical profession can escape the impact of political decisions made by Congress and the state legislatures. Government influence in medical practice will continue in the future. It is therefore important for pathologists to become actively involved in politics in order to be able to influence government policy.

Individuals either participate actively within the political and policy-making arena, or they are detached from the policy development process and thus unable to influence its direction. It is vitally important that every physician understand that political decisions will determine the future of pathology and medicine. As an active partner in the political process, the personal relationships you develop with your representatives can help determine the outcome of those political decisions. As former US House Speaker Thomas “Tip” O’Neill often said, “All politics is local.” Your involvement in local politics is nearly as important a part of your practice as patient care, because what is ultimately at stake is the quality of health care that best serves your patients—and your elected representative’s constituents.

As a pathologist, you are a constituent of three members of the US Congress—the senators who represent your state and the representative who serves the district in which you reside—as well as their counterparts on the state and local level. These elected officials are elected by voters to represent the interests of their constituents, and they place great value on communications from their active constituent supporters. After all, these constituents are the people who will either re-elect them to another term in office or elect someone else to take their place. These are the representatives that you, as an individual citizen, are most likely to be able to influence. For that reason, these are the people you should get to know personally.

When local constituents try to influence legislative issues, it is commonly described as “grassroots lobbying.” Today more than ever, grassroots lobbying on an issue is critically important if organized pathology is to succeed in passing, amending, or defeating a legislative proposal. The College offers its members the opportunity to help shape legislative

outcomes through the Pathology Advocacy Network (PathNet). PathNet provides the information, tools, and guidance for pathologists to be effectively and quickly heard on Capitol Hill. Additionally, pathologists may be trained in legislative advocacy in the College's annual Advocacy School in Washington, DC. Information on all the College's advocacy programs can be found on the CAP Web site. CAP members are encouraged to look at the site for more information on PathNet and to contact the CAP Washington Office at 800-392-9994, ext 7105.

1. The Importance of Congressional Staff

The overwhelming demands on an elected official's time make staff very important. Staff members serve as a representative's "eyes and ears," alerting the representative to issues and interpreting constituent concerns.

While there is no substitute for working directly with the office-holder at key points in the legislative process, building a strong rapport with their staff is usually an essential part of effective grassroots lobbying. For that reason, if the lawmaker is unavailable, you should schedule the initial meeting with staff. After the meeting, the staff member is likely to summarize the meeting in a memorandum to the representative. If you present a complex problem, your legislator will probably seek a staff recommendation before taking any action.

Although each legislative office is organized a little differently, most congressional offices include several key staff positions.

- The director of the district office oversees the office that is the closest to the grassroots and, as a result, is particularly sensitive to constituent concerns. Getting to know the district director can be important in establishing a relationship with a representative.
- The administrative assistant is the chief of staff and is usually based in Washington. The "AA" directs the rest of the staff and usually follows both local and national issues, especially political ones.
- Legislative directors are the legislator's issue coordinators. They keep the weekly schedule of legislation and make sure all the necessary background information is available to the representative.
- The appointment secretary is the keeper of the legislator's schedule. Develop a cordial relationship with the scheduler if you want to get to see the representative.
- Legislative assistants are issue specialists. Each "LA" is assigned different issues. You should get to know the person who is in charge of health care issues.

2. Effective Communications and Actions

As a citizen and as a representative of the medical community, you have an opportunity to establish continuous effective communications with your lawmakers. However, your contacts will have much greater impact if a personal relationship exists between you and your elected officials and their staff.

Most representatives want to know as many of their constituents as possible, and you should have little or no trouble getting acquainted with them if you simply take advantage

of opportunities to meet them—and if you create other opportunities. Patience and persistence are essential in developing a personal relationship with your representative. Once acquaintances with lawmakers have been made, you should:

- Be aware of what your representatives are doing and the votes they cast on issues of concern to you.
- Let your representatives and their staff know when you are pleased with a vote or position taken. Elected officials are no different than anyone else; they like to feel that their efforts on behalf of their constituents are noticed and appreciated. On the other hand, if you disagree with a vote or position taken, do not hesitate to let your lawmaker know it.
- Invite your representative to dinner parties or social gatherings with other physicians and their spouses or friends and neighbors.
- Attend political functions and fundraisers. At each function, introduce your representative to as many people as possible.
- Get involved personally or financially in political campaigns or in district projects that the representative may undertake.

When representatives or their staff members begin to seek out your advice on legislative matters, a productive relationship has been established.

When meeting with your senator or representative or their staff, remember that you are there to advise and give them information. They want to talk to you.

Although you need to know the basic facts about a bill, you are not expected to be an expert on legislative details. You are a physician, and you are there to provide them with the views of an expert in the field of pathology. You will be most effective when you speak from your own personal experience as a physician and as a voting constituent in your legislator's state or district.

3. Personal Meeting Tips

- Be candid. Your representatives recognize your self-interest, and you need not apologize for it.
- Be honest. Tell your representatives what you think and why; they expect your honest appraisal.
- Be brief. Your time with any elected official is limited, so you must make the most of it. One rule of thumb that often works best in meetings is to use half the time of the meeting to lay out your points; leave the remaining time to answer questions, clarify points, and listen to what your representative has to say.
- Be to the point. Avoid getting into discussions of extraneous topics.
- Be a listener. Pay attention to what your representative says so that you can respond to it effectively.

- Be informative. Make sure your representatives understand the situation you are talking about; take care not to “talk over their heads.”
- Be constructive. If you oppose something, try to offer a positive alternative; elected officials are looking for positive solutions.
- Be accurate. Know your facts—they are your strongest, most persuasive weapons. Answer any questions with facts, not guesses. If you don’t know an answer, say you don’t know and that you will provide an accurate response after researching the issue.
- Be understanding. Don’t expect your representatives to make a commitment on an issue before they have all the facts and hear arguments from all sides. Present your case favorably and persuasively.
- Be gracious. Don’t impugn your representative’s integrity or motives. Don’t be argumentative. Be sure to express appreciation for taking time to meet with you.

4. Letter Writing Tips

Personal letters are the basic tool for expressing your views to your elected representatives. Telegrams, mailgrams, and e-mails are particularly useful when timing becomes crucial on legislative action. If you e-mail your legislator, be sure to type in your name, address within the district, and postal code at the end of the e-mail message. New software being used on Capitol Hill permits members of Congress to quickly identify mail from district constituents.

In any form of communication with public officials, it is helpful to know how to address them:

President of the United States

The President
The White House
Washington, DC 20500
Dear Mr. President:

US Senator

The Honorable (full name)
United States Senate
Washington, DC 20510
Dear Senator (surname):

US Representative

The Honorable (full name)
US House of Representatives
Washington, DC 20515
Dear Representative (surname):

Mayor

The Honorable (full name)
Mayor of (City)
City Hall
(City, State, Zip Code)
Dear Mayor (surname):

Governor

The Honorable (full name)
Governor of (State)
State Capital
(City, State, Zip Code)
Dear Governor (surname):

When contacting a representative about a legislative issue, it is important to remember to:

- Keep your comments short and to the point. Try to cover a single issue per letter.
- Use personal stationery, and write legibly or type, using the addresses and salutations mentioned previously.
- Identify the subject clearly. When writing about legislation, try to refer to the House and/or Senate bill number and sponsor.
- State your reason for writing. Explain how the issue affects you, your family, your practice choices, and your patients. Personal anecdotes are particularly effective.
- Take a position, and ask your representative's position on the issue in question.
- Be polite but firm. Never use threats or wave the power of your vote. Use a constructive informative tone.
- Avoid cliches that may give your letter the appearance of a form letter. Avoid using technical terms, acronyms, or jargon that non-medically-trained persons would have a difficult time understanding. While staff are energetic and bright, most have no medical background.

E. Relationships to Funeral Directors

Funeral directors provide essential services to the community. They have the responsibility of disposing of the dead in accordance with state law and with the wishes of the decedent or the surviving family. Much must be accomplished in a timely manner to meet the schedule of visitation, funeral services, and burial or transportation of the deceased. Close cooperation between pathologists and funeral directors is therefore necessary. Pathologists should view their activities in the performance of an autopsy not only with respect for the deceased, but also with careful consideration for the wishes of the bereaved family.

The hospital should notify the funeral director that a postmortem examination is to be performed. The autopsy should then be performed without undue delay. After the autopsy is completed, the funeral director should be notified promptly, and the attending physician

should be informed of the gross findings so that the physician can fill out and sign the death certificate. The pathologist should notify the funeral director of any special information necessary for appropriate embalming. The pathologist should also relay the possibility of communicable disease as may be required by hospital policy, local ordinance, or state law.

Pathologists are encouraged to develop a cooperative relationship with funeral directors by meeting them and discussing mutual problems. Often, this can be accomplished through state or local societies. Mutual cooperation and understanding can be of immeasurable value in many instances.

F. Medicolegal Aspects of the Practice of Pathology

1. Communicable Diseases

It is advisable that a pathologist be a member of the hospital infection control committee. Pathologists can refer to the current Centers for Disease Control and Prevention (CDC) manual regarding reportable communicable diseases and should be familiar with any local laws and regulations on reporting communicable diseases. The pathologist should ensure that when a reportable disease is diagnosed, a mechanism exists to notify the proper authorities. The pathologist should be knowledgeable of current regulations and recommendations regarding the handling, shipment, and disposal of infectious specimens and materials. They should also ensure proper staff education and policy adoption regarding the handling of blood products. Confidentiality requirements for reporting of test results for communicable diseases (eg, AIDS) must be followed to protect the patient's privacy and to avoid liability for unauthorized disclosure, without undue risk to health care providers.

2. Forensic Autopsy

Medical examiner and coroner laws vary greatly from state to state and from one community to another. In some communities, the systems are highly organized and scientifically sophisticated, and the personnel are capable of performing a wide variety of examinations. In other areas, where the coroner may be an elected lay person without any medical knowledge, a pathologist's expertise can be essential. Every pathologist should become familiar with pertinent local laws, their limitations, the extent of the pathologist's responsibility and that of the coroner, and the manner in which permission for a medicolegal autopsy may be granted. The manner and amount of compensation for professional services should be defined from the outset. (See Appendix K, "Payment and Performance of the Autopsy Service.")

The protocol of a medicolegal autopsy should provide a clear documentation of pertinent findings, both positive and negative. Since the report is to be read by individuals who may have little or no medical background, it should avoid excessive medical terminology and complex syntax. Pathologists should be aware of whether others may be able to gain access to autopsy reports through Freedom of Information Act requests or other mechanisms.

Many physicians fear appearing in court. The key to success is to prepare adequately by studying the subject to be discussed. Materials for testimony should be prepared as carefully as when preparing for a medical staff conference, a medical school lecture, or an in-depth

discussion with residents. A pretrial conference with the attorney is essential to review the case and the potential problems that are likely to arise during the trial.

Testimony should be given in a straightforward, uncomplicated, organized manner. It should be limited to areas of competence. Questions posed by an attorney should be answered with short accurate replies, avoiding complex dissertations on the many variables that might exist. It should be kept in mind that pathologists represent neither the plaintiff nor the defendant, but rather, as expert witnesses, should state the facts without bias, according to their own evaluation and interpretation.

Both the pathologist and the community benefit greatly from the involvement of a pathologist in the investigation of death. Many law enforcement agencies are in serious need of such professional help and will be extremely grateful for the pathologist's interest and cooperation.

3. Paternity Investigation

Immunochemistry and DNA testing have become so sophisticated that paternity testing may be beyond the ability of many hospital pathologists. For those lacking competence in this field, it is best to refer paternity cases to those pathologists who have demonstrated expertise. Paternity may sometimes be excluded by investigation of only the major blood groups, and pathologists can consider offering this service with the understanding that further testing will be necessary if the screening examination is inconclusive.

The qualifications of the investigator and the tests performed are subject to careful scrutiny by the courts. It is not uncommon for simple requests to end up in a courtroom battle requiring chain-of-custody documentation and expert testimony. General pathologists can avoid embarrassment and best serve the parties involved by referring the problem to an expert at the outset.

4. Sexual Assault

Pathologists are frequently consulted on the procurement and examination of specimens in cases of rape and other sexual assaults. All specimens should be promptly labeled with the source, date, time, patient's name, and initials of the physician obtaining the specimen so as to facilitate later identification in court. Furthermore, chain-of-custody procedures must be followed. After prompt microscopic examination for motile sperm and the recording of time and results, smears should be prepared, identified, fixed, and stained with the usual Papanicolaou stain for further examination and filing. The pathologist is advised to consult with law enforcement officials to ensure that the proper scientific and legal procedures are adopted and followed. Detailed study may be referred to an expert after determination of need.

5. Blood Alcohol and Drugs of Abuse

State laws governing the performance and court acceptance of blood alcohol determinations vary widely. Every pathologist should be familiar with pertinent legal requirements.

Recognized laboratory methods, using appropriate standards and controls and appropriate chain-of-custody procedure, will usually meet the requirements of law.

It should be remembered that some medical diagnostic determinations might later turn medicolegal; this should therefore be considered when developing the laboratory procedures

for obtaining and analyzing these specimens. Department of Transportation (DOT) drug testing regulations require adherence to additional regulations and testing methodologies. Laboratories wishing to become involved in collection or testing for the DOT should be aware of these requirements prior to agreeing to provide these services. Similarly, other agencies or employees may impose specific requirements. The pathologist should also be aware of these.

Drug analysis has become an extremely complex field, requiring considerable time, effort, expertise, and highly sophisticated equipment. The pathologist should carefully consider the purpose of such drug testing prior to becoming involved in a substance abuse testing program. Scope of testing and requirements for confirmatory analyses should be considered. The pathologist should clearly delineate the drugs that are being tested, the level of sensitivity and specificity required, and the purpose of the drug testing program (eg, forensic, voluntary screening, involuntary screening). If the results are to be used for forensic purposes, for employment, or in a treatment program, specific protocols that preserve individual rights are mandatory.

Confirmatory testing is a necessary component of a substance abuse testing program. National Institute of Drug Abuse (NIDA) certification and guidelines must be considered, where appropriate. Accreditation and specialized proficiency testing for laboratories performing confirmation testing and screening testing are available through the CAP Forensic Urine Drug Testing (FUDT) and Athletic Drug Testing programs.

6. Professional Liability

Recently, pathologists have seen a dramatic increase in professional liability claims, especially related to Pap smear interpretation. Pathologists may be named individually and jointly with other physicians, cytotechnologists, and institutions. Additional areas of high exposure include misdiagnosis or misinterpretation of surgical pathology and fine-needle aspiration specimens, and use or provision of blood products and transfusions.

The recent exponential increase in professional liability in cervicovaginal cytology claims has resulted in a proliferation of important literature aimed to help the profession minimize exposure. It is beyond the scope of this manual to thoroughly discuss this important area. Readers are directed to:

- The proceedings from the CAP conference, “Liability and Quality Issues in Cervicovaginal Cytology” (*Archives of Pathology & Laboratory Medicine*, March 1997).
- Publications from professional organizations, including, *Risk Management Guidelines for Cervical Cytology* (The Doctors’ Company, 1997).
- The CAP’s “Guidelines for Review of Pap Tests in the Context of Litigation or Potential Litigation” and “Expert Review of Histologic Slides in the Context of Litigation.” (See Appendices H and M.)

The following are several important points to help minimize pathologist malpractice liability exposure, which are common to these publications.

- *Understand and communicate the inherent limitations of the Pap smear.*
The false-negative rate for Pap smears has been reported to be 15% to 25%. The fact

that the Pap smear examination is not infallible must be communicated to clinicians as well as patients. These groups need to understand that a false-negative result does not equate to a negligent lab, but may result from sampling errors, screening errors resulting from insufficient numbers of abnormal cells, small dysplastic cells, or hyperchromatic crowded groups. Many pathologists suggest adding a reminder on all gynecological cytology reports stating that false-negative results are possible. Because cervicovaginal cancer is often slow growing, annual Pap smears are to be encouraged.

- *Operate a quality cytopathology laboratory.*
Although an injured plaintiff may not be impressed by your laboratory quality standards if she perceives her Pap smear was misinterpreted, a jury will likely look unfavorably toward a laboratory that does not adhere to acceptable levels of institutional quality. A conscientious quality improvement plan specific for cytopathology should be adopted and followed. Consider additional quality control measures, like rescreening ASCUS (atypical squamous cells of undetermined significance) cases. ASCUS is a poorly reproducible diagnosis, which is subsequently associated with a diagnosis of low-grade squamous intraepithelial lesion in about 80% of patients. For this reason, rescreening all ASCUS cases is a useful quality control activity. Proficiency and continuing education, including the CAP Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP), are encouraged. CLIA and additional state regulations must be understood and followed. CLIA standards have become part of the standard of care to which pathologists are held. Over the last several years, the cytopathology section of the CAP Laboratory Accreditation Program (LAP) has blossomed and is a convenient and well-recognized way to build and document a satisfactory level of laboratory quality.
- *Follow legal and regulatory mandates affecting the Pap smear.*
CLIA requires a 5-year look-back at prior negative smears when a high-grade lesion or carcinoma is identified. An amended report and physician notification are required if the amended diagnosis would affect the current (ie, not retrospective) treatment of the patient. Unbiased rescreening of these cases should be attempted. Results of the rescreening should be kept within the quality assurance records to come under the purview of any applicable state peer review laws. CLIA and the CAP LAP both require a 5-year Pap smear slide retention. Unless state requirements differ, laboratories should consider discarding older slides.

In regard to noncervicovaginal pathology practice, litigation is frequently the result of miscommunication or poor communication. Pathologists should endeavor to communicate clearly and concisely, and to document that proper communication was made, and that proper procedures and protocols were followed. Failure or delay in obtaining consultation has also served as a basis for legal action. Adequate insurance coverage is essential for pathologists and all other personnel at risk.

A pathologist may be summoned as a witness in a professional liability action to give expert opinion. It is important that the pathologist review carefully all medical documents and facts in order to present a logical and lucid discussion of the case during testimony. When providing expert testimony in Pap smear litigation cases, one should ask, "How

should this smear have been read by a competent cytologist in the usual practice situation?” and preferably attempt a “blind rescreening.”

A pretrial conference with the attorney is important. At this time, the pathologist should be made aware of the relevant facts and should acquaint the attorney with the points and extent of their testimony. Testimony should always be limited to areas of expertise. Consultation with pathologists having experience in the area of controversy may be helpful.

IV. Guidelines for Evaluation of Medical Care and Professional Performance

A. Standards for Professional Practice

The American Board of Pathology has established a Maintenance of Certification program that, beginning in 2006, requires the issuance of time-limited primary and subspecialty certificates of 10-years duration. The Maintenance of Certification (MOC) program is based on evidence of professional standing, commitment to lifelong learning and periodic self-assessment, evidence of knowledge, and evaluation of performance in practice. The maintenance of certification process must be completed no later than 10 years and as soon as 8 years after the initial time-limited certification. Pathologists holding current certificates that are not time-limited are encouraged to participate in the Board's Voluntary Maintenance of Certification (Recertification) program.

The successful practice of pathology involves numerous skills, both medical and nonmedical. The periodic evaluation of a pathologist therefore should take into consideration these many different components of professional practice. More specifically, professional performance evaluation should consider the following components.

1. *Academic Component*

Board certification is highly desirable, and in many institutions required, for active staff privileges. Subspecialty board certification may also be essential, depending on the particular type of practice and institution. After board certification has been attained, it is also essential to not only maintain one's academic foundation but also, as in any lifelong learning process, to continually build upon it. The CAP, United States and Canadian Academy of Pathology (USCAP), and other organizations provide continuing medical education (CME) that meets criteria for Category I of the AMA's Physician Recognition Award and is accepted by the American Board of Pathology as evidence for voluntary recertification and maintenance of board certification.

2. *Behavioral Component*

Day-to-day interaction with physician colleagues, technical and clerical support staff, and patients is an extremely important part of a successful practice. Many of these skills are intrinsic to one's personality. However, pathologists, especially those in a leadership role, need to cultivate these skills and always conduct their practice within an atmosphere of professional demeanor and propriety. The successful pathologist should be adept at handling sensitive issues, such as personnel discrimination and sexual harassment.

3. *Management Component*

For those pathologists in management roles, additional skills are necessary. The successful pathologist-manager needs considerable expertise in areas such as fiscal management, personnel management, contract negotiation, conflict resolution, and practice management. Training in these areas may be obtained through programs offered by the College. Information updates regarding legislative and reimbursement issues may also be obtained through the Contract and Practice Management Seminar as well as programs at the CAP national meeting.

It is highly recommended that all pathologists, including those in leadership roles, participate in an annual performance evaluation. Such an evaluation should assess both medical and nonmedical components. Within the medical arena, an assessment may include some or all of the following.

- *Medical recordkeeping*: adherence to standards, completeness and adequacy of reports.
- *Diagnostic ability*: ability to provide accurate, complete, and timely diagnostic information.
- *Referral services*: soundness of logic and judgment in acquisition and utilization of consultations, and coordination of follow-up information.
- *Medical staff interaction*: analysis of comments, both formal and informal, both positive and negative, regarding the specific pathologist.

An assessment of nonmedical issues may include some or all of the following.

- *Knowledge of institution*: ability to demonstrate an understanding of the particular institution's basic organization and policies.
- *Interpersonal relationships*: ability to function within a departmental situation, with a minimum of conflict.
- *Flexibility*: ability to adapt to changing work situations and demands.
- *Social interaction*: willingness to accept constructive criticism; demonstrate initiative with central projects, educational programs, and committees; demonstrate the ability to communicate effectively with others; demonstrate a sound attitude which displays enthusiasm, interest, and commitment.
- *Bylaws and department regulations*: demonstrate adherence to these elements.
- *Leadership potential*.

In addition to an annual assessment of these areas, an overall assessment of the previous year, with a delineation of strengths and weaknesses, is helpful. It is also helpful to delineate potential goals for the upcoming year. The objective of such a performance evaluation process is that the individual pathologists will continue to grow both academically and behaviorally throughout their career. Specific areas needing improvement will be identified early, and remedial actions will theoretically be instituted before the situation is out of control.

B. The Impaired Physician

The American Medical Association and most state medical societies have developed programs to deal with the impaired physician. The AMA definition of the impaired physician is one who is unable to practice medicine with reasonable skill and safety to patients because of physical or mental illness, including deterioration through the aging process or loss of motor skill, or excessive use or abuse of drugs, including alcohol.

It is important for physicians to recognize the factors that predispose to impairment, both in themselves and others, and to intervene as soon as possible so treatment may begin. Physicians should advise impaired physicians to seek help or to curtail their practice. Such advice is not easily given and may not be well received. However, physicians should attempt to help rehabilitate impaired colleagues. Medical societies and hospital staffs have a responsibility to restrict or prevent the medical practice of an impaired physician.

Practically, this may be extremely difficult. Several states have developed “sick doctor statutes” to deal with the legal aspect of physicians who are unable to practice medicine with reasonable skill and safety to patients. Many state and county specialty societies have developed hot-lines for immediate advice and consultation. Hospital medical staffs may also impose requirements.

C. Peer Review of Pathology Practice

Since the inception of the Laboratory Accreditation Program, peer review has been an essential component of pathology and laboratory practice. Medical peer review within a department of pathology may take several forms but should adhere to the basic tenets of quality assurance and continuous quality improvement. Both of these processes deal essentially with outcome analysis, which, in the case of pathology practice, focuses on a specific diagnosis. Peer review programs therefore revolve around analyses and correlations of various pathology reports. The College of American Pathologists publication, *Quality Improvement Manual in Anatomic Pathology, Second Edition* (2002), provides pathologists with a framework for a complete and organized approach to quality improvement in the anatomic pathology laboratory. The manual provides guidance on designing a quality improvement plan and defining and handling errors in surgical pathology, as well as quality assessment and improvement in cytopathology and autopsy pathology.

D. Standards for a Pathologist’s Laboratory

Throughout the years, organized pathology has made a progressive effort to improve the quality of service provided to patients, to expand testing capability, and to improve the reliability of test results. The College has developed and implemented expanding programs designed to further improve laboratory service by establishing standards of performance and methods for monitoring accuracy and precision. The following is a brief discussion of College programs available to assist the pathologist in achieving these ends. To obtain more information about College laboratory improvement programs, call 800-323-4040, or visit the CAP Web site (www.cap.org).

1. Laboratory Accreditation Program

The goal of the Laboratory Accreditation Program (LAP) is to improve the quality of clinical laboratory services through voluntary participation, professional peer review, education, and compliance with established performance standards. Upon successful completion of the inspection process, the laboratory is awarded CAP accreditation and becomes part of an exclusive group of laboratories worldwide that have met the highest standards of excellence. The LAP inspection process examines all aspects of quality assurance in the laboratory, including methodology, reagents, control media, equipment, specimen handling, procedure manuals, reports and proficiency testing, personnel, safety, and the overall management principles that distinguish a quality laboratory. Inspections are generally conducted biennially by pathologists and other laboratory professionals trained in inspection techniques. During the 2-year period of accreditation, the proficiency of the laboratory is continuously monitored through the College Surveys or other programs. The College LAP program accredits more than 6000 clinical laboratories.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all laboratories must be certified by the Secretary of Health and Human Services (HHS). Those laboratories that are inspected by a private accreditation program approved by the Centers for Medicare and Medicaid Services (CMS) are “deemed” to meet CLIA standards and are not inspected by CMS-contracted inspectors. The CAP Laboratory Accreditation Program (LAP) has deemed status.

2. CAP Surveys and Anatomic Pathology Educational Program

The CAP Surveys and Anatomic Pathology Educational Program is an interlaboratory comparison program that has been approved by the Centers for Medicare and Medicaid Services (CMS) for meeting the CLIA '88 proficiency testing requirements. This interlaboratory comparison proficiency testing program provides three testing events per year, with five challenges per analyte. Performance is measured through peer comparisons. Laboratories participating in the College's Laboratory Accreditation Program may participate in the College's Surveys program or other CMS-approved testing programs accepted by the Commission on Laboratory Accreditation.

The Performance Improvement Program in Surgical Pathology (PIP) provides a practical approach to pathologist continuing education and external quality assurance for surgical pathology services. Continuing Medical Education (CME) credit is awarded upon pathologist completion of the program.

The Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP) is designed for pathologists and cytotechnologists providing gynecological cytology services. The program uses referenced glass slide material representing a variety of cytopathologic conditions affecting the female genital tract. CME credits for pathologists and continuing education credits for cytotechnologists are available. More than 2000 laboratories are enrolled in the PAP program.

The Interlaboratory Comparison Program in Non-Gynecologic Cytopathology (NGC) is designed to provide pathologists with an effective tool for comparing peer performance in nongynecologic cytology.

3. PathFocus

The CAP Path*Focus* program is a subscription practice management tool designed to assist the pathology group in objectively assessing activities and staffing needs. Through a series of reports, it provides useful information about the pathology practice relative to other similar subscribing practices. Path*Focus* considers practice service loads, education and research efforts, complexity of the practice environment, and other factors to help the pathology group evaluate staffing requirements and analyze distribution of work performed by pathologists. To subscribe, call CAP Customer Service at 800-323-4040, option 1#.

4. Laboratory Licensure

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all laboratories must be certified by the Secretary of the Department of Health and Human Services. Some states also require inspection and licensure, usually by the State Department of Health Services. Unless the state program has applied for state exemption from CLIA '88

and has been approved by the Centers for Medicare and Medicaid Services (CMS), it serves as an additional program, not as a replacement for CLIA.

5. Q-Probes and Q-Tracks Programs

Q-Probes is an interinstitutional quality improvement program that studies the preanalytic, analytic, and postanalytic phases of clinical and anatomic pathology services. The program allows the laboratory to assess timeliness, accuracy, and appropriateness of services. Q-Probes studies enable laboratories to benchmark quality performance against their peer groups through the identification of factors associated with best practices. Q-Probes studies have measured outpatient test order accuracy, emergency department turnaround time, and follow-up on abnormal gynecologic cytology.

Q-Tracks is a convenient and comprehensive continuous quality improvement (CQI) monitoring system that examines those key laboratory processes that have a direct impact on patient care. The program helps drive the quality improvement process by providing participants with objective quantitative information about their performance and benchmarks that are derived from external peer comparisons. Q-Tracks studies have looked at patient identification accuracy and gynecologic cytology outcomes by measuring biopsy correlation performance.

E. Patient Care Quality Assurance Programs

During recent years, there has been ever-increasing consumer concern with the quality, safety, and reliability of all goods and services. Many questions have arisen relating to the quality of medical care, the necessity for surgical procedures, and the assurance that the result of therapy will be successful. Legal decisions have held hospitals accountable for the competence of the members of the medical staff and have required justification of their privileges. In addition, federal legislation requires physicians and hospitals to demonstrate that hospitalization, length of stay, and utilization of facilities and services are justified, at least for patients of federally-funded programs.

As a member of the medical staff concerned with the quality of medical care, the pathologist should work actively with other staff members to develop and implement a quality assessment program that combines the principles of utilization review, quality assurance, and continuous quality improvement. Indeed, the pathologist, being in a pivotal position on the medical staff, should be among the leaders in all aspects of quality assessment.

The pathologist's direct contributions to a quality assessment program include the punctual performance of postmortem examinations, followed by demonstration and discussion of the pertinent lesions. While the autopsy remains the ultimate in quality control, the attendance of the pathologist at mortality conferences is equally important. In addition, participation in the meetings of the infection, medical record, and medical care evaluation committees is important. Statistical review of utilization of clinical laboratories may provide helpful information on appropriate utilization of specific tests. The College, through its Q-Probes and Q-Tracks programs, can provide the tools for meaningful laboratory-specific quality assessment.

Section II: Contractual Relations

I. Relations Between Pathologists and Institutions

A. General Principles

The first contact between a pathologist and an institution may be through the institution's administrator or trustee. The pathologist also may want to communicate with the incumbent or previous pathologist(s). The pathologist should also contact the credentials committee or other official representatives of the medical staff in order to be appointed to the medical staff, if offered a position. These additional contacts may also serve to identify particular idiosyncrasies, philosophies, and requirements of the institution, as they pertain to pathology services.

If, after appropriate investigation by both the pathologist and institution, it is determined that a contractual relationship would be beneficial, negotiations to determine the details of the relationship can begin. Agreements between a pathologist and an institution should be in writing. Integrity and good faith constitute the basic elements of all good contracts. The agreement should be prepared in consultation with an attorney who represents the pathologist and who is familiar with hospital-based physician contracts, the nuances of local law, and applicable government regulations. The pathologist should recognize that a sound agreement will help prevent misunderstandings. The discussions related to the development of the contract will provide a framework for the development of strong bonds of mutual understanding and respect between the pathologist, the administrator, and the medical staff. The contract is not intended to replace trust between the parties; rather, its formation should allow for communication necessary to build this trust.

B. The Chronology of Negotiations

In contractual negotiations, it is better to take the initiative with a positive comprehensive plan than to adopt a negative posture by opposing provisions suggested by the institution. Negotiations should focus upon contractual provisions that ensure quality of personnel and laboratory procedures; opportunities for service, teaching, and research; and adequacy of equipment. When conditions of practice are good, income arrangements are more likely to be mutually satisfactory.

The pathologist should consider the following steps:

1. Study this manual carefully.
2. Consult with the incumbent or previous pathologist and other pathologists and laboratorians in the area to become familiar with local conditions and practices.
3. Request information from the institution's medical staff to be assured that you are eligible for staff membership.

4. Obtain and study a copy of the bylaws and rules and regulations of the hospital and the medical staff.
5. Prepare a checklist of items to be discussed with the institution's representatives.
6. Discuss this checklist item-by-item with the administrator or trustee, and come to an understanding on each item.
7. Determine what additional resources are available regarding contract development both for general information and assistance. Possibilities include local medical societies, state medical societies or related organizations, as well as the American Medical Association. State pathology societies also may have resource materials that are pertinent to local or state conditions.
8. Retain the services of an attorney with expertise in writing contracts for hospital-based physicians and, preferably, pathologist contracts. Provide the attorney with your decisions, a copy of this manual, and sample contracts from the CAP, which are available to CAP members. Do not try to draw a contract yourself.
9. Present a draft contract to the institution for further discussion and clarification, or have the attorney you have retained revise the hospital's draft contract. Although it may be advantageous for the initial draft contract to be prepared by the pathologist's attorney, many times the institution will present its own contract. The pathologist and attorney will need to decide whether to revise the hospital's proposed contract or present their contract as an alternative.
10. Meet with appropriate institution officials on each item in question.
11. Ask your attorney to discuss with you all points in the contract that are relevant for negotiation purposes. Try to negotiate these points with the authorized agents of the institution.
12. Involve the attorney as needed to advise you or to deal with the institution until a final agreement has been reached.

C. Enhancing the Pathologist's Bargaining Position

The ability of a pathologist to negotiate a favorable hospital contract depends on the strength of the pathologist's bargaining position. A number of factors affecting bargaining position are not under the control of the pathologist. These factors include the financial condition of the hospital, the hospital's position in the marketplace, the number of pathologists in the area, the prevalence of alternative delivery systems, and the number of other laboratories in the market. However, pathologists can improve their bargaining position by taking advantage of factors within their control.

The pathologist should understand the hospital's financial condition. The pathologist should try to obtain and review the financial statements of the hospital. A hospital in financial trouble seeks to cut all costs, including those incurred by profitable departments. A financially strong hospital may also try to cut costs but may have more flexibility on economic issues. Key factors to watch include the overall bottom line; the percentage of patients who are covered by Medicare, Medicaid, managed care, or traditional

indemnity third-party insurance; and the hospital's profitability with respect to each of these classes of patients. The percentage of uninsured patients is a key indicator of uncollectable charges. In addition, the pathologist should compare the profitability of the laboratory with that of other departments.

The pathologist should also consider whether there are opportunities to improve the financial performance of the laboratory or even of the hospital as a whole. For example, some pathologists have been active in developing clinical pathways that can reduce the costs of hospitals within certain DRG categories. Pathologists can evaluate whether tests are being ordered in an efficient and cost-effective manner. Or, in some cases, earlier or more extensive uses of certain tests might help expedite the diagnostic process and thus shorten hospital stays. The pathologist should also consider the extent to which the hospital laboratory serves nonhospital patients by serving as a reference laboratory for physician offices and outpatient clinics. Expanding the reference laboratory market could represent additional income for the institution and the pathologist.

The pathologist should regularly meet with hospital administration to volunteer to solve problems, offer suggestions, and keep the administrator informed of the pathologist's activities and successes. In addition, knowing the administrator's background and managerial approach may be helpful in negotiating a contract. Does the administrator focus on the bottom line or the quality of care? Is the administrator confrontational or a consensus builder? Does the administrator like to innovate? To determine the administrator's managerial approach, it may be helpful to contact pathologists at the administrator's prior position. It may also be helpful to ascertain the terms adopted in the hospital/pathologist agreements at the administrator's prior hospital.

The pathologist should get to know the members of the hospital's board. It may be especially helpful to identify the key members on the board, and to cultivate and maintain good relations with them. In some cases, a friendly board can help a pathologist deal with an unreasonable administrator.

The pathologist should know whether the hospital has retained consultants to study some aspect of hospital operations—particularly laboratory operations. That fact is a clear signal, indicating that the hospital is dissatisfied with certain operations. Consultants may be hired to reinforce management decisions or to be the hatchet people of the administrator. Consultants often wield considerable influence since administrators generally are reluctant to ignore a consultant's recommendations. A number of consultants in the laboratory area follow rigorous guidelines to reduce staffing or a hospital's Part A reimbursement costs. It therefore is important to check with pathologists at other institutions where the consultant has provided services to learn about the methodology used by the consultant and the nature of the advice given. If the consultant has a history of urging dramatic reductions in staffing, it can be useful to gather information about how effective the advice of the consultant has been in practice at a hospital which attempted to implement the consultant's recommendations. Identification of problems in the laboratory by the pathologist may lessen the institution's perceived need for outside analysis.

The pathologist should regularly review the current agreement with the hospital. Important terms include compensation, duration of the contract, responsibilities for performing work for alternative delivery systems, authority over the laboratory, hospital controls over the pathologist's charges, the contract reopener, noncompete provisions, and

privileges upon termination. The pathologist who identifies terms in the existing agreement that should be changed and who prepares a negotiating strategy at least 6 months before the end of the contract's term is in a stronger position than the pathologist who waits for the hospital's first move.

The pathologist should be aware of the contract status of the other hospital-based physicians. Some hospitals renegotiate all contracts with hospital-based physicians at the same time. During this mass renegotiation process, the hospital will often attempt to include onerous new terms and conditions in all of its hospital-based physician contracts. If the hospital is in the process of renegotiating all hospital-based physician contracts, the pathologist may want to meet with fellow hospital-based physicians to share intelligence. Each group, of course, must make its decisions independently to avoid antitrust concerns. In any event, how the hospital handles its relationship with other hospital-based physicians may provide insight into what the pathologist can expect.

The pathologist should ascertain what other hospitals in the area are seeking with respect to contract terms for pathologists or other hospital-based physician contracts. Terms that are just starting to be proposed by some hospitals in the area are likely to soon be proposed by most hospitals in the area. Alternatively, if a pathologist learns that their particular hospital is offering terms much more onerous than other hospitals in the area, that knowledge can be used to seek the elimination of the objectionable provisions.

The pathologist should consider likely reimbursement changes. Medicare rules and regulations only apply to the Medicare program, although other third-party payers may attempt to use them. In many parts of the country, however, some third-party payers may have considerably less clout and contractual bargaining power than Medicare and BlueCross BlueShield.

The pathologist in the best position to bargain is the pathologist with other options, who is prepared to move on if the hospital does not agree to an acceptable contract. To create options, the pathologists should keep abreast of professional opportunities and maintain professional contacts. Hospitals that offer one-sided contracts often refuse to bargain, unless the hospital fears that a popular pathologist will reject the offer. The fear of losing their current positions has led a number of pathologists to accept onerous contracts.

Each pathologist should identify all professional strengths and assets. The most secure pathologists are those who are perceived as an asset by the hospital. The pathologist should seek to be known and respected by the medical staff. Other professional assets include involvement in key hospital committees, ownership of a key piece of equipment or service, or development of a profitable outreach venture that benefits the hospital. Pathologists should not be shy about reminding the administrator of these assets at contract negotiation time.

Each pathologist should consider the managed care environment and the level of participation in managed care by hospital-based physicians. Increasingly, hospitals are seeking provisions that ensure that all hospital-based physicians participate in all of the managed care plans in which the hospital participates. Pathologists should be aware that the refusal of a hospital-based physician to participate in a managed care plan that is important to the hospital will weaken the bargaining position of the pathologist in negotiations with the

hospital. Pathologists should be aware of the kinds of provisions addressing managed care participation that hospitals currently are seeking in hospital-based physician contracts.

The pathologists should consider the size of the group with which a hospital or hospital system is contracting. It is much harder for a hospital system to replace a group of 12 or more pathologists with subspecialty credentials than it is for a single hospital to replace a small group of 3 or 4 pathologists without subspecialty credentials. Pathologists should keep this consideration in mind as they evaluate possible practice consolidation options.

The pathologist should avoid unnecessary confrontations with the hospital administration. Hospital-based physicians should be cautious about being the front person for an assault on the administration by the medical staff. Administrators often seek to terminate the contracts of leaders of medical staff revolts.

D. Relationships with Institutions

Pathology is the practice of medicine. Contracts are vehicles for expressing the relationship between a hospital and pathologist as the pathologist assumes professional responsibility for pathology services to the patient. Contracts should not infringe on the pathologist's professional responsibilities or performance of duties.

The pathologist/hospital contract must be developed with careful attention to Medicare law and regulations as well as state and federal statutes, including the Health Insurance Portability and Accountability Act (HIPAA). The law, regulations, and interpretive guidelines should be studied and understood before a pathologist attempts to develop or change the relationship with an institution. The provider-based physician regulations and the Medicare prospective payment system (PPS) for hospital inpatient and outpatient services, as well as the Stark regulations, significantly affect the contractual relationship between hospitals and pathologists with respect to services to Medicare patients. It should be noted that Medicare regulations do not govern payment for services to non-Medicare patients. The pathologist should also be familiar with the requirements of non-Medicare third-party payers.

1. The Provider-based Physician Regulations

The Medicare provider-based physician regulations, which implement the 1982 Tax Equity and Fiscal Responsibility Act (TEFRA), require a clear distinction between physician services performed for patients as contrasted to physician services performed for the provider. Physician services performed for patients are defined as services ordinarily requiring performance by a physician and which contribute directly to diagnosis or treatment of an individual patient. Pathologist services that satisfy this requirement are defined by the regulations. They include surgical pathology services; specific cytopathology, hematology, and blood banking services; clinical pathology consultations; and certain clinical pathology interpretive services. Physician services for individual patients must be separately identified using CPT procedure codes and are paid under Part B of the Medicare program.

In contrast to pathologist services for individual patients, services for the provider as defined by the Medicare regulation are covered by Part A of the Medicare program. Examples of physician services for the provider under those regulations are medical

direction and supervision of a hospital laboratory, quality control, performance of autopsies, and supervision of personnel in the clinical laboratory. (See Appendix I.) The pathologist is precluded by Medicare regulations from billing Medicare patients for services classified as Part A services. Therefore, the contract with the hospital should include a provision for fair and reasonable payment by the hospital for these services.

Outpatient hospital services for Medicare patients that are not covered by the Medicare clinical diagnostic laboratory test fee schedule are paid on the basis of the Medicare ambulatory payment classification (APC) prospective payment system. As a result of the adoption of APCs, reasonable compensation equivalents (RCEs), which are based on the number of full-time equivalent (FTE) pathologists performing clinical laboratory services, no longer should be applicable. However, the RCE values that have been published, appropriately updated for inflation, can still be useful benchmarks for fair Part A compensation.

2. Medicare Prospective Payment System

Under the Medicare prospective payment system (PPS), most hospitals are paid a predetermined rate for Part A inpatient hospital services. The payment generally is a fixed amount, covering all of the services provided from the admission to the discharge of each Medicare patient. The payment rate varies according to the assignment of the discharge into one of approximately 500 diagnosis related groups (DRGs). The DRGs are weighed to represent average hospital resources used to furnish inpatient services.

Since August 2001, most hospitals have been paid for Medicare outpatient services under another prospective payment system based on ambulatory payment classifications (APC) groups. The hospital outpatient prospective payment system (HOPPS) is fundamentally different from the inpatient DRG system in that hospitals are paid for most outpatient patient-specific services, including the technical components of pathology physician services, on a service-by-service basis. Payment rates, however, are the same for services grouped under the same APC and are based on hospital median costs in prior periods. There are three APC groups for the technical components of anatomic pathology services. Payment for hospital outpatient clinical diagnostic laboratory tests is not included in the HOPPS. Outpatient clinical diagnostic laboratory tests have, since 1984, been paid on the basis of a charge-based fee schedule.

Under the prospective payment system, hospital management has a strong financial incentive to keep costs as low as possible. When costs incurred are lower than the DRG rate, the hospital retains the difference. On the other hand, if costs exceed the DRG rate, the hospital will incur losses. Hospital efforts to lower average length of stay, reduce utilization of ancillary services (including clinical pathology services), and negotiate lower prices for supplies and services are viewed by many as essential steps for survival because Medicare payments account for almost 40% of total inpatient revenues.

Payments to pathologists for Part A services (as opposed to Part B services for individual patients) are covered by the DRG rate. Thus, the pathologist is expected to look to the hospital for payment for such services to Medicare patients. In addition, Medicare pays for the clinical laboratory tests for outpatients on the basis of the clinical laboratory fee schedule. Hospitals (as well as independent laboratories and physician office labs) are paid the lower of the fee schedule amount or the actual charge for the test. A significant portion

of the hospital's outpatient laboratory activity is no longer paid on a reasonable-cost basis. Other payers also frequently pay for lab services on the basis of a fee schedule. Many of these fee schedules are derived in part from the Medicare fee schedule. As a result, the hospital has substantial financial incentives to reduce the cost of outpatient tests by controlling costs and increasing test volume.

3. *Types of Contracts*

Professional contracts for pathology services fall into two broad categories: agreements in which the pathologist furnishes professional services to the institution and its patients, with no or moderate capital investment; and agreements that involve major capital investment by the pathologist. In both categories, the pathologist is responsible not only for high-quality professional services to individual patients but also is accountable for the medical direction and supervision of the laboratory department.

a. Agreements for remuneration involving no or moderate capital investment by the pathologist include:

- Direct billing of the patient or insurer for professional services on a fee-for-service basis.
- Negotiating per diem, per discharge, or a capitated basis reimbursement plan with managed care plans.
- Salary agreements.
- Composite agreements.

Under each of these contracts, the institution bears all or a major portion of the capital expenditures of the laboratory, providing not only space and utilities, but also equipment, supplies, and personnel. These costs are billed by the hospital in accordance with the rules and regulations established by the various third-party payers (eg, Medicare, BlueCross BlueShield). The pathologist assumes professional responsibility for the operation of the department. There is a broad spectrum of contractual variations available for compensating the pathologist for professional activities. Each contract should clearly specify how the professional services of the pathologist will be compensated and billed.

The pathologist may either directly bill the patient or the insurer for specific identified professional services, or negotiate with the managed care plan or other payer to arrive at a reimbursement formula. For non-Medicare patients, the pathologist may negotiate a payment arrangement for clinical pathologist services. Possible negotiated reimbursement formulas for clinical pathology services include per diem payments (\$x per patient day), per discharge payments (\$x per patient discharge), or capitation payments (\$x per member per month.) Alternatively, the pathologist may negotiate a compensation arrangement with the hospital for all clinical pathology services, including medical direction and supervision of the clinical laboratory.

The billing requirements of all third-party payers should be carefully considered. For example, under the Medicare program, if the pathologist is not compensated by the hospital for professional services to individual patients (ie, Part B services), then the pathologist may bill either Part B of the Medicare program under assignment or the patient directly for the

service. If the hospital compensates the pathologist for Part B services, the right to bill for these services is reassigned to the hospital, and the hospital is then paid under Medicare Part B.

Professional services covered under Part A (eg, autopsy, administration of the laboratory) by the Medicare program must be compensated by the hospital, because only the hospital can bill Medicare for Part A services. However, the pathologist is not precluded by Medicare from billing non-Medicare patients for services in assuring timely and medically reliable results for such patients. Accordingly, the pathologist should ascertain how private payers pay for such services and should take the information into account in negotiating the contract with the hospital. More specifically, if payers will pay the pathologist for such services, the contract can so provide; if not, the pathologist should look to the hospital for payment for services to non-Medicare patients as well as for services to Medicare patients. (See Appendix I.)

When the agreement provides that the pathologist will directly bill the patient or third-party insurer for professional services, the pathologist may incur moderate capital costs, working capital, and billing service expenses. In this situation, the pathologist bears the risk of collection as well as the expense of dealing with third-party payers.

Composite agreements include a combination of remunerative arrangements designed to meet the varying requirements of different third-party payers. For example, Medicare rules require that most clinical pathology services (except for those that have been specifically defined as Part B service) be billed by the hospital under Part A as part of the DRG rate. The contract could provide for hospital payment of fixed compensation for Medicare Part A services (on a mutually acceptable basis) and the direct billing of a fee-for-service to non-Medicare patients for clinical pathology services. Anatomic pathology services could continue to be directly billed to Medicare and non-Medicare patients.

b. Agreements for remuneration involving major capital investment by the pathologist include:

- Leases.
- Independent laboratory agreements.
- Joint ventures.

Under these agreements, the pathologist bears all or a major portion of the fiscal responsibility for the department. The pathologist owns or leases the equipment and provides the supplies and necessary personnel. The method of compensating the institution for providing space, utilities, marketing services, and other resources may include a variety of arrangements, depending on the nature of the agreement as well as third-party reimbursement considerations.

Medicare regulations have important consequences for the pathologist's contract, involving major capital investment by the pathologist. The provider-based physician regulations stipulate that the operating cost of a hospital department in which a physician furnishes services to the provider's patients is included in the Part A payments to the hospital. Therefore, if a pathologist assumes some or all of the operating costs of a hospital-based laboratory (eg, supplies, equipment, or employment of nonphysician personnel) under a lease arrangement, these costs must be recovered from the hospital; they cannot be billed

by the pathologist to Part B of the Medicare program. If operating costs are assumed, the pathologist/hospital contract should provide for payment by the hospital of a fee to cover these costs insofar as Medicare patients are concerned. Other payers may have different rules that may make it possible for the pathologist to continue billing non-Medicare patients for clinical laboratory services. In a leased department situation, the hospital will want capital costs separately identified, because these costs are treated differently than other types of costs under the Medicare prospective payment system (PPS). Moreover, the pathologist will need to make records available to verify these costs.

Medicare regulations prohibit the “unbundling” of nonphysician services provided to hospital inpatients under Part A. Prior to the enactment of the PPS, many services to inpatients could be billed under Part A by the hospital or under Part B by a supplier or by a physician (eg, clinical laboratory services, lens implants). Because the DRG rate paid to the hospital is intended to cover all inpatient costs (with the notable exceptions of capital, teaching, and certain other costs), the regulations prohibit any party other than the hospital from billing for these items and nonphysician services. The prohibition relates only to services covered under Part A; physician services for individual patients (eg, anatomic pathology) are paid under Part B.

The practical effect of the unbundling prohibition is to extend the Medicare rule concerning physician assumption of provider operating costs to all services to Medicare patients covered by Part A in the hospital. For example, clinical laboratory services furnished to inpatients by an independent laboratory must be billed to the hospital. Such services can no longer be billed to Part B because they are defined as inpatient hospital services and are therefore paid under Part A through the DRG rate.

In a lease arrangement, the pathologist agrees to pay the hospital for space and utilities at a fixed monthly rental. A pathologist operating under an independent laboratory agreement then bills the hospital for services to hospital patients. The hospital subsequently bills the patient or patient’s insurer for clinical laboratory services.

Another arrangement involving significant capital investment by pathologists that has become popular is the independent laboratory histology laboratory. Under this arrangement, the pathologist takes over responsibility for the histology technical component through an independent laboratory. The independent laboratory should not be located on the premises of the hospital or be controlled by the hospital. Under this arrangement, the pathologists can bill for both the professional and technical component of anatomic pathology services.

The independent laboratory histology laboratory arrangement is available under a significant exception to the Medicare hospital patient bundling prohibition, which allows certain independent laboratories to bill under the physician fee schedule for pathology physician service technical component (TC) services through December 31, 2003. Under the exception, hospitals that had an arrangement in effect as of July 22, 1999, under which a laboratory furnished the TC of pathology services to hospital patients and submitted claims for the TC to the Part B carrier, are defined by Medicare as “covered hospitals.”

Covered hospitals can continue to have such arrangements with the independent laboratory of their choosing and have Medicare payment made directly to the laboratories through 2003. Certain other requirements must be met, and the types of pathology services covered by the exception are generally limited to the services unbundled as of July 22, 1999.

Medicare Program Memorandum Transmittal AB-02-177 describes these requirements and is available on the CAP Web site.

The authority for this exception expires at the end of 2003, but the CAP is seeking a permanent extension of the provision. Pathologists involved in or interested in these arrangements should contact the CAP Division of Membership and Advocacy for the status of the exception after 2003.

For agreements involving capital investments as well as those that do not, the contact should specify how pathology services for individual patients should be billed. Growing competition in the health care industry, the Medicare prospective payment system, and Medicare's outpatient clinical laboratory fee schedule have caused physicians and hospitals to reassess their economic relationship. New business entities designed to pool resources in order to raise capital, acquire management skills, and expand markets can take a variety of forms. Joint ventures between the hospital and pathologists, or other innovative arrangements, may be effective ways of addressing these challenges. The joint venture may function under such forms as a separate corporation or a limited partnership. Some joint ventures do not involve creation of a new legal entity; the entire agreement may be set forth in a contract between the pathologist and the hospital (eg, lease agreement).

The choice of legal structure of a joint venture depends on tax considerations and reimbursement regulations as well as licensure and accreditation requirements. The pathologist should assess the benefits and risks of a proposed joint venture from the standpoint of financial feasibility as well as the implications for the provision of quality medical care. The pathologist should also consider whether a joint venture with the hospital will enhance the pathologist's value to the hospital and thereby improve the pathologist's bargaining position.

The increase in the share of patients covered by some form of managed care has resulted in a number of alternative organizational arrangements for providing health services. Managed care plans include health maintenance organizations (HMOs), preferred provider organizations (PPOs), point of service plans (POSs) and provider sponsored organizations (PSOs). Increasingly, these managed care organizations or independent practice associations (IPAs) or group practices seek discount pricing arrangements from pathologists. Pathologists entering into contracts with these organizations often agree to accept payment from the entity with which they contract as payment in full for services. The agreements also generally require pathologists to participate in credentialing and peer review. The agreements may involve a percentage discount from usual fees or, more commonly, involve a fee schedule proposed by the managed care plan. In many cases, the fee schedule proposed is calculated on the basis of the Medicare resource-based relative value scale (RBRVS).

The pathologist may wish to establish a private (nonhospital) practice in addition to other institutional relationships. Any agreement that would limit the pathologist's right to conduct an outside practice should be carefully considered.

4. Independent Contractor Status

One of the more important questions with respect to a pathologist's relationship with a hospital is whether the pathologist will be considered to be an independent contractor or an employee of the hospital. The question is important for a number of reasons. If the

pathologist is found to be an employee, the hospital will be responsible for withholding taxes from compensation and paying Social Security (FICA) and unemployment (FUTA) taxes. A pathologist found to be an employee of the hospital must look to the hospital for participation in any benefits and retirement programs. Such pathologists cannot maintain their own retirement plan, other than Individual Retirement Accounts (IRAs).

A group of pathologists can join together as a professional corporation, association partnership, or professional limited liability company and enter into a contract with the hospital to provide services as an independent contractor. Another alternative is for a pathologist to contract with the hospital as an independent contractor and then subcontract with other pathologists as independent contractors. Either arrangement is acceptable. The following discussion is equally applicable to the pathologist as independent contractor to the hospital and to the pathologist who is an independent contractor to another pathologist.

If the pathologist is an independent contractor, the pathologist will be responsible for paying estimated taxes, relieving the hospital of all tax obligations. An independent contractor pathologist can maintain a separate retirement and benefit program.

The issue of employment versus independent contractor status is also important for other reasons. If a pathologist is considered to be an employee, the pathologist may be in a better position to invoke laws against employment discrimination on the basis of age, race, gender, or foreign origin. By contrast, the pathologist who is an independent contractor may not be able to take advantage of the remedies afforded by these laws.

Despite the importance of the determination of whether a pathologist is an independent contractor, the rules for that determination are not completely clear. Indeed, the employee/independent contractor issue has been an area of IRS scrutiny and activity. There has been an effort in the past by the IRS to restrict the availability of independent contractor status. In any event, the determination is very fact specific.

In determining whether an individual is an employee, the IRS looks to a variety of factors. The 20 factors most frequently considered by the IRS are set forth in Revenue Ruling (Rev Rul) 87-41. The factors are summarized as follows.

1. Whether the worker is required to comply with another person's instructions about when, where, and how the worker is to perform services.
2. Whether the worker is provided training in the performance of services or is required to attend meetings.
3. The degree of integration of the worker's services into the business operations of another entity.
4. Whether the services must be rendered personally by the worker.
5. Who is responsible for hiring, supervising, and paying assistants for the worker.
6. Whether the parties have a continuing relationship.
7. Whether the entity that obtains the services designates set hours of work.
8. Whether the arrangement requires the worker to devote substantially full-time to providing services for the entity.

9. Whether the work is performed on the premises of the entity contracting for the services.
10. Whether work must be performed in the order or sequence determined by the entity.
11. Whether the worker is required to submit written reports.
12. Whether the worker is compensated by the hour, week, or month.
13. Whether the entity pays a portion of the worker's business and/or travel expenses.
14. Who furnishes the tools and materials required for the services.
15. Whether the worker has a significant investment in the facilities used by the worker.
16. Whether the worker can realize a profit or loss as a result of the worker's services.
17. Whether the worker performs services for more than one firm.
18. Whether the services of the worker are available to the general public.
19. Whether the entity has the right to discharge the worker.
20. Whether the worker can terminate the relationship without incurring any liability.

Many of the foregoing factors are not easily applied to pathology. For example, the IRS has recognized that there is very little supervision of a physician-employee. Of perhaps greater significance is how the IRS has determined whether a hospital-based pathologist is an employee or independent contractor. In Rev Rul 73-417, the IRS ruled that a pathologist would be considered to be an employee if the pathologist was required to follow the hospital's rules and regulations; the hospital billed and collected for all services, paying the pathologist a percentage, with a guaranteed minimum; the pathologist was responsible for hiring and firing and scheduling the services of the hospital's technical employees; the pathologist could not perform pathology services outside of the contract with the hospital; and the pathologist did not incur any investment or bear any business risk.

The IRS contrasted the foregoing facts with the situation in Rev Rul 66-274. In that case, the pathologist could perform services for others, hired and fired other professional associates that provided services, apparently received a professional component equal to a percentage of the gross receipts of the department, but was not explicitly required to follow the hospital's rules and regulations and did not receive any benefits from the hospital. The key distinctions probably were the ability of the pathologist to perform services for others and the lack of any guaranteed payment.

More recently, the IRS has ruled that a hospital's chief of anesthesiology is an employee for federal tax purposes (Private Letter Ruling 9219020). In that case, the anesthesiologist was responsible for hiring, supervising, and scheduling the hospital personnel in the department; operating the department within budget; and performing administrative services. The anesthesiologist devoted 95% of his time to the hospital and received a monthly salary with a guaranteed minimum. The hospital furnished all facilities required for the performance of anesthesia services. The anesthesiologist was required to provide the services personally.

Similarly, in a Private Letter Ruling 9149001, the IRS ruled that physicians who entered into long-term contracts to staff a clinic during regular hours were employees. In that case, the IRS looked to whether the clinic had the requisite control, considering such factors as:

- The degree to which such individual has become integrated into the operating organization of the person or firm for which the services are performed.
- The substantial nature, regularity, and continuity of their work for such person or firm.
- The authority vested in or reserved by such person or firm to require compliance with its general policies.
- The degree to which the individual under consideration has been accorded the rights and privileges which such person or firm has created or established for its employees generally.

In finding that the physicians were employees, the IRS noted that the physicians had entered into long-term contracts to provide services at specified times, did not risk anything, agreed to work solely for the clinic, received a monthly salary based on fees collected by the clinic, and entered into a covenant not to compete. These factors were sufficient to establish the necessary employment relationship.

In sum, the pathologist should consider the potential implications of each proposed contract provision on the pathologist's status as an independent contractor. Unfortunately, there can be no assurance that any arrangement under which a pathologist provides substantially full-time service at a hospital will not be found to be an employment arrangement. However, factors that suggest employment status include:

- Designation of a particular person to provide pathology services.
- Hospital billing and collection for pathology services.
- Designation of hours during which services will be provided.
- Characterization of the pathologist as a "full-time" pathologist for the hospital.
- Agreement to answer to the CEO or other hospital administrator.
- Statement that the pathologist is providing services for the hospital rather than the patient.
- Reference to payment to the pathologist by the hospital as a wage or salary, rather than a fee.
- Hospital payment of professional liability insurance premiums or other costs that typically are incurred by independent contractors.
- Authority to hire and fire laboratory technicians.
- Noncompete clauses or other clauses that restrict the pathologist's ability to perform services for other entities.

Factors that enhance the argument that the pathologist is an independent contractor include:

- Providing some of the equipment used by the pathologist or the department.
- Providing a significant amount of services for persons outside of the hospital.
- Bearing a significant portion of the business risk of the arrangement (eg, direct billing patients or insurers for services).
- Including a joint venture or other component under which the pathologist invests in the enterprise and performs a significant amount of services off the premises of the hospital.
- Employing other personnel who are necessary for the performance of services to the hospital.
- Having the pathology group designate the lab director,
- Reference to payments by the hospital as fees.
- Having the pathology group set its fees for patients without control by the hospital.
- Avoiding as many provisions as possible that are suggestive of employment status.

In many cases, negotiating out of the agreement terms that jeopardize the independent contractor status can be quite difficult. In any event, the pathologist should avoid agreeing to an indemnification clause under which the pathologist indemnifies the hospital if the pathologist is found to be an employee. In most cases in which the pathologist is found to be an employee, it will be on the basis of a contract provision that the pathologist tried to avoid. Requiring the pathologist to pay in those circumstances is both unfair and an inappropriate shifting of the risk.

In cases where a pathologist seeks to retain an independent contractor to provide some services, issues might arise under the Medicare prohibition on reassignment. Medicare generally requires that bills for pathology services be made in the name and Medicare provider number of the pathologist who signed out the case. In some cases, a pathologist may reassign the claim, and the right to obtain payment, to another entity (eg, an employee assigning to the employer the right to bill and collect on behalf of the employed physician). Under Section 3060 of the Medicare Carriers Manual, any such reassignment must meet one of the exceptions set forth in that section. There is a clear exception for employees. Independent contractor pathologists, however, generally cannot reassign claims to another pathologist except in the limited case of a limited duration *locum tenens* arrangement (no longer than 60 days).

5. Tax Exempt Hospital Relationships

Tax-exempt hospitals must structure their relationships with physicians and other private entities to ensure compliance with Federal tax laws. In order to be a tax-exempt hospital under Section 501(c)(3) of the Internal Revenue Code, the hospital must be organized and operated primarily for a charitable or other exempt purpose. Federal tax law provides that an organization is not operated primarily for an exempt purpose if its earnings “inure” in whole or in part to a private individual (ie, “private inurement”).

The Internal Revenue Service (IRS) *Examination Guidelines Handbook* for tax auditors includes guidelines for reviewing hospital-based physician compensation arrangements with hospitals. According to the guidelines, such arrangements must result in reasonable compensation to physicians to avoid private inurement. The determination of what is reasonable compensation is a facts and circumstances test; the IRS does not utilize formulas to determine what is reasonable because of the many different and complex compensation arrangements that exist. The guidelines do state that when compensation is based on a percentage of hospital profits, such arrangements should be closely scrutinized for potential private inurement.

Until 1998, the only penalty available to the government to thwart excess benefits transactions was revocation of the tax-exempt status of the organization. The Internal Revenue Code provides, effective September 1998, “intermediate sanctions” for individuals who participate in arrangements that are determined to be “excess benefit transactions.” These intermediate sanctions call for punitive excise taxes imposed on the recipient of the excess benefit equal to 25% of the amount of the excess benefit. If excess benefits are not returned, there is an additional tax of 200% of the excess benefit. In addition, “organizational managers” who participate in excess benefit transactions are subject to tax in an amount equal to 10% of the excess benefit. Because of the stringent nature of these penalties, pathologists and hospital administrators must ensure that contractual provisions call for compensation arrangements that are at fair market value for the services provided.

Hospitals financed with tax-exempt state or local bonds must negotiate service contracts in accordance with IRS rulings designed to ensure that tax-exempt bonds are not used to finance facilities for “private business use.” Private use makes the interest taxable to the bond holder. Hospital bond counsel will scrutinize hospital-based physician contracts closely before issuing a favorable opinion on the tax status of proposed tax-exempt financings. The interest paid on the bonds is not held to be taxable to the bondholder. IRS Revenue Procedure 97-19 sets forth guidelines for determining whether there is private use. The guidelines outline permissible time periods for the contract and require that the contract be cancelable by the hospital upon reasonable notice at the end of the contract term, without penalty or cause. Contract term requirements vary (2 to 15 years), depending on the type of compensation arrangement. Under the most common compensation arrangement for pathologists, the Revenue Procedure provides for a term of contract not to exceed 3 years, with the hospital having the right to terminate the contract at the end of the second year. As a general rule, service contracts cannot be based in whole or in part on the net profits of the hospital.

It is important to note that hospitals have a certain amount of discretion in determining whether a facility is in fact receiving any tax-exempt bond benefits. For example, there are some not-for-profit hospitals that have entered into long-term (eg, 10 years) contracts with pathologists. These hospitals have been able either to find an entity that does not receive any tax-exempt bond proceeds as the contracting entity or to account for uses in a way that does not implicate the tax-exempt bond rules.

6. Pension Requirements

To discourage schemes in which highly-compensated employers fired employees and then rehired them under lease arrangements simply to avoid inclusion of the employees in tax

qualified pension plans, the federal tax code has required since 1984 that “leased employee” be included in the pension plan of the “service recipient” (ie, the leasing employer.) The Internal Revenue Code defines “leased employees” as those individuals who are under the “primary direction and control” of the recipient. This is particularly significant for the hospital-based, independent contractor pathologist with an independent tax-qualified pension plan, who serves as medical director of the laboratory in which hospital employees work. To avoid a requirement to include hospital laboratory employees in the pathologist’s pension plan, it is reasonable to take the position that it is the hospital, not the hospital-based, independent contractor pathologist, that has primary direction and control of laboratory employees. It may be useful to include a statement in the pathologist’s contract that clearly specifies that the relationship between the pathologist and the hospital laboratory employees involves medical supervision only, and that the hospital has primary direction and control of the hospital employees. Internal Revenue Service regulations implementing the “leased employee” provisions of the tax code were proposed and then withdrawn after widespread criticism from the College and other physician groups.

E. Elements of an Agreement

Regardless of the type of agreement, the contract should be in writing and drafted by an attorney. The precise form and wording will vary, but the following items generally are considered for inclusion in agreements between a pathologist and an institution.

1. Introduction

The introductory section of a contract usually names the parties entering into the agreement, describes the reasons for an agreement, and sets forth general principles and qualifications recognized by both parties.

The pathologist should be appointed to, or removed from, the medical staff in the same manner as any other physician. The institution’s pathology service should be organized as a division of the medical staff, equal in all respects to other major divisions, such as medicine, surgery, and radiology. The status of the chief pathologist should be equivalent to that of any other chief of service of the medical staff. The terms of the agreement between the institution and the pathologist should conform to the bylaws of the medical staff and the institution.

The pathologist’s contract is separate from the pathologist’s medical staff privileges. There is no legal reason why maintenance of the pathologist’s privileges must be linked to maintenance of a service contract with the hospital; keeping them separate probably enhances the pathologist’s bargaining position with the hospital. However, hospitals now generally seek to tie privileges to the existence of a service contract to avoid disruptions that may occur when multiple pathology groups serve the same hospital. In any event, staff privileges in the absence of a contract with the hospital generally have little practical value for the pathologist. As a practical matter, most pathologists are likely to be required to agree to give up staff privileges upon termination of the contract.

2. Pathology Services and Standards

This section of the agreement sets forth the standards of practice that the pathologist promises to maintain and should specify the areas of anatomic and clinical pathology to which these standards apply.

The pathologist generally agrees to provide pathology services to patients upon the request of their attending physicians at a level consistent with the facilities available and the standards established in the medical community. The pathologist and institution should agree jointly to maintain and provide these services in such a manner that the laboratory is eligible for accreditation by the CAP Commission on Laboratory Accreditation or its equivalent, and to maintain such accreditation during the term of the contract. Statements in the contract that the pathologist will provide services of the highest quality, or words to similar effect, are inadvisable because they may expose the pathologist to an unduly high standard of care in malpractice cases.

The contract generally provides that the pathologist is responsible for the medical direction of the laboratory. The pathologist should be responsible for the timely performance of laboratory examinations, for the preparation and submission of written reports, and for the retention of appropriate materials. The pathologist should be available for consultation concerning medical questions about individual patients. The pathologist should also be responsible for directing the clinical laboratory, including medical supervision of laboratory personnel, maintenance of an effective quality assurance and quality improvement program, and review of new procedures.

The pathologist generally agrees to maintain accurate and complete records, including a proper filing system. The slides and other records of the pathology department should be conveyed to the institution at the termination of the agreement.

The pathologist also generally agrees to provide consultation for staff physicians, including operating room consultation. Whenever absent, the pathologist should be responsible for the continuity of professional service, unless the contract specifies otherwise or is a salaried-employee arrangement in which the responsibility for service continuity resides with the institution.

Generally, the pathologist should agree to perform autopsies when requested for properly admitted patients when the patient has died in the hospital, the autopsy is duly authorized, and the autopsy is otherwise appropriate. Reports, including those of both gross and microscopic findings, should be made available promptly for the medical record, the attending physician, and the department files. Laboratory records and materials should be retained in accordance with policies that meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). The CAP has developed recommendations for the minimum retention requirements for laboratory records and materials, which meet or exceed CLIA requirements. (See Appendix A.) Applicable state laws also should be carefully reviewed when record retention policies are developed.

In the interest of providing laboratory work at a reasonable cost to the patient, the pathologist may find it advantageous to arrange with another laboratory for the provision of some procedures. Such arrangements should be evaluated carefully and should be in conformity with CLIA regulatory requirements, medical staff bylaws, and JCAHO standards.

3. Equipment and Facilities

Appropriate equipment is essential for the practice of pathology. Cooperation with the hospital administration is extremely important. Both the pathologist and the administration should stay abreast of recent trends and constantly review changing equipment and space requirements.

Each type of agreement handles the provision of equipment and facilities differently. Where the pathologist does not contract to provide capital investment, the institution generally will own the scientific and nonscientific equipment. The agreement under these circumstances should state that the hospital will furnish all the necessary equipment and facilities required for the proper practice of pathology.

Under a lease or an independent laboratory agreement, the pathologist may acquire the existing scientific equipment of the laboratory. The pathologist is responsible for providing new equipment, as needed. The agreement also may provide for sale to the institution of all equipment upon termination of the lease agreement. The pathologist's equipment costs can only be billed to the hospital under Medicare payment rules.

4. Supplies

Under a lease or an independent laboratory agreement, the institution does not provide expendable professional supplies. Under such a contract, the pathologist would furnish required supplies and may purchase supplies from any source. Careful compliance with Medicare regulations, however, is essential. There should be a provision in the contract to allow the pathologist to bill the hospital for the cost of supplies so the pathologist may recover these costs.

Under other types of agreement, the institution is obliged to provide supplies, and the agreement should state that the institution will provide, at its own cost, all expendable supplies and accessories required for the operation of the department. It should state clearly that these will meet the standards of quality and quantity established by the pathologist. The pathologist should agree to conform to the budgeting and purchasing practices of the institution. Deviations from these practices should require prior agreement between the pathologist and the administration.

It is best for the pathologist to recommend biological and reagent supplies. The pathologist is expected to use good judgment in recommending the purchase of high-quality supplies, in quantities that will be reasonably cost-effective. The pathologist should anticipate departmental needs, utilize normal purchasing channels, and conform to budgets, in the interest of orderly management and economy.

5. Maintenance

The owner of the equipment generally is responsible for its proper maintenance and repair. When the pathologist does not provide the capital investment, the agreement should state that the institution will maintain and repair all of its equipment, facilities, and fixtures to a standard satisfactory to the pathologist, and that it will provide utilities and services, such as heat, water, gas, electricity, telephone, laundry, janitor, decorating, and physical upkeep of the laboratory.

6. Personnel

In agreements without major capital investment by the pathologist, this section of the contract should state that the institution will employ the technical and nontechnical personnel required for the proper functioning of the department. The institution should agree to employ only individuals who meet standards of training, experience, and ability agreed upon jointly by the pathologist and the administration.

The pathologist should be responsible for the scientific activities of all departmental personnel and for making recommendations to the institution regarding hiring, firing, and disciplining departmental personnel. Only properly trained and experienced personnel can accomplish high-quality laboratory work. Personnel standards established by the regulations implementing the Clinical Laboratory Improvement Amendments (CLIA '88) establish minimum experience and education requirements for testing personnel. The pathologist should have the authority to set the standards and qualifications necessary for jobs that may be higher than CLIA's minimum standards. Discussion, understanding, and agreement between the pathologist and the institution in this area are essential for the operation of an efficient laboratory.

A lease or independent laboratory agreement should state that the pathologist will employ, at the pathologist's own cost, all assistants and employees deemed necessary in order to provide adequate pathology services. Under these circumstances, laboratory personnel should be the employees of, and responsible to, the pathologist. The discipline and discharge of personnel is the responsibility of the pathologist, in accord with established institutional procedures. Interdepartmental problems should be resolved by discussion with the hospital administration or the department heads involved. As is the case with supplies, there should be a provision in the contract for the pathologist to bill the hospital for personnel costs incurred by the pathologist. Under Medicare rules, these costs are considered hospital costs and can only be paid to the hospital.

7. Professional Fees and Pathologist Remuneration

The agreement should define in detail the method by which the pathologist will be paid for professional services. This portion of the contract should be detailed and specific.

8. Information for Billing

Pathologists who bill patients or their insurers will need detailed patient billing information from the institution. The contract should provide that the institution will provide such information in an accurate and timely fashion. The information should be presented in a fashion or form that is readily usable. There should be satisfactory audit capability so that Medicare carriers' or third-party payers' requirements are met.

9. Insurance and "Hold-harmless" Clauses

Every pathologist, the pathologist's associates, and physician-employees, regardless of the type of practice or remunerative agreement, should be covered by adequate professional liability insurance. Under a salary arrangement, premiums may be paid by the institution; under other contractual arrangements, premiums are usually paid by the pathologist. Partnerships and professional corporations should provide for adequate insurance of the group entity as well as for each individual physician-member. A pathologist should carry

general liability/public liability insurance under a lease or independent laboratory agreement. Under other circumstances, general liability/public liability insurance should be the responsibility of the institution.

With the aid of professional insurance consultants, the pathologist should be sure that there is full protection in all areas of exposure. The pathologist may also want to consider an “umbrella” liability policy. The medical staff of the hospital or the managed care organization with whom the pathologist contracts to provide services may also have requirements for professional liability insurance. The pathologist must also satisfy these requirements.

The hospital or other organizations with which a pathologist may contract (HMOs, IPAs, PPOs, etc) may attempt to have the pathologist indemnify them against acts of malpractice. Such “hold-harmless” clauses may jeopardize the pathologist’s own liability insurance coverage and should not be accepted without first obtaining a written approval from the insurance company underwriting the professional liability policy. Generally, it is preferable to have the hospital or other organization listed as a named insured on the pathologist’s insurance policy, rather than to have the pathologist indemnify the entity. An indemnification undertaken by contract is not likely to be covered by the pathologist’s insurer.

Regardless of the professional liability insurance arrangement, if coverage is on a claims-made basis rather than on an occurrence basis, there should be a clear understanding of who is responsible for extended (tail) coverage. It is essential to determine who should pay for this prior to a decision to leave or discontinue practice. Some policies may include extended coverage under specified conditions. In some situations, extended coverage premiums are costly.

10. Reports

Orderly management of the institution and of the activities of the medical staff often requires the mutual exchange of information. This section of the agreement should describe any reports that are required of the pathologist in cooperation with the institution.

Medicare regulations require the institution to submit an annual report on allocation of physician compensation between Medicare Part A and Part B if it claims reimbursement for physician compensation payable on a reasonable-cost basis. Changes in Medicare payment policy have substantially diminished the importance of the reasonable-cost payment system. With certain limited exceptions (eg, services at a DRG exempt hospital), Medicare no longer pays hospitals on a reasonable-cost basis. Even though very little hospital reimbursement is based on reasonable costs, hospitals are obligated to file cost reports.

The Medicare allocation agreement allocates physician time among services to the provider (Part A), services to individual patients (Part B), and noncovered activities, such as research. Part A time is then allocated among activities that are paid for on a reasonable-cost basis (if any), activities that are paid through the hospital DRG rate, activities that are paid through the ambulatory payment classification (APC) system, and activities that are compensated through the Medicare clinical laboratory fee schedule.

Institutions have some discretion as to the types of records they maintain on the allocation of physicians’ time to various services, but the allocation agreements must be supported by adequate documentation to allow verification by Medicare auditors, and the

documentation must be retained for 4 years. Daily logs or time records are not required by the Medicare program, and contract provisions requiring daily or frequent time records to support allocation agreements generally are unnecessarily burdensome. Note that for most hospitals, the allocation of pathologist compensation likely has no impact on Medicare payment. However, hospitals do continue to file cost reports and to require allocation agreements and documentation.

Where there are some components of reasonable-cost reimbursement, adequate documentation must be maintained to support the total number of hours claimed for Part A services to permit application of the Medicare reasonable compensation equivalent (RCE) limitation. The RCE serves as a limit on the amount of compensation for which the Medicare program will provide reasonable-cost reimbursement to the hospital for a full-time (2080 hours per year, 40 hours per week) physician. RCE limits are based on American Medical Association Socio-Economic Monitoring System survey data and were last updated in 1997.

The RCEs for pathology services are:

<i>Specialty</i>	<i>Non-Metro</i>	<i>Metro, Less Than 1 Million</i>	<i>Metro, More Than 1 Million</i>
Pathology	\$180,000	\$190,000	\$186,700

Any other reports that may be required of the pathologist, or for which the pathologist would be expected to contribute substantially, should also be described in this section of the contract.

11. Payment to the Institution

Payment to the institution is not generally applicable to an independent laboratory agreement or to agreements in which the pathologist has no capital involvement. In some situations, the pathologist may pay for billing services or for the technical component of anatomic pathology provided to nonhospital patients (eg, physician office patients). If payments are made to the hospital, they should be based on fair market value for goods or services received in order to avoid raising fraud and abuse concerns. (See the Department of Health and Human Services Office of Inspector General report on “Financial Arrangements Between Hospitals and Hospital-Based Physicians,” available at <http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>.)

Some hospitals are now seeking reimbursement from hospital-based physicians for the cost of office space, secretarial support, transcription services, and other costs that the hospital incurs in supporting the services of the hospital-based physician. The hospital may claim that these costs support the practice of the physician and thus should be reimbursed by the physician. In most cases, however, these costs are properly viewed as hospital costs, which should be borne by the hospital. For example, the office space generally is used by the pathologist to provide services to the hospital as the medical director or laboratory director or other Part A services. Transcription services are commonly provided to all physicians in the hospital without charge for medical records (which will be owned by the hospital anyway). Indeed, the services for which the hospital seeks reimbursement often are indistinguishable from the services that the hospital provides to surgeons or others who use the hospital without any separate charge from the hospital to the physician. Charging hospital-based physicians for services that historically have been a hospital cost and which

are not billed to nonhospital-based physicians poses the same kind of fraud and abuse issues as those identified in the above-referenced Inspector General report.

Under a lease, this section usually is limited to a statement of the amount and method of payment and the specific details of services to be provided to the institution.

12. Education and Extradepartmental Professional Functions

This section of an agreement should specify any activities that may be required of the pathologist outside of daily departmental professional responsibilities. All staff physicians have a responsibility to participate in organized medical staff activities relating to patient care. The time and effort contributed by the pathologist should be substantially equivalent to that provided by other members of the medical staff.

Pathologists, by virtue of their base of operation in the hospital and the broad liaison they have with the medical staff, often are asked to assume more than their share of these responsibilities. When called upon to devote more time to committees and other hospital functions (eg, infection control, medical education) than other physicians, the pathologist is entitled to reasonable compensation for this additional professional effort.

13. The Autopsy

The autopsy is of value to medicine as an educational tool, a measure of performance and outcomes, and a resource for research. The autopsy is used to assess the quality of patient care, to evaluate diagnostic accuracy, to monitor effectiveness of new technologies, and to determine the efficacy of therapeutic regimens. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the CAP state that autopsy information should be used as a source of clinical information in the quality assessment and improvement programs of the hospital.

Pathologists should be compensated for their professional autopsy services. A variety of methods for payment for the autopsy services of the pathologist are available. The hospital should be responsible for payment for the autopsy in the case of hospital-related autopsies. Such payment can be made in various ways. The pathologist may seek a per-autopsy payment from the hospital. Alternatively, the pathologist may negotiate a fixed amount for a package of designated services that includes the autopsy (eg, providing autopsies requested by hospital medical staff, serving on committees, providing education programs).

There should be a clear understanding as to the types of deaths for which the pathologist is responsible for examination. The JCAHO has requirements for the medical staff to develop criteria to be used to identify deaths in which an autopsy should be performed. There are also requirements that the medical staff attempt to secure autopsies in deaths meeting these criteria, that the mechanism for documenting autopsy permission be defined, and that a system is established for notifying the attending practitioner when an autopsy is being performed. Ordinarily, the contract will require that the pathologist perform autopsies on hospital patients, properly admitted, whose deaths are classified as hospital deaths. However, requests are also often made for autopsies on persons who die shortly before or after arrival in the emergency room. These may or may not be considered hospital deaths, and some will fall under the jurisdiction of the medical examiner or coroner. On occasion, the family of the deceased requests the examination, either on a hospitalized

patient or on one who dies at home. For autopsies on nonhospital deaths, the institution should pay for the service, or the pathologist should submit a bill for this additional service. (See Appendix J, “Criteria for Autopsies”; and Appendix K, “Payment and Performance of the Autopsy Service.”)

14. Independence of Practice

Whether the pathologist is an independent contractor or employee should be specified in the contract. If an independent contractor, the pathologist’s agreement should reflect the absence of hospital control or direction over the manner in which the pathologist practices. Pathologists should agree to use currently acceptable methods and practices of their specialty. The interest of the hospital should be that pathology services are provided in a competent, efficient, and satisfactory manner.

15. Outside Activities

The pathologist’s responsibilities to the community may best be fulfilled if services are also made available to nonhospital patients. If such outside activities are important to a pathologist, this section of the agreement should provide that the pathologist may engage in teaching, consulting, research, and practice outside the institution, provided there is no conflict of interest with the pathologist’s obligations under the agreement, and that needed pathology services are maintained in the hospital. Any restrictions should not compromise the independent contractor status.

The amount of time required of a pathologist or any physician for institutional duties will vary. Therefore, the term “full-time” should not be used in any agreement in which the pathologist wants to be an independent contractor. Instead, it should require the pathologist to provide a level of service and supervision that will meet the needs of the patients, to the satisfaction of the medical staff.

16. Exclusive Contracts

Many pathologists’ contracts with hospitals imply or specifically include an exclusive practice arrangement for the professional services. Although the principle of an open medical staff has been predominant for many specialties, the organization of the pathology department as a practical matter often has precluded significant involvement by other pathologists except where a specialized consultation was required. When there have been antitrust challenges to exclusive contracts for hospital-based physician services, the courts have generally upheld such contracts when the hospital can show such arrangements help ensure patient access to quality services.

If the pathologist intends an exclusive arrangement, it should be addressed in the contract. Exclusivity of service might be addressed by limiting access to the facilities of the pathology department to other pathologists acceptable to the medical staff, providing that prior arrangements are made with the director of the laboratory to minimize interference with the normal direction and operation of the department. A more restrictive contract might provide that pathology and any related specified services under the contract will be provided exclusively by the contracting pathologist, with like services of any other consultant subject to approval by both the contracting pathologist and the hospital. The contract might support the need for exclusivity by providing that the arrangement will not

preclude the patient's right to adequate consultation, will promote efficient operation of the department, and will assure availability of quality pathology services at all times.

17. Staff Privileges

In theory, a pathologist's staff privileges need not be tied to the existence and maintenance of a contract with the hospital. In recent years, however, many hospitals have sought to include provisions in the pathologist's contract requiring the pathologist to resign from the medical staff in the event that the contract is terminated for any reason. Hospitals seek such a provision to avoid some of the disruptions that sometimes occur in situations in which two pathology groups simultaneously seek to provide services at the same hospital. Generally, it is very difficult to avoid such a provision if the hospital includes it in the contract.

From the standpoint of the pathologist, linking privileges to a contract has both disadvantages and advantages. Obviously, the preservation of staff privileges and clinical laboratory privileges gives the incumbent pathologist a certain amount of job security. Even if the contract is terminated, the pathologist can continue performing some services for patients at the hospital. This ability may enhance the pathologist's bargaining position with the hospital.

The maintenance of privileges, however, does not guarantee the pathologist an adequate volume of business. In most cases, the new pathologist under contract with the hospital will obtain most of the anatomic pathology work. The pathologist with privileges but no contract will need to have physicians designate the pathologist by name in order to perform services.

On the other hand, a case can be made for the orderly termination of privileges to avoid cases where two pathology groups battle over the patients at one hospital. It is very difficult for a new pathologist to provide services in a situation where there is competition from the incumbent pathologist. In some cases, the competition may be between two existing pathologists, for example, when the hospital has lost confidence in one of the pathologists and is seeking to terminate that pathologist. A contract provision that provides for some appropriate mechanism to terminate staff privileges when a contract is terminated can help prevent the development of a situation that is not advantageous for either pathologist.

There are a number of arguments that a pathologist can make against a clause that automatically terminates all privileges if the existing contract is terminated for any reason. There are a number of circumstances where automatic termination is not appropriate. For example, termination would not be appropriate where the contract terminates while the parties are still negotiating a new contract. Such automatic termination could leave the hospital without any pathology services or subject the hospital to possible liability for permitting the existing pathologists to practice after their privileges were automatically terminated. Termination also would not be appropriate where the existing contract is terminated, but the hospital seeks a new contract with many of the existing pathologists.

There may be a number of middle positions that a hospital might be willing to accept that are less onerous than automatic termination. For example, the contract could provide that privileges continue for some fixed period of time (eg, 45 days) after termination of the contract. During that period, either the hospital or the pathologist can initiate a due-process hearing under the medical staff bylaws to determine whether the privileges of the

incumbent pathologist should continue. The hospital could argue at the hearing that continued privileges could be disruptive. The parties would have an opportunity to negotiate an arrangement that would not be disruptive. If no such arrangement could be negotiated, the medical staff and the hospital could take action to terminate privileges. By requiring the invocation of the staff bylaws due-process mechanism, all parties should be reasonably protected without the unfairness of automatic termination.

18. Access to Books and Records

Section 952 of the Omnibus Reconciliation Act of 1980 states that the reasonable costs of a provider for Part A services may not be reimbursed by Medicare unless the contract contains a specific right of “access to books and records” clause. This applies to all subcontractors whose services reimbursable by Medicare exceed \$10,000 per year. Such a clause need not be broad and all-inclusive. Rather, access can be limited to those records necessary to verify the nature and extent of costs for services reimbursable under Part A of Medicare. In addition, the access clause can provide that books and records will be made available to the Secretary of Health and Human Services or the Comptroller General of the United States only after written request. As a practical matter, the virtual elimination of reasonable-cost reimbursement at most hospitals makes it unlikely that the access to records clause would ever be invoked.

19. Managed Care Terms

Hospitals increasingly are seeking to include in the pathology services agreement provisions requiring the pathologists to participate in the same managed care plans as the hospital. The hospital basically wants to ensure that it does not lose managed care business because the hospital-based physicians refuse to agree to managed care contracts. At the same time, the pathologist would like to retain as much discretion as reasonably possible in negotiating with managed care plans.

Pathologists should expect that most hospital agreements will contain some provision relating to managed care contracting. The least onerous simply require the pathologist to negotiate in good faith with designated managed care plans. Other contracts may seek to mandate that the pathologists participate in the local IPA or physician/hospital organization and accept whatever contracts might be negotiated by that organization. Other contracts might seek to give the hospital complete discretion, with the ability to bind the pathologists to managed care contracts.

From the pathologist’s perspective, there should be some protection to ensure that the pathologist is not bound to a managed care contract that poses an unreasonable risk of professional liability or which has completely inadequate reimbursement terms. Oftentimes, the hospital contract will provide a floor on the pathologist’s obligation, so that the pathologist is not obligated to enter into a contract that offers pricing below the floor. In other cases, the contract will provide that in the case where the pathologist does not enter into a contract with a third-party payer, the pathologist will bill the hospital for such services at an agreed-upon discounted rate. In still other cases, the pathologist might agree to an exception to the exclusivity provision in any case where the pathologist has not agreed to a contract with the managed care plan.

It is useful for the pathologist to try to develop a creative resolution to the hospital's managed care dilemma of trying to ensure that all of its hospital-based physicians participate in designated managed care plans. There are a variety of options for the pathologist to consider. It is key that the resolution of this dilemma balance the hospital's needs with the pathologist's concerns over being forced to accept a bad managed care arrangement.

20. Term and Termination

The term of the agreement should be stated clearly, and provisions should be made for renewal and periodic renegotiation. Generally, a term of up to 3 years should not raise antitrust concerns and will provide some measure of security (unless there is a provision for termination without cause). A provision should be made that, should the period of renegotiation extend beyond the anniversary date, the agreement will be kept in effect on a specified short-term or month-to-month basis.

Some contracts specify that termination may only occur on or after a specified date (eg, term of the contract, fiscal year). If this is not done, the term of the agreement generally is merely the notice period required prior to termination (eg, 6 months or less). There is, however, a drawback to linking the notice of termination to a particular date. Under such an agreement, the pathologist is legally bound to complete the contract year and therefore may not be free to accept another position at the time it is offered. Both aspects should be considered before the contract is drafted.

The contract should specify the circumstances under which the contract may be terminated by either party prior to its expiration. Agreements often include provision for termination with cause and/or without cause.

If the contract may be terminated without cause, the contract should specify the length of advance notice that is required to be given by either party. A mutual requirement of a reasonable notice period should be specified. The pathologist should be aware that inclusion of a termination-without-cause provision effectively shortens the term of the agreement to the length of the notice period for termination (eg, 90 days) and makes the longer term set forth elsewhere in the agreement essentially meaningless.

If the contract may be terminated for cause, the grounds for termination should be specified. A list of causes may be stated, or a general statement calling for termination for a material breach of contract may be included. In any case, the contract should provide for written notice of an intent to terminate for good cause. A minimum time period for allowing either party to correct or cure a material breach of the contract should be allowed. This can avoid misunderstandings as to what may be required under the contract.

The pathologist also may want to seek to have the contract specify that the medical staff has some involvement in determining whether there is good cause for termination. While it might be desirable to seek a due-process hearing to determine whether there is a good cause, it is unlikely that the hospital will agree to such a restriction. Moreover, an adverse determination of the medical staff on the good cause could give rise to other disciplinary proceedings. However, it is sometimes possible to get the hospital to agree to consult with the medical staff before giving any notice of termination for good cause.

In rare cases, pathologists have been able to get provisions in the contract that provide for fair hearing under the medical staff bylaws before the contract may be terminated or nonrenewed by the hospital for any reason. Such a provision may be useful to pathologists since it provides protection from an unfair decision by administrators. It is extremely rare for hospitals to agree to such a provision, however.

21. Restrictive Covenant, Covenants Not to Compete

Covenants not to compete generally limit the right of one contracting party to compete with the other contracting party during the term of and after the termination of the underlying contract. It generally is not in the interest of the pathologist to agree to such a restriction within the context of a hospital-services contract. One of the strongest arguments that a pathologist can make to resist such a clause relates to the independent contractor status of the pathologist. If the contract between a hospital and pathologist includes a restrictive covenant, it is more likely that the IRS will characterize the arrangement as one of employment, rather than as an independent contractor arrangement.

Covenants not to compete are enforceable, in most states, if the restrictions on competition are reasonable as to geographic and time limits. Generally, the restraint must be no greater than necessary to protect a legitimate interest of the party to whom the promise not to compete is made, must not be unduly oppressive on the physician promisor, and must not be injurious to the public. The interpretation of “reasonable” depends on the individual circumstances of each case. However, the pathologist should try to avoid any covenant not to compete. After all, the pathologist is not usually in competition with the hospital, and the existence of such a covenant may impair the ability of a pathologist to find a new position if the original contract is terminated.

If the pathologist is unable to dissuade a hospital from insisting on a limitation on the pathologist’s ability to contract or provide services to competing hospital systems, or by or through an independent laboratory, the pathologist should at least seek to minimize the scope of the noncompete covenant. In particular, the noncompete covenant should not apply after termination of the agreement so that the pathologist can contract with other hospitals in the event that the arrangement with the initial hospital ends. At a minimum, the noncompete covenant certainly should not apply if the hospital terminates or refuses to renew the contract for any reason other than material breach or cause. The pathologist should also pay particular attention to the geographic scope of any noncompete covenant. The scope should be set out as precisely as possible and should not extend beyond a reasonably small area, eg, the county or 10-mile radius from hospital.

The usual method of enforcing restrictive covenants is by injunction—an equitable order requiring the person violating a contract to cease and desist from the prohibited activity. Another method employed for enforcement is an assessment of damages. The latter is generally delineated in the written contract, specifying a dollar amount of damages to be paid the employer if the contract is terminated and the restrictive covenant violated. This method has, in many cases, been upheld by the courts as a reasonable business restriction. However, covenants not to compete are less likely to be strictly enforced in the medical area.

22. Procedures for Settlement of Disputes

Many agreements contain a section, in conformity with the hospital and medical staff bylaws, that provides for the settlement of disputes that might arise between the parties with respect to their obligations under the agreement. The use of professional arbitrators also may be considered. The parties should agree to abide by the findings and recommendations of the arbitration. However, if there is a provision for arbitration of malpractice claims or other claims going to the performance of the pathologist, it should be made clear that the finding of the arbitrators is not intended to be binding in malpractice litigation against the pathologist; the pathologist does not want to have an adverse arbitration finding used in a malpractice case against the pathologist.

23. Business Associate Requirements

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishes new privacy requirements for the protection of patients' health information. The rules apply to "covered entities," a term that includes pathologists and laboratories if they transmit health information electronically (eg, for billing). Although not all information will need to be protected, most patient information will be considered "protected health information (PHI)." PHI includes all individually identifiable health information, including electronic and paper records as well as oral communications.

Unless a pathologist or laboratory handles *all* health information on paper, with no electronic transactions, pathologists will be subject to HIPAA's requirements. Generally, HIPAA requires pathologists to: (1) monitor the uses and disclosures of PHI; (2) give certain rights to patients with respect to their PHI; and (3) establish certain administrative policies and procedures to ensure that privacy is prioritized. In addition to these requirements, pathologists are likely to be affected by HIPAA through its business associate requirements.

The HIPAA privacy rules require covered entities (eg, hospitals or physicians such as pathologists providing certain services to hospitals) to enter into written agreements with their business associates. These *business associate agreements* ensure that a business associate will provide the same privacy protections to the covered entity's information as the covered entity would.

Generally speaking, a pathologist will be a business associate of a hospital when the pathologist is providing medical direction and supervision services in the hospital's clinical laboratory as an independent contractor. If the pathologist is an employee of the hospital, the pathologist is not a business associate of the hospital, even if the pathologist is serving as the medical director of the hospital's laboratory. A pathologist who provides only patient (Part B) services, but does not provide medical administrative services on behalf of the hospital, will not be a business associate of the hospital.

Pathologists should also consider whether they need to develop business associate agreements with entities that provide services to pathologist and have access to patient information in the course of providing these services. For example, a pathologist's billing service will clearly be the business associate of the pathologist. Similarly, an attorney, accountant, or consultant who provides services to the pathologist may be a business associate if such individuals have access to patient information in the course of providing their services.

Once a pathologist or laboratory has determined that it will be a party to a business associate contract (either as the covered entity or as the business associate), the pathologist or laboratory will need to ensure that the contract includes the appropriate language. A business associate agreement is likely to include (1) an explanation of permitted uses and disclosures that the business associate may make, (2) an explanation of the business associate's responsibilities, and (3) other supporting provisions. Pathologists should seek competent legal counsel to review business associate contracts with hospitals and other entities.

24. Amendments

Many agreements include a provision allowing amendments upon the written agreement of the parties. This allows renegotiation of the contract to conform to significant changes in federal or state laws and regulations without requiring termination of the agreement when such changes occur. The pathologist should, however, oppose any provision that permits unilateral amendment by the hospital or other entity.

25. Signature and Certification

The final section of an agreement consists of the witnessed and dated signatures of the contracting parties. All parties to the contract should be clearly identified. The proper names of the legal entities entering into the contract should appear in the contract along with the signatures of those persons signing the contract.

F. Small Hospital Coverage

The pathologist's relationship to the rural or small hospital is a unique and challenging opportunity to provide direct professional services and to be both a consultant and an educator. The amount and nature of direct professional service rendered by the pathologist depends in a large measure on the sophistication of the rural institution or, more importantly, of its medical staff. In the hospital laboratory, the consulting pathologist should assume an active role to ensure that the laboratory is providing clinically relevant results. All of the contract options discussed in this manual are as applicable to a small hospital as they are to the larger institution.

The type of contract and compensation will of necessity be dependent upon the amount of activity required on the part of the pathologist. In some cases, the pathologist may serve only as a consultant. In other situations, the pathologist is named as the laboratory director. Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) limit the number of laboratories in which one individual can serve as a director to five laboratories.

G. Patterns of Professional Remuneration

This section outlines the variety of remuneration patterns in existence today. They range from traditional to innovative, from simple to complex. The pathologist should consider each type of arrangement before choosing the arrangement that best serves the needs of the pathologist and patients. The pathologist should then take the lead in developing an appropriate contract with the institution.

It must be emphasized that the College of American Pathologists takes no position on what form of contract is appropriate for an individual. Pathologists must make their own decisions in light of all applicable considerations.

As we have noted previously, the basic arrangements between a pathologist and an institution are:

- Those with no or moderate investment by the pathologist.
- Those in which the pathologist makes a major capital investment.

Each basic arrangement allows several variations. These are discussed below.

1. Agreements With No or Moderate Capital Investment: Part A Compensation Arrangements

In this category of arrangements, the institution bears all or a major portion of the capital expenditures, providing not only space and utilities, but also equipment, supplies, and personnel. Under these arrangements, the compensation received by the pathologist is limited to fees for professional services. The pathologist does not receive any compensation for the technical component.

Most pathology agreements have separate provisions covering compensation for Part A services and compensation for Part B services. The discussion which follows addresses Part A compensation and Part B compensation. “Part A” is used as a generic term to describe pathologist medical direction and supervision of the hospital clinical laboratory; “Part B” is used as a generic term to describe pathologist direct patient care services to individual patients (eg, surgical pathology, hematology, cytology, and clinical pathology consultations and interpretations).

Part A services encompass the pathologist’s medical direction and supervision of the hospital laboratory. Pathologist-directors of hospital laboratories spend a significant amount of time and effort providing medical direction and supervision of clinical pathology services. The pathologist is professionally responsible and legally accountable for laboratory results. (A listing of laboratory director responsibilities under CLIA ’88 is available at <http://www.phppo.cdc.gov/clia/regs2/toc.asp>.) The pathologist-director of a hospital clinical laboratory should be adequately compensated for clinical pathology services. A variety of acceptable methods for paying for the pathologist’s medical direction and supervision services in the hospital laboratory are available and are discussed below.

Under the Medicare programs, Part A services are reimbursed to the hospital as part of the DRG payment. The pathologist must look solely to the hospital for payment for these services and not bill Medicare patients for these services. The Medicare regulations, however, do not govern pathologist billing arrangements for non-Medicare patients.

There are a number of possible compensation arrangements for Part A services. Compensation arrangements include the following:

- a. Hospital compensation of the pathologist, with a fixed Part A stipend covering Part A services for all hospital patients (both Medicare and non-Medicare).
- b. Hospital compensation of the pathologist, with a fixed Part A stipend plus a bonus or incentive compensation component, covering Part A services for all hospital patients.
- c. Hospital compensation of the pathologist on a per-test basis, covering Part A services for all hospital patients (both Medicare and non-Medicare).

- d. Hospital compensation of the pathologist on the basis of a percentage of laboratory revenues, covering Part A services for all hospital patients (both Medicare and non-Medicare).
- e. Payment by the hospital of a Part A stipend limited to Medicare services, with an explicit recognition of the right of the pathologist to direct bill non-Medicare patients for Part A services. This method of payment is sometimes referred to as a “split Part A” arrangement because there are different compensation methods for Part A services to Medicare patients as compared to non-Medicare patients. This method of billing for clinical pathology services is often called “professional component billing.” (See Appendix I, “Pathologist Professional Component Billing for Clinical Pathology Services.”)
- f. Hospital compensation of the pathologists for “Part A” services on a per diem or per discharge basis.

The following discusses each of these models. There is no single best model. Each pathologist should consider which Part A approach is best for the particular circumstances. Indeed, in an appropriate case, the pathologist and hospital may want to develop an entirely different compensation model.

a. Fixed Part A Stipend

One type of Part A compensation for pathologists is the fixed Part A stipend. The parties agree as to the appropriate level of payment for each year, which typically is paid in equal monthly installments. The compensation does not vary with hospital or laboratory income or with workload.

The key question is the appropriate level of Part A compensation. That question, of course, must be resolved by the parties in their contract negotiations. Each pathologist should consider the value of the time and the services provided and seek appropriate compensation.

In the early years of the TEFRA regulations, many hospitals claimed that compensation could not exceed the reasonable compensation equivalent (RCE) level established by Medicare. In fact, there never has been a legal prohibition against compensating pathologists more than the RCE level. In any event, RCEs generally have been out of date. Indeed, the RCEs were last updated in 1997. (See page 73 for the 1997 RCE amounts.) Whether based on the RCE or some other value, the pathologist should consider seeking a contract provision for automatic adjustment of the stipend for inflation.

More recently, a number of hospitals (particularly those operated by for-profit chains) have sought to require pathologists to agree to provide Part A services for little or no hospital compensation. The ability of the pathologist to resist these attempts will depend on the bargaining strength of the pathologist. A useful argument that can be raised by the pathologist to resist this form of contract is that such an arrangement potentially violates the Medicare antikickback statute. The Office of Inspector General (OIG) has issued a management advisory report indicating that the agreement of a hospital-based physician to provide significant services at no charge or at a greatly discounted charge in return for the ability to bill for Part B services constitutes illegal remuneration in return for referrals from the hospital. (See the OIG regulation, “Financial Arrangement Between Hospitals and

Hospital-based Physicians,” available at <http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>.) Moreover, the 1998 OIG compliance guidelines for hospitals include inadequate compensation for pathologist Part A services as a “risk area” for potential violation of the antikickback laws. (See the OIG regulation, “Compliance Program for Hospitals,” available at <http://oig.hhs.gov/authorities/docs/physician.pdf>.) A violation of the fraud and abuse provision potentially subjects both the pathologist and the hospital to civil and criminal penalties, imprisonment, and exclusion from participation in federal health care programs.

b. Part A Stipend with Incentive Bonus

One of the big drawbacks with the fixed stipend is that it fails to recognize incremental effort by the pathologist. Some arrangements seek to address this deficiency with the addition of various incentive bonus mechanisms. The bonus may be keyed to any number of performance factors, including volume, reduction of costs, productivity, profitability of the laboratory, achievement of certain quality objectives, or the addition of new services.

Some bonus arrangements are wholly discretionary with the hospital. It is also possible to make both the qualification for the bonus and the computation of the amount based on some objective factors set forth in the contract. This reduces the chance that the bonus mechanism may be manipulated by the hospital. Some hospitals seek to base a substantial percentage (eg, 80% or more) of the Part A compensation on the incentive bonus. Such an arrangement can be very risky for the pathologist, especially when the bonus is discretionary with the hospital.

c. Per-test Compensation

Another acceptable arrangement that has been used by some hospitals and pathologists is to base compensation on a series of per-test charges. For example, the pathologist might bill the hospital a professional component of a fixed dollar amount for each clinical laboratory test. So long as the professional component bill is paid by the hospital and not the patient or Part B of Medicare, this arrangement is consistent with Medicare regulations.

The principal advantage of this arrangement is that compensation is tied to the level of services in the laboratory. Unlike the fixed-stipend arrangement, the pathologist’s income increases with increased laboratory volumes. Compensation is thus more closely linked to the professional services of the pathologist. This compensation arrangement also helps reinforce the important professional role of the pathologist in the clinical laboratory.

d. Percentage of Laboratory Revenues

Another possible Part A compensation arrangement that ties compensation to the level of laboratory activity is the percentage-of-revenues method. The hospital and pathologist agree on a fixed percentage of gross revenues or net collections after write-offs for bad debts and contractual adjustments. This method also has the advantage of tying pathologist compensation to the volume of services provided.

Percentage agreements were originally developed as a means of relating the pathologist’s income to workload. The percentage arrangements became less acceptable to institutions after the 1982 provider-based physician regulations capped hospital reimbursement at the RCE level. Under a prospective payment system, however, RCE limits are not applicable.

Some tax exempt hospitals that have had percentage arrangements in the past are now questioning whether the arrangements remain acceptable under recent pronouncements

from the Internal Revenue Service and the Office of Inspector General. In particular, some hospitals are using a general counsel memorandum from the Internal Revenue Service (GCM 39862) as a rationale for terminating existing percentage-of-revenue arrangements with pathologists. The question of the propriety of percentage compensation arrangement for not-for-profit hospitals has not been finally settled, however.

With respect to fraud and abuse, the form of compensation paid to the pathologist should not be cause for concern. The pathologist generally is not in a position to make or influence referrals to the hospital laboratory; instead, the pathologist is a provider of services to the laboratory. There should be no problem with compensating the pathologist on the basis of the volume of work in the laboratory. This is particularly true where the volume of work is a reasonable measure of the services provided by the pathologist.

With respect to IRS concerns, GCM 39862 basically holds that a hospital's sale of its revenue stream to a joint venture of its medical staff constitutes private inurement and jeopardizes the tax-exempt status of the hospital. The rationale of the GCM is that the hospital essentially receives nothing in return for the transaction. The transaction does not support the hospital's tax-exempt purposes.

In contrast, certain percentage arrangements with hospital-based physicians do support the hospital's tax-exempt purposes. Indeed, the IRS has recognized the benefit of some percentage arrangements in the past. For example, in Revenue Ruling (Rev Rul) 69-383, 1969-2 CB 113, the IRS approved a percentage of gross revenues compensation arrangement with a radiologist. In that case, (1) the arrangement was negotiated at arm's length, (2) the physician had no control or influence over the hospital, and (3) the amount received did not represent excessive or unreasonable compensation. Indeed, GCM 39862 recognized the legitimacy of Rev Rul 69-383 in an appropriate case.

Thus, if a pathologist can show that a percentage arrangement satisfies the conditions of Rev Rul 69-383, a percentage compensation arrangement should not jeopardize the tax-exempt status of the hospital. Indeed, in some cases, a strong case can be made for a percentage arrangement. The arrangement is a mechanism for basing compensation on the volume of work in the laboratory. It causes the pathologist to share in the risk of swings in volume. As long as total compensation is reasonable, a percentage arrangement should be acceptable.

On the other hand, if a hospital is intent on avoiding a percentage arrangement, trying to persuade the hospital that the arrangement remains acceptable to the IRS is unlikely to be successful. In view of the concerns expressed in the GCM, some hospitals that supported percentage arrangements in the past now resist those arrangements. In many cases, however, it is possible to structure fee-for-service or bonus arrangements with the hospital, which provides the pathologist with similar economic incentives and benefits as a percentage-of-revenues arrangement.

e. Split Part A Arrangements

Some pathologists and hospitals have entered into an arrangement under which the hospital provides a fixed stipend that is expressly limited to clinical pathology services on behalf of Medicare patients only. The contract expressly recognizes that no compensation is being paid by the hospital for Part A services for non-Medicare patients. The contract also expressly provides that the pathologist is to bill patients or their insurance companies

directly for the pathologist's clinical pathology services (ie, the "professional component" for clinical pathology services).

There is nothing in the Medicare regulations that prohibits this type of arrangement. Many insurance companies have agreed to reimburse pathologists directly for clinical pathology services. However, an increasing number of insurance companies are attempting to follow the Medicare policy and deny payment to the pathologist for clinical pathology services. Some have claimed that the pathologist cannot bill for services unless the pathologist has had hands-on involvement for the particular test, notwithstanding the direct involvement of the pathologist in medical direction and supervision of the laboratory.

In light of the controversy, pathologists should be aware that there is some risk associated with direct-billing arrangements for clinical pathology. At a minimum, the pathologist should be sure that the written agreement with the hospital explicitly states, (1) the pathologist is obligated to provide clinical pathology Part A services for non-Medicare patients, (2) the hospital is not paying any Part A amount for the pathologist's clinical pathology services for non-Medicare patients, and (3) the pathologist is to bill patients directly for all clinical pathology services. Even with an explicit contract, some pathologists have met resistance from some third party-payers. It also should be noted that this type of arrangement may establish a precedent that hospitals do not need to pay pathologists for their clinical pathology services.

f. Per Diem or Per Discharge

Another compensation arrangement that allows compensation to vary according to laboratory activity is the per-diem or per-discharge compensation arrangement. Increases in laboratory activity associated with increased number of patient days or increases in number of patients are reflected in "Part A" payments.

2. Agreements With No or Moderate Capital Investment: Part B Physician Services Compensation Arrangements

Compensation arrangements for Part B physician services are generally more straightforward. An individual bill can be issued to the patient or the applicable third-party payer for physician services to specific patients. The basic questions are:

- Who bills and collects for the physician services?
- If the services are billed and collected by the hospital, how should the pathologist be compensated?

Possible Part B arrangements include:

- a. Direct billing for physician services.
- b. Percentage agreement.
- c. Capitation arrangements.
- d. Salary agreements.
- e. Composite agreements.

a. Direct Billing for Physician Services

Many pathologists seek to bill patients or their insurers directly for Part B services. The right to direct bill gives the pathologist more control over income. It also helps support the pathologist's status as an independent contractor and makes the patient aware of the pathologist's contribution to the diagnostic process.

Billing procedures for the physician services of the pathologist is a major consideration in negotiating compensation arrangements. If the pathologist intends to bill patients for Part B services, the contract should specifically recognize the pathologist's right to do so. It also should require the hospital to provide the pathologist with necessary patient information to facilitate patient billing.

In this manual, the term "direct billing" refers only to situations where the pathologist (or the billing agent) submits a bill directly to the patient or insurers for professional services. Direct billing involves a separate identifiable charge to the patient for services rendered by the pathologist. This practice frees the hospital from the responsibility of paying the pathologist for Part B services.

Direct billing also has significant administrative costs. It requires the establishment of a system to bill the patient and to follow up when bills are not paid. The pathologist will incur capital costs as well as working capital costs associated with the time lag between submission of bills and receipt of payment. The pathologist then bears the risk of collection (bad debt experience) as well as the expense of dealing with third-party payers.

Direct billing, of course, must be done in a manner that complies with Medicare rules. For example, Medicare will not pay a professional fee for pathologist evaluation of clinical laboratory tests in the hospital unless specific requirements for the provision of clinical pathology consultations and clinical pathology interpretive services are met. Medicare does pay professional fees for Part B services, which include anatomic pathology services, clinical pathology consultations, clinical pathology interpretive services, and certain hematology and blood bank services. Competent professional advice should be obtained prior to embarking on direct billing. The advice of an accountant, attorney, or business consultant can be helpful. Particular care should be taken to make sure there is compliance with Medicare rules as well as the requirements of private third-party insurance companies. The success of direct billing also is dependent on patient acceptance of the system. The patient must understand that the fee charged represents direct physician services in connection with the diagnosis and treatment of the patient.

b. Percentage Agreements

If the hospital and pathologist decide to have the hospital bill patients for the pathologist's Part B services, the pathologist will need to negotiate a Part B compensation arrangement with the hospital. A hospital that compensates the pathologist for Part B services has the right to bill for these services if the pathologist agrees. The Medicare Part B carrier pays the hospital for these services.

One type of Part B compensation arrangement that is possible when the hospital bills for these services is a fixed-percentage arrangement. Under these arrangements, the hospital pays the pathologist a fixed percentage of either billed or collected professional charges. It should be noted, however, that questions may be raised if the amount retained by the hospital exceeds reasonable billing, collection, and administrative costs. Under these

arrangements, it could be argued that the additional amount retained by the hospital is remuneration in return for referrals, in violation of fraud and abuse laws.

c. Capitation Arrangements

Under a capitation arrangement, the pathologist is asked to provide specified services to managed care organization (MCO) enrollees for a fixed payment, regardless of the amount of services the patient utilizes. This payment is often specified on a monthly basis per enrollee, or a per-member per-month (PMPM) rate. To the extent that physician payment moves from fee-for-service to capitation, the risk for the cost of providing services is shifted from the insurer to the pathologist. The pathologist takes the risk that utilization and costs may be greater than anticipated when the capitated contract was accepted.

Detailed utilization data are essential in estimating practice costs and assessing the risk pathologists face under capitation. The MCO initiating the capitation request is an obvious source of utilization data. In many cases, however, the MCO does not have or is unwilling to provide the information. In this situation, the pathologist may wish to suggest a trial period during which the pathologist provides services on a fee-for-service basis. The advantage of this approach is that the actual utilization rates for the MCO's enrollees can be determined through encounter experience. In addition to estimating utilization, pathologists should carefully consider other steps that can be taken to limit and manage financial risk under capitation. Stop-loss insurance, carve-out of services that present the greatest risk to the practice, and contract provisions that allow renegotiation of rates if utilization is unexpectedly high are examples of ways to manage the risk. Capitation arrangements for anatomic pathology services (other than certain cytopathology services) are uncommon.

d. Salary Agreements

Another alternative that is available for compensating the pathologist for Part B services when the hospital is responsible for billing and collecting is a salary, possibly including performance bonuses. Salary arrangements are also the most common method of compensation in some circumstances (eg, government hospitals).

It is just as essential for a pathologist who is remunerated by a salary to negotiate an employment agreement or contract with the institution as it is for a pathologist operating under any other form of institutional relationship. A contract will provide security for both parties, help to answer questions before they arise, and may provide the basis for a lasting, mutually beneficial working relationship.

A major risk of a salary arrangement is the uncertainty of arriving at satisfactory periodic adjustments. Some mechanism for periodic review of salary levels, therefore, should be provided. A schedule of salary increases related to workload and cost of living may be written into the contract.

The essential elements for all types of agreements are fundamentally the same. Thus, a salaried pathologist should be provided with an adequate departmental personnel budget, adequate space and equipment, and high-quality supplies. The contract should provide that the pathologist should define the standards for technical employees and recommend the hiring and firing of employees, subject to institutional personnel policies. In short, a salary

agreement should include a modified form of the elements of an agreement, previously discussed in this manual.

A salary agreement should also detail the following items peculiar to a strict employee-employer relationship.

- Income tax withholding and social security payments.
- Retirement program.
- Hospitalization, health, and accident insurance.
- Paid annual vacation (the employer should be responsible for the compensation of a vacation substitute).
- Paid sick leave.
- Public liability and malpractice insurance, including tail coverage (premium should be paid by the employer because of the master-servant relationship inherent in a salary agreement).
- Dues for professional societies.
- Allocations of funds to allow the professional and technical staff to attend scientific meetings.
- Purchase of scientific books and subscriptions to professional periodicals.

In addition, employment status gives the pathologist rights under federal and state antidiscrimination laws.

e. Composite Agreements

It is possible to develop a composite or combined agreement under which different methods of compensation are used for different aspects of the pathologist's services. Each of the pathologist's activities may be treated separately in selecting the method of remuneration. By incorporating the various elements of several different remunerative patterns into a single contract, the combined agreement can offer considerable flexibility to both the pathologist and the institution in the development of a sound and rewarding contractual relationship tailored to the needs of the parties.

3. Agreements with Major Capital Investment by the Pathologist

In a number of cases, the pathologist assumes all or a portion of the considerable capital and overhead costs associated with a laboratory. In return for being responsible for the technical component, the pathologist obviously must recover these costs through some appropriate billing arrangement. Possible models for such arrangements that are discussed in this section are:

- a. Leases.
- b. Independent laboratory agreements.
- c. Joint ventures.

a. Leases

Prior to 1983, hospital laboratory lease arrangements were reasonably common. Under the lease agreements, the pathologist bears all or a major portion of the fiscal responsibility for the department. The pathologist would agree to pay the institution for space and utilities at a fixed monthly rate. Some agreements would require the pathologist to pay a fixed fee for the privilege of operating a laboratory in a hospital without formal lease conveyance of the space occupied. With a shift to the prospective payment system, however, such lease agreements are less attractive.

Under lease arrangements, the pathologist bears the cost of the equipment and provides supplies and the necessary personnel. In essence, these arrangements shift some of the business risk of the laboratory from the hospital to the pathologist. Under Medicare regulations, the operating and capital costs of hospital departments in which the physician furnishes services to hospital patients are covered by Part A payments of the Medicare program to the hospital. Therefore, if a pathologist assumes some or all of the operating costs of a hospital department under a lease arrangement, these costs must be recovered from the hospital; they cannot be billed by the pathologist to Part B of the Medicare program. Thus, the contract should provide for payment by the hospital of a fee to cover the costs incurred by the pathologist in operating the leased laboratory.

As discussed under the above section, “Direct Billing for Professional Services,” agreements with major capital investment by the pathologist should also specify how Part B services will be billed. Medicare rules allow direct billing by the pathologist, or separate billing by the hospital if the hospital compensates the pathologist for Part B services. The rules of the third-party payers should also be considered in determining appropriate methods for billing for Part B services of the pathologist. In most circumstances involving major capital investment by the pathologist, the pathologist direct bills for these services.

b. Independent Laboratory Agreements

Another alternative by which the pathologist bears the business risk of the laboratory is by establishing an independent laboratory. Under Medicare regulations, a laboratory must not be a “provider-based” laboratory to be considered as an independent laboratory. The laboratory and pathologist then contract with the hospital to provide necessary coverage and services through the independent laboratory.

The pathologist operating an independent laboratory enters into an agreement with the hospital to provide laboratory services. Since the Medicare regulations prohibit billing patients for Part A services, the independent laboratory bills the hospital for the Part A services that the independent laboratory performs. The hospital then bills the patient or the patient’s insurer for these services. The independent laboratory must comply with non-Medicare third-party payer rules.

The pathologist operating an independent laboratory directly bills Medicare and non-Medicare patients for Part B physician service. In many cases, the independent laboratory also services a number of hospitals and physicians’ offices.

c. Joint Ventures

Ventures between hospitals and pathologists afford numerous possibilities both for increasing market position and controlling costs. These ventures may take the form of joint efforts to

market laboratory services to other health care providers, such as physician offices, ambulatory surgical centers, and health maintenance organizations. Some pathologists provide anatomic pathology services to nonhospital patients from the hospital laboratory. The pathologist purchases the technical component (eg, supplies and slide preparation) from the hospital and bills the patient (Medicare and non-Medicare) for the professional interpretation and the technical component. In other cases, the hospital and pathologist might create a joint marketing organization to market outreach laboratory services. In still other cases, the hospital and pathologist might create a venture to operate a centralized laboratory for both hospital and nonhospital laboratory testing.

The pathologist should seek competent legal and business advice before entering into a joint venture business relationship. In particular, it is important to structure arrangements to comply with statutory and regulatory developments. For example, the Medicare program prohibits a physician with an ownership interest in a laboratory from making referrals to that laboratory. Thus, no physician who makes referrals to a laboratory should have an ownership or other financial interest in the laboratory.

Another issue that may be raised by some hospitals is whether hospital participation in a joint venture might jeopardize the hospital's tax-exempt status in light of recent pronouncements by the IRS. The law on this issue is still evolving. In general, however, it would appear that hospital participation in a joint venture that lowers the hospital's costs and is structured on a fair-market-value, arms-length basis should not jeopardize the hospital's tax-exempt status. It probably is necessary, however, to have the joint venture provide lab tests to the hospital at a price that reflects the cost savings associated with the venture in order to minimize the chance that the arrangement could be construed as private inurement.

Pathologists also need to focus on the business elements of a joint venture proposal. Joint ventures create a business relationship in which the parties share economic risk and reward. The pathologist must weigh and balance the potential rewards against the risks assumed. Key issues to consider in a joint venture involving laboratory services are:

- *Basic objectives.* What are the objectives of the venture? How will attainment of objectives be evaluated? Is there a long-range business plan?
- *Control.* Will the venture be a 50/50 partnership? How will key operating decisions be made? What is the relationship of the hospital to the new venture? Will other medical staff members have a stake in the venture?
- *Deadlocks.* How will potential deadlocks on the board be resolved? Are the objectives of the hospital sufficiently close to the objectives of the pathologists to create a common vision?
- *Structure.* What kind of legal entity will be formed—a partnership, a limited liability company, a new corporation, or a subsidiary of an existing entity? Will the new organization be for profit or nonprofit? Will the new entity be a hospital laboratory or an independent laboratory?
- *Legal constraints.* What are the antitrust implications? What about the potential for allegations of fraud and abuse violations?

- *Financial aspects.* How will the joint venture be capitalized? What are the start-up costs? How will revenues and expenses be allocated?
- *Buy-out issues.* If the parties are deadlocked, who will have the right to buy out the other party? How will the buy-out price be determined?

All of these issues should be considered and resolved before the parties embark upon the venture.

II. Practice of Pathology in Groups

A. Relationships Among Pathologists

When pathologists engage in joint practice, there necessarily will be a division of duties and responsibilities. The managing partner should speak for the group in business negotiations and should be responsible for most of the day-to-day administrative duties. The head or chief pathologist of a department in a hospital should be selected by the pathology group holding an exclusive contract and should be appointed in accordance with medical staff bylaws. In academic departments or where there is no exclusive contract, the department head should be selected in accordance with medical staff bylaws.

Some department chiefs step down from their position several years before their anticipated retirement so that another pathologist can gain experience in management while the retiring member is still available to give support and counsel. A few groups apportion or rotate these duties among the members. As in any group endeavor, it is important to ensure that members' assignments suit their qualifications. All members of a group should recognize that administrative duties are time consuming. Work schedules should be adjusted accordingly.

Group practice allows its members to subspecialize and provide a wider range of services than would be possible otherwise. Since some subspecialties produce more direct revenue than others, an income distribution plan must give fair credit for work that is necessary but produces little or no revenue. Most groups negotiate agreements under which each member is remunerated in proportion to their contribution. Other practices recognize the diversity of practice settings within the group and share income equally after a group member has reached a benchmark, such as equal partnership. Productivity of each member is then evaluated internally for the purpose of sharing the workload equitably. This will ensure the integrity of relationships within the group and with any institution the group serves.

In some arrangements, pathologists may enter into a formalized agreement with the chief pathologist, who in turn holds the contract with the institution. Alternatively, a pathology group as an entity may hold the contract with the hospital. Under the latter arrangement, the individual pathologist members of the group may or may not be named in the contract.

A single contract between the institution and a group of pathologists often reduces conflicts among pathologists. In those circumstances in which separate contracts between the institution and individual pathologists are unavoidable, each contract should contain provisions delineating each pathologist's responsibilities and should specify which pathologist is responsible for running the department. Such provisions should be drafted to circumvent potential conflicts among the individual pathologists.

Not uncommonly, pathologists are employees when they first join a group. After a specified period of time, they may be offered a partnership. It should be clear to all parties what the duration of "employee" status is likely to be and what factors will be considered in determining whether or not the pathologist will be made a partner.

B. Agreements for Association Among Pathologists

Where pathologists practice in a group, it is important that these associations be formalized in written agreements for the benefit and protection of all concerned.

While there are many advantages to association, pathologists also should assess the drawbacks before entering into any agreement. Members of groups should be prepared to temper their individuality, and each should be willing to work for the sake of the mutual endeavor. Among the advantages of group practice are readily available consultation and the opportunity for more specialized practice. Coverage of service is continuous, since one or more pathologists should always be available. A solo practitioner may not have these advantages and thus may have more difficulty satisfying the needs of the institution.

Advantages of group practice include economies of scale with regard to administrative and technical costs; income security for each member in case of sickness; and increased opportunity for participation in research, postgraduate education, scientific meetings, and recreation.

Successful group practice is predicated upon the sharing of responsibilities and benefits in a mutually acceptable manner. Income should be equitably distributed among the members of the group, and members should be treated fairly in the allocation of vacations and in the opportunity to attend scientific meetings. In order to achieve effective and efficient group management, a single member of the group often assumes overall responsibility for administrative duties. In many groups, this is a permanent position, while in other groups, it is rotated or shared among several members with administrative expertise. In larger group practices, especially if operated as a professional corporation, administrative duties are shared among the group's elected officers and executive committee. The time and effort associated with these duties must be considered in any determination of work and should also be considered for additional compensation.

There may be increased legal liability in group practice, even in the absence of a written agreement, since each member is included in the business and professional obligations of all. A written agreement among pathologists practicing in an association is therefore essential and must be legally sound. It must be drawn by a well-qualified attorney. One somewhat controversial issue that often arises in these agreements is a covenant not to compete.

In group practice, new members eventually should be given the opportunity to share in the ownership of capital assets, based on the group's assessment of their performance and contribution to the practice. This ownership may be acquired over a specified period of time. In the corporate form of practice, specified purchases of stock may be spread over a period of years. Whatever manner of buy-in is agreed upon should be spelled out in the employment agreement.

Capital assets consist of the current value of equipment, holdings (real estate, stocks, bonds, etc), cash, and current accounts receivable, minus uncollectibles and costs of collection. Good will may be highly nebulous as a capital asset and difficult to value. Similarly, contracts, no matter how long-standing, are always subject to termination. Hence, their value as a long-range asset is limited.

The following contains a discussion of partnerships and professional corporations. Both have advantages, and the form to be adopted can best be determined only with guidance

from appropriate legal and tax counsel. Since state laws vary widely and tax laws are subject to varied interpretations, sound legal advice is important.

C. Special Considerations for Pathologists Recently Completing Residency Training

The majority of pathologists, after completing their residency training, will join an established pathology group. Many will do so aspiring to become a partner, whereas others desire a more traditional employee/employer relationship. Residents should objectively analyze the alternatives of practice arrangements in the pursuit of their career objectives.

1. Personal Prioritization and Checklists

Before beginning the task of seeking a position, a certain amount of introspection should be undertaken to prioritize personal preferences and to ensure future job satisfaction and success. Many factors must be considered, including family desires, community characteristics, and professional interests (academic versus private practice pathology, etc).

It is wise to keep a personal checklist describing each practice when evaluating employment opportunities. Obvious observations, such as workload and lifestyle, are usually easy to remember. The technical support, the degree of sophistication, and the range of expertise of the staff in the laboratory are also important factors to consider. The status and relationships that the pathologists share with each other, the technologists, hospital administrators, and clinicians should not be overlooked. The degree of competition between pathology groups or between hospitals may also make the seemingly “perfect” job less ideal. Moreover, the payment practices of local insurers may be a relevant consideration. The overall quality of the laboratory is obviously important. CAP accreditation and opinions of the laboratory clients can prove valuable. It is not unreasonable to request that the director of the laboratory permit you to review the most recent CAP inspection report.

2. Group Dynamics

By necessity, the relationship one has with associates is often close. It is therefore wise to focus on group dynamics during the application and interviewing process. Interviewers also will be determining if a candidate will “fit in” with the rest of the group.

Group dynamics change significantly between small and large organizations. Applicants should evaluate their own personality characteristics to determine which type of group best suits them. Some individuals may work well in a larger group, which might be less flexible and more structured. On the other hand, some may thrive in a smaller group, in which they might have a larger voice in group decisions (although it may be more difficult to arrange vacation coverage, etc).

Applicants should also determine which type of practice arrangement best suits their goals. For some, it may be important to be directly involved in the operations of the group as a partner. Others may prefer to work as an employee and practice pathology without numerous other business concerns. It is important to discuss these issues with practicing pathologists in both private and academic settings. Attending national and regional pathology society meetings is an excellent way to accomplish this. Residents may want to review an American Medical Association publication catalog for recent publications that

provide useful information on employment contracts and other matters of interest to residents seeking a new position.

3. Position Analysis

When assessing a specific opportunity, the prospective employee/partner should ask why a position is available and what is expected of the newly-hired pathologist position. If the opening is due to a recent vacancy, it may be wise to contact the individual who has just left to learn more about the organization and their reason for leaving. It also may be wise to inquire about the employment history of the group. Rapid turnover may be a sign of an unpleasant working environment, unstable business situation, compatibility problems, substandard remuneration/benefits, or other causes of employee/partner dissatisfaction. Strong national pathology associations have made networking with other pathologists an excellent way to learn about potential partners as well as possible potential problems. Many groups use this resource. Residents can also use this method to identify strengths and weaknesses of possible future associates. Residents are also encouraged to learn more about the many special considerations of group practice. If one is evaluating a position with a multihospital pathology practice—especially if the hospitals are small—be aware that there may be significant potential management responsibility as a sole pathologist in a small hospital. These management skills are rarely taught in pathology training programs and must be acquired through experience.

Most applicants and groups look for a long-term arrangement. Nonetheless, despite careful planning, some arrangements may prove unsatisfactory. Residents should be aware of this and prepare accordingly.

4. Negotiations/Contracts

When an applicant is seriously considering a position, negotiations ordinarily occur to resolve differences between the applicant's and the group's expectations. Contractual negotiation is a process for which a pathology resident may have little experience or training. It must be remembered that compromises are common. To avoid future misunderstandings, the proposed agreement should be in writing. When the proposal is agreeable to both parties, a contract should be drafted, traditionally by the group's attorney. It is recommended that the applicant also seek legal counsel's advice on the document to help prevent misinterpretation. Attorneys specifically trained in contract law involving hospital-based physicians are recommended.

Details, such as future salary increases, terms of becoming a partner, and other significant provisions of the contract, should be discussed to the satisfaction of all parties. Only after all the details of the contract are understood should it be signed. Sample contracts are available to CAP members. They may be ordered on the CAP Web site or by calling Customer Service at 800-323-4040, option 1#. It should be stressed that, although an acceptable contract gives a sense of security to those signing it, it does not replace trust. Trust is the bedrock on which all contracts are based.

D. Forms of Group Practice

1. Partnership

In a partnership arrangement, two or more physicians agree to conduct their practice under terms by which they participate mutually in profits and losses. In recent years, partnerships have become more attractive as the amount of funds that can be set aside under the Keogh plan has been increased (currently 25% or \$30,000 annually, whichever is less). Thus, those involved in partnerships are able to set aside significant pre-tax retirement funds, while benefiting from fewer legal restrictions than those involved in a professional corporation.

The provisions and conditions of partnership should be spelled out carefully in a written partnership agreement. Partnership agreement provisions generally address ownership of assets, capitalization, division of income, professional expenses, accounting procedures, vacations, professional meetings, disagreements, death benefits, expulsion, life insurance, disability, dissolution, and other items that might pertain to special situations.

The partnership agreement should specify clearly which income is partnership income and which is separate income to the individual. The partnership may decide to include all fees for professional services as partnership income, while excluding royalties on publications, lecture fees, military service benefits, and the like as individual income. In any case, the question should be addressed openly, and the details put in the partnership agreement.

It is advisable that the agreement incorporates a buy-and-sell clause to provide for the continuation of the partnership upon the retirement, withdrawal, or death of a partner. Otherwise, the partnership terminates when a partner dies or withdraws, and a new partnership must be established. In any such buy-and-sell agreement, it is unwise to place an unrealistically high value on intangibles, such as contracts and good will. An important consideration when evaluating the partnership structure is liability. Each partner generally is jointly and severally liable for claims against the partnership. To some extent, of course, this risk can be mitigated through adequate insurance.

2. Professional Limited Liability Companies

A comparatively recent form of organization for business is the limited liability company (LLC). In essence, an LLC combines the tax and operational features of a partnership with the limited liability of a corporation. With respect to the tax aspects of the LLC, each member of the LLC generally is taxed on the member's share of any earnings of the LLC, without regard to whether there has been any distribution of earnings. The LLC itself generally is not separately taxed. This avoids the double taxation on the profits of an entity that occurs with the corporate form.

As for liability, the owners of an LLC generally are only at risk to the extent of their investment in the LLC. The personal assets of the members of the LLC generally are not subject to the claims of creditors of the LLC (except to the extent that the claims may relate to the individual liability of a physician member of a professional limited liability company [PLLC], as discussed below). There also is more flexibility in structuring the governance and operations of an LLC as compared to a corporation.

An LLC generally is formed by drafting the operating agreement for the LLC, and making appropriate filings with the state and the Internal Revenue Service. The operating

agreement sets forth the organizational structure, governance, and income distribution methodologies for the LLC. The operating agreement is much like a partnership agreement but also shares some characteristics with the articles of incorporation and bylaws of a corporation. The investment of each member is credited into a capital account for that member. Any earnings that are not distributed to the member are also credited to the member's capital account.

Whether the LLC form can be used as the legal structure for a physician group depends on state law. As is the case with the corporate form, the LLC structure generally can only be used for a physician practice to the extent that state law recognizes PLLCs, and then only when specific state requirements for the creation and maintenance of the PLLC are satisfied. Generally, only licensed physicians are authorized to be members of a PLLC.

As is the case with the professional corporation discussed below, state law generally limits the limited liability protections available to a professional who elects to practice in a PLLC. In particular, the PLLC structure cannot be used to limit the liability of a physician for the professional liability that might result from that physician's own actions. However, the PLLC structure may in certain cases limit the liability of other members of the group in connection with a claim against another physician in the group. In the partnership structure, each of the partners generally has unlimited joint and several liability for any professional liability of anyone employed by or associated with the group. Under the PLLC structure, however, a member of the PLLC may have unlimited liability for that physician's professional liability but is only at risk to the extent of the physician's investment in the PLLC with respect to claims relating to services provided by other physicians associated with the PLLC.

In certain cases, the PLLC structure may not be as desirable for a physician practice as the professional corporation structure described below. That is because the PLLC generally will be taxed as a partnership. For many years, the tax provisions applicable to partnerships were somewhat less advantageous for a physician group seeking to maximize the deductibility for such expenses as health insurance and certain other benefits. Those differences, however, are largely being eliminated.

The PLLC/LLC structure can offer long-term advantages in the event of certain contemplated future sales. More specifically, the PLLC/LLC structure can be useful to reduce taxes in the event of a sale of the assets of a practice in a transaction which otherwise would involve a substantial amount of taxable gain. Thus, the PLLC/LLC structure often is used by practices that are contemplating an eventual sale of the assets of their practice to a physician practice management company or a hospital. A practice that believes it is likely that it will at some point seek to sell its assets in such a transaction might consider whether the desire to avoid double taxation of profits in the event of such an asset sale by the practice outweighs the tax downside of an LLC structure (relating to the deductibility of health insurance premiums and certain other benefit costs). Most practices that do not contemplate an asset sale opt for the professional corporation structure.

3. Professional Corporation

Another organizational alternative is to form a professional corporation. A professional corporation may be formed either by a solo practitioner or a larger group. Members of a group can each individually incorporate, and the individual corporations can form a

partnership, ie, a partnership of corporations. Incorporation generally requires reserving a name, filing the Articles of Incorporation or Corporate Charter, and paying the initial filing fees. The corporation will need to pay annual fees to the Secretary of State, maintain separate accounts, and file separate tax returns.

A group of pathologists can join together as a professional corporation (or as a partnership) and enter into a contract with the hospital to provide services. Another alternative is for a pathologist to contract with the hospital as an independent contractor and then subcontract with other pathologists as independent contractors. Either arrangement is acceptable.

The corporation then will need to adopt corporate bylaws that set forth the duties of the officers and the manner in which the corporation will conduct its business. The corporation will need to maintain a board of directors that holds regular meetings documented by minutes. The corporation also will need to adopt appropriate corporate resolutions for major decisions.

After the corporation is formed, it is capitalized through the sale of shares. Shares may be sold in exchange for cash or other assets that have a value to the corporation. The amount of capital required will be determined by the business needs of the corporation.

To qualify as a professional corporation in most states, the shares generally can only be owned by other physicians or, in some cases, by the immediate relatives of the physicians. Each shareholder will maintain a tax basis in the shares acquired equal to the value of the consideration initially paid for the shares. The shareholders will experience a taxable gain when the shares are subsequently sold to the extent of the difference between the sale price and the taxpayer's basis in the shares.

The modest tax advantages discussed below are available only if the corporation is established as a taxable C Corporation. This means that the income of the corporation will be taxed once at the corporate level and again at the individual shareholder level when the earnings are distributed as dividends. To avoid this double taxation, most professional corporations are operated with very little income. The revenues of the corporation from physician fees closely match the expenses of the corporation, including salaries to physician-employees. If the corporation has additional earnings, it generally will pay physician-employees an end-of-year bonus. End-of-year bonuses calculated on the basis of revenues derived from physician services to the corporation should be defensible as reasonable compensation for physician services and not considered to be a disguised dividend.

All of the physician-shareholders will be employees of the corporation. Their compensation will be in the form of salary and end-of-year bonus. The corporation will be responsible for withholding taxes, paying the employer portion of FICA taxes, and providing benefits for all employees.

It is advisable for the corporation to enter into written employment agreements with each of the professional employees. The agreements will set forth the duties and obligations of each employee and will delineate the base compensation, bonus terms, vacation and CME time, and fringe benefits available to each employee. Depending on the desires of the parties and the enforceability of such clauses under state law, the contract also can include a noncompete clause.

Finally, it generally is advisable for the parties to enter into a shareholder agreement. The shareholder agreement can include special governance and shareholder voting

provisions. It also should include provisions addressing the circumstances under which the corporation or the other shareholders will repurchase the shares of each shareholder. For example, a typical provision will require such a purchase and sale in the event that the employment of a pathologist is terminated, or the pathologist retires or is deceased or disabled. The provision also should include a restriction on the transferability of the shares and a right of first refusal if one of the shareholders should seek to transfer the shares.

4. Advantages of the Professional Corporation

The principal reasons to consider forming a professional corporation are tax benefits and liability considerations. Both of these considerations are discussed below. Each pathologist will need to consider whether these potential advantages justify the expense and burden of forming and maintaining a professional corporation.

a. Tax Advantages

The Internal Revenue Code provides some tax benefits to a professional corporation that is maintained as a tax-paying C Corporation. These tax advantages are not available, however, to a professional corporation that is established as an S Corporation under the Code or to a PLLC. Both S Corporations and PLLCs generally are treated as partnerships for tax purposes.

In particular, an individual employed by a professional corporation can exclude from personal income the cost of certain benefits that are paid for by the corporation. If the same benefits are provided by a partnership or PLLC to the partners, the cost of the benefits is not excluded from income. Specific benefits that qualify for this exclusion include the following:

- The cost of the first \$50,000 of group life insurance coverage paid for by the corporation.
- 100% of the cost of premiums on health insurance that are purchased by the corporation. (In recent years, the tax code has been amended to permit partners and owners of LLCs to deduct an increasing percentage of the cost of health insurance premiums. Ultimately, partners will be able to deduct the same 100% as corporations.)
- Payments toward a corporation-sponsored Cafeteria Plan.

Prior to 1984, professional corporations could provide physician employees more advantageous pension plan arrangements than a partnership. Those differences have been eliminated. Thus, the principal tax advantages of a professional corporation are those listed above.

In order to qualify for the foregoing benefits, the professional corporation generally will need to satisfy various nondiscrimination rules. These generally require the coverage of most qualifying employees, including physicians who have not yet become shareholders and lower paid support employees. In some cases, the cost of covering other employees of the professional corporation may exceed the value of the tax benefits for the physician shareholders.

b. Liability Considerations

Neither a professional corporation nor a PLLC can shield a physician from a professional liability action brought against that physician. Thus, the personal assets of the individual physician are potentially at risk in any action brought against an individual pathologist, regardless of whether the pathologist is a partner in a group, a member of a PLLC, or an employee of a professional corporation. Either a professional corporation or a PLLC may, however, shield a pathologist from a claim brought against another pathologist who practices in the professional corporation or PLLC. A pathologist who is a partner in a pathology partnership, however, is at risk without limitation for any action brought against the partnership.

The foregoing advantage of a professional corporation, however, may be more theoretical than real. Initially, partners can take a number of steps to protect their personal assets. Adequate professional liability insurance can substantially reduce this risk. In a state with a patient compensation fund, maintaining the levels of insurance required to qualify for the protections of the fund generally will eliminate the risk to personal assets. If partners have substantially equal amounts of assets, they can enter into cross-indemnification agreements to protect against a judgment relating to the activity of the other partner. Of course, the value of an indemnification agreement is dependent on the indemnifying party having sufficient assets to protect the indemnified party.

Moreover, in many cases, a plaintiff can circumvent the barrier of a professional corporation or PLLC through artful pleading. For example, the plaintiff may allege that all of the other physician employees of the professional corporation or PLLC were themselves negligent in their supervision, selection, and/or employment of the physician who was directly responsible for the malpractice. It also may be possible for a plaintiff to “pierce the corporate veil” if the parties did not sufficiently adhere to the requirements of the corporate form or if the corporation was not sufficiently capitalized.

5. Disadvantages of the Professional Corporation

a. Cost of Establishment and Maintenance

There are several expenses that must be met in the formation of a professional corporation. The largest is probably the fee of an attorney skilled in the details of corporate law as it applies to professional corporations. The costs vary depending upon the size of the group, but an initial expense of \$2500 to \$5000 per physician-shareholder should be anticipated. Accounting and additional legal fees may be substantial, depending on the size and tax structure of the professional corporation, and should be expected to continue at a significant level during the life of the corporation.

b. The Constraints of Corporate Behavior

An incorporated group of physicians must act like a corporation. Meetings must be scheduled, detailed minutes must be kept, employment agreements must be executed between each pathologist and the corporation, all corporate policies must be documented, and IRS and Department of Labor (DOL) reports must be filed carefully.

Many pathologists, of course, receive most of their income under the terms of a contract between the hospital and the pathologist. If incorporation is to result in the

intended financial advantage, such contracts usually must be rewritten between the hospital and the corporation. Such a change may be difficult to accomplish in some situations, but it is essential if the full tax advantages of the corporation are to be attained.

c. Limitations Imposed by Cash Flow

Despite the tax advantages, it may be impractical to incorporate if net corporate income is insufficient to maintain an adequate professional salary schedule. Incorporation may not be advisable if the physician cannot afford to divert funds regularly into a retirement plan. This, of course, is a matter to be evaluated with the help of counsel.

d. Cost of Inclusion of Nonprofessional Employees

Pathologists with large numbers of employees may find that the cost of including these employees in the pension and profit-sharing plans outweighs the advantages to the pathologists themselves. This factor may be minimized by coordinating the plans with social security benefits.

e. Forfeiture of Benefits

The pathologist who leaves a corporation before becoming fully vested in such benefits as pension plans obviously loses some or all of the benefits upon departure. Early vesting may lessen this cost and permit an associate or employee to leave an undesirable association without penalty. Early vesting also may reduce the appearance that the shareholders are “dumping” employees in order to retain these corporate benefits. However, a pathologist who is not sure of a reasonably permanent association with the group should not become a shareholder.

f. Investment Management Problems

The management of the retirement funds of a professional corporation may give rise to dissension among the shareholding members. One member may favor high-risk, high-yield investments; another may prefer a more conservative approach. The problems of money management may create serious tensions and irreconcilable differences among the shareholders. In defined contribution plans, this may be obviated by creating individually managed (earmarked) accounts.

g. Attitude of the Internal Revenue Service

Although many IRS rulings have recognized the validity of the professional corporation, the concept will remain under close scrutiny. Continuing vigilance will be required to ensure that all future regulations are met. TEFRA rules are important for federal and state partnerships of corporations and for a corporation providing service to a single entity.

h. Double Taxation of Surplus Profits

If surplus funds are paid out as dividends, personal income tax also must be paid on these funds, which have already been subject to corporate taxation. Some physicians have formed “Subchapter S” corporations, which are taxed only as partnerships, but these do not have the other benefits of the “Non-Subchapter S” corporations, as represented by this review.

i. Age Limitations

Older members of a group may not find it advantageous to form a professional corporation if they will be unable to accumulate sufficient funds in their plans prior to retirement. This decision should be subjected to thorough actuarial analysis.

j. Workers' Compensation Costs

Most states require corporations to maintain workers' compensation insurance for all of their employees, including professional employees. The cost of this premium should be considered in evaluation of corporate expense.

k. Personal Holding Company Pitfall

In order to avoid classification as a personal holding company, it is essential that all contractual arrangements be consummated between the corporation, rather than an individual employee pathologist, and any institution or organization served by the corporation.

l. Cost of Liquidating the Corporation

There will be significant legal, accounting, and tax costs in disincorporation. Costs of partnership formation or other resulting arrangement must be considered. The decision to incorporate is complex.

This summary cannot do more than outline the ramifications to be evaluated. A pathologist considering a professional corporation should seek the most competent legal and accounting advice available. The professional corporation is not for everyone, but obviously it has worked well for many physicians.

E. Consolidation of Pathology Practices

Advances in technology, managed care, and shrinking payments are rapidly changing the practice environment for all physicians. In the case of pathology groups, the risks and challenges of practice in a rapidly evolving health care system are many:

- Competing for and obtaining managed care contracts.
- Dealing with declining reimbursement and capitation.
- Losing long-standing hospital contracts as the result of hospital consolidations.
- Take-it-or-leave-it hospital contract offers.
- Loss of competitiveness due to inability of a hospital or medical staff to obtain managed care contracts.

In the current competitive environment, many smaller pathology groups are finding it necessary to combine with other groups. This is especially true in cases where the hospitals served by separate pathology groups have themselves consolidated. The consolidated hospitals tend to encourage or require the pathology groups servicing the new system to consolidate. Such consolidations may permit the new group to compete more effectively for managed care contracts, cover several hospitals, operate a centralized laboratory, manage the risks of capitation, or otherwise weather the economic storms facing all of medicine.

It is advisable for pathology groups seeking to consolidate to form a working group or committee composed of representatives from each group, with knowledgeable consultants to advise the committee. The working group should initially consider the appropriate structure for the new entity. An important issue is whether any consolidation of practices should be complete or partial. There are numerous structure options, including a fully-integrated new professional corporation, a partnership of old professional corporations, or a new professional corporation with transitional governance and compensation arrangements to ease the way to full integration. The consideration of the new group's structure allows the committee of pathologists to begin thinking about governance, control, and economic issues, which are the most important considerations in structuring any consolidation.

After the working group agrees on an overall structure, it then needs to turn its attention to conceptual resolution of governance and economic issues. In resolving these issues, the group should work with experienced counsel, who can make suggestions and recommendations. It is important for the working group to be actively engaged throughout this process to ensure that a workable structure is developed. Ultimately, the success or failure of the new group will be determined by the ability of the pathologists to work together in an organization reflecting the corporate culture of the group.

III. Relations Between Pathologists and Other Physician Groups

New concepts in the delivery of health care have made it necessary for pathologists to develop relationships with many different types of groups. The pathologist may:

- Be a member of a medical group practice.
- Serve as an independent contractor providing services to a medical group practice.
- Provide services to a health maintenance organization or other managed care organization.

A pathologist may relate to these groups, regardless of their internal organization, either as a member of the group or association, or as an independent contractor of services. Arrangements with any such groups or organizations should be formalized only after careful consideration of federal and state laws and regulations, particularly those relating to fee splitting, self-referral prohibitions, and the corporate practice of medicine.

A. The Pathologist as a Member of a Multispecialty Medical Group Practice

A medical group practice is defined by the American Medical Association as the application of medical services by three or more physicians, formally organized to provide medical care, consultation, diagnosis, or treatment through the joint use of equipment and personnel, and with the income from medical practices distributed in accordance with methods previously determined by members of the group.

The patterns for remuneration of physicians may vary greatly, since the groups vary from simple partnerships or professional corporations to complex organizations in which subsidiary corporations or foundations provide medical services, real estate, equipment, research, and other facilities. Any new member joining such a group usually will serve a probationary period of one or more years, during which the environment and mutual compatibility may be assessed before the parties enter into a long-lasting legal relationship. During this period, the new member usually will be an employee of the group, usually compensated by salary. This new member should have a written agreement, however, that not only covers responsibilities and compensation during the probationary period but also sets forth the details and criteria for advancement to full participating membership. These considerations should be discussed candidly and in detail at the outset of the employment arrangement, with consideration of the advice of legal counsel. Care should be taken to ensure that the conditions of capitalization do not impose an unreasonable financial burden on an incoming member.

B. The Pathologist as an Independent Contractor of Laboratory Service (Without Group Membership)

In this type of practice, the pathologist may be called upon either to provide professional services in a laboratory owned and operated by a medical group, or independently through the pathologist's laboratory. In this practice scenario, the pathologists must be particularly aware of the self-referral prohibition laws ("Stark Law") and the numerous exceptions to these regulations to ensure that an arrangement can be made with the contracting group which will not run afoul of these regulations. The regulations implementing the "Stark

Law” were revised in 2001 to make it clear that it is acceptable for a pathologist to serve as an independent contractor-director of the medical group practice laboratory without becoming a member of the group practice. Before this clarification, the regulations required the director of the laboratory to be a member of the medical group owning and operating the laboratory. The pathologist should also consider Internal Revenue Service guidelines for determining whether an individual is an employee or independent contractor with respect to the medical group.

1. Medical Group Operated Laboratory

The pathologist may be retained by the group solely for professional expertise in areas such as quality control, the implementations of new procedures, and the education, training, and supervision of laboratory personnel. The pathologist may be compensated on a fee basis, which may take the form of an annual or monthly stipend related to time and responsibility. The group will include this cost in the overhead expense of laboratory operation. However, when providing professional service to individual patients, the pathologist may bill the patient, Medicare, or other third-party payer. This may be done directly or through the group’s billing mechanisms. Such fees should, of course, be at fair market value for the service.

2. Pathologist Operated Laboratory

The laboratory services required by individual medical groups vary greatly. Some may need a full-service laboratory at the site of their practice, others a less sophisticated laboratory, and still others merely a collection station or courier service. In the latter situations, most of the work is done in the pathologist’s independent laboratory. The pathologist then may bill the patient, third-party payer, or the group, as mutually agreed upon and as appropriate under applicable state and federal law.

Careful attention to billing procedures for outpatient clinical diagnostic laboratory tests provided to Medicare outpatients is necessary. These tests are paid in accordance with a clinical laboratory fee schedule put into place by the Deficit Reduction Act of 1984. The direct billing provision of the act provides that, in most situations, only the person or entity performing the test can bill Medicare for the test. Therefore, outpatient tests performed for a group in the pathologist’s laboratory must be billed directly to Medicare, rather than to the group.

IV. Relations Between Pathologists and Other Groups

A. Industry

Pathologists, by virtue of their training and experience in laboratory medicine, offer unique and desirable capabilities to industry. Many businesses or industrial entities need laboratory services to evaluate specimens from their employees. For the pathologist, this need creates practice opportunities that differ greatly from the ordinary diagnosis of patients.

Laboratory testing might be provided as part of a health screening or “wellness” program. Screening and confirmatory testing of urine or other fluids for drugs of abuse (pre-employment or episodic) and toxicologic testing related to exposure to potentially hazardous substances are other important services. A company physician, medical director, or review officer may be involved in directing and interpreting such testing, in accordance with company policy, state or federal regulations, or labor contracts. Such testing may not necessarily be initiated by a physician order, but rather by a company policy, a benefit plan, or individual patient wishes.

In these arrangements, a pathologist’s contractual relationship may be that of a salaried employee or an independent contractor. The preceding comments regarding the various contractual arrangements should be reviewed for applicability to industrial situations.

Special consideration should be given to functions falling under state medical practice acts as well as to liability insurance coverage. Medical directorships and staff positions as pathologists in industrial or business operations are complex. State and federal laws regarding medical or clinical laboratories should be consulted, as should laws that concern the specific business or industrial entity.

B. Commercial Clinical Laboratories

In most states, a clinical laboratory may be owned by an individual, a partnership, a corporation, or another entity, whether organized for profit or not, provided that it is operated under the active supervision of a qualified director. State legislation relating to ownership and operation of laboratories by nonphysicians does not alter the status of pathology as a specialty of medicine. The pathologist performs many important activities that are limited by law to licensed physicians. The pathologist is not only authorized to perform diagnostic tests and services but also is qualified to provide consultation services.

The basic types of ownership that may be of importance to a pathologist considering affiliation with a laboratory company are (1) the company may be owned and operated by a group or professional corporation controlled by pathologists, or (2) it may be part of a for-profit entity.

The intensely competitive marketplace of commercial laboratories creates conditions that require careful consideration by pathologists who affiliate with them. The business leaders of the enterprise should work together with the medical directors/pathologists to develop policies to ensure that the patient’s interest will be served.

Pathologists affiliated with a laboratory company may relate to the company as an independent contractor, a salaried employee, or as a member of a professional corporation or other organized group. A professional corporation independent of the laboratory corporation permits some greater flexibility in the development of hospital contracts and

in the determination of professional fees. Such a group may contract to provide professional medical services, technical laboratory services, or both to the company.

A pathologist may enter the employment of a company as the director of a laboratory facility or as a member of a staff of pathologists and other physicians. It is essential that, in all instances, the pathologist be allowed to retain and exercise professional judgment and expertise in directing the laboratory.

The role of the pathologist in commercial laboratory companies will vary according to the needs of the company. Most pathologists will direct a clinical laboratory facility, with the total or shared responsibility for technical and administrative functions. Sales and marketing activities may or may not be included. As a physician, the pathologist will be called upon to consult with other physicians using the laboratory. Consultation with other pathologists who refer specimens may be an additional responsibility.

Forms of compensation include a salary, or stipend. Some contracts may provide for a base salary plus a percentage of gross billings or net operating profit. The contract may permit the pathologist to supplement income by fees billed directly to patients. The contract may include the fringe benefits available to pathologists in professional corporations, but in any event, an employee pathologist should determine how the following benefits are addressed in the contract:

- Paid annual vacation.
- Sick leave with full pay.
- Attendance at medical and scientific meetings, without deduction from pay and at the expense of the corporation.
- Public liability and malpractice insurance.
- Participation in a medical insurance and retirement program.
- Payment of dues to professional societies.

In many cases, coverage for books, dues, journals, and/or continuing education may be covered by a “discretionary fund” that the pathologist controls.

The agreement may also contain performance requirements and a covenant not to compete. Noncompetition clauses are sometimes necessary and reasonable; however, these are subject to wide statutory variation from state to state. It is important for the pathologist to seek appropriate legal consultation before entering into restrictive covenants. Consideration should be given to the contractual and statutory remedies for breach of the restrictive covenant. Noncompetition clauses also may be used to protect the interests of the pathologist as well as the commercial corporation.

The following principles should provide an appropriate working relationship between a laboratory company and a pathologist.

- The company and the pathologist should work together to provide laboratory services of medically acceptable quality.
- The company should bill for the pathologist’s services to patients or insurance companies only with the pathologist’s consent.

- The pathologist should take the initiative in discontinuing technical procedures if they are shown to be obsolete, inefficient, or ineffective.
- The pathologist should have the absolute right to determine the manner in which the pathologist's name will be used in solicitation and advertising.
- The pathologist should participate in policy decisions.

C. Physician Practice Management Organizations

In recent years, physician practice management companies (PPMs) have proliferated. PPMs have raised millions of dollars from the public equity markets to acquire physician practices and establish management service organization networks. Some physicians are selling their practices to PPMs that integrate and manage the practice. There are numerous PPMs, including some publicly traded companies that are aggressively acquiring primary care and multispecialty practices as well as specialty practices. Several PPMs specialize in acquiring hospital-based and independent laboratory-based pathology practices.

Three primary business models have emerged in the PPM market. In the “network model,” physician practices affiliate with a management services organization that provides administrative services, such as billing, managed care contract negotiation, information systems, and even recruiting and staffing. The physician may be offered an opportunity to purchase equity in the management service organization and participate in profits. Usually the management service organization charges a membership fee and bills market-rate fees for services provided to the physician practice. The physicians remain independent, with their own hospital contracts, employees, and facilities.

The “equity model” involves the sale of all or a portion of the physician practice in return for cash and/or ownership of some of the outstanding stock in the PPM. In a corporate practice of medicine state, the selling physician generally sells all of the assets held in the physician's professional corporation, and the physician becomes an employee of a captive professional corporation that enters into a long-term management agreement with the PPM. Under that management agreement, the PPM generally receives all of the costs of managing the practice plus a portion of the revenues less expenses of the practice.

In the “employment model,” the PPM acquires all of the stock of the selling physician's PC or all of the assets of the practice. The PPM then generally employs the selling physician. This structure only works in a state that does not prohibit the corporate practice of medicine.

Under either arrangement, the transaction has the effect of lowering the physician's income unless the PPM can expand and grow the practice or reduce the expenses of operating the practice. The difference between the pre-sale physician income and the post-sale physician income is the cash flow, which justifies the purchase price paid by the PPM for the practice. In return for agreeing to a significant reduction in income, the selling physician receives up-front cash and/or stock. Thus, the transaction basically causes a shift of income from later periods to the current period, where the income may be taxed at long-term capital gains rates rather than under ordinary income taxes. At the same time, the selling physician is relieved of the burdens of managing the practice and dealing with the administrative portion of medical practice.

Under either the “equity model” or the “employment model,” the physician conveys a significant portion of the value and cash flow of the practice to the PPM. Thus, a critical consideration in the negotiation and sale is arriving at a fair value for the portion of the practice that will be conveyed to the PPM. Medical practice valuation should include an expert analysis of the projected market value, earnings, and discounted cash flows associated with the portion of the practice conveyed to the PPM. The pathologists contemplating the sale of a medical practice should retain a qualified appraiser who can develop the fair market value of the physician practice. In addition, the pathologists should retain qualified tax planners, accountants, and attorneys to ensure that the sale is at a fair price, considers tax implications, and is structured in a manner that is fair to the pathologist.

Regardless of the arrangement chosen, it is important to ensure that the arrangement is acceptable to the clinicians and health care facilities served.

V. Relations Between Pathologists and Third-party Payers

Efforts to contain the cost of medical care have produced the establishment of a variety of new plans for delivery and payment of health care. Some plans serve only as the insurer, while others serve as both insurer and provider of health care services. It is important for pathologists to be knowledgeable about the types of third-party insurers operating in the geographic areas in which they practice or in which the patients whom they serve live. By being familiar with the various types of third-party insurers in the area, and by becoming familiar with the coverage and claims processing requirements of the insurers, the pathologist will be in a better position to assist the patient in receiving coverage and payment for pathology services.

Some insurers establish physician advisory positions or committees to assist them in developing payment and coverage policies. Medicare carriers are required to have a physician Carrier Medical Director (CMD), although increasingly a single CMD is responsible for multiple states within a region. Medicare carriers are also required to have a Carrier Advisory Committee (CAC), with representatives from various medical specialties, including pathology, and to include a representative from the independent laboratory community and other designated populations. A single CAC may, however, serve multiple states within a region. Private insurers may also have state or regional physician advisors on either a volunteer or a fee basis and increasingly seek to establish national panels of physicians to advise them on coverage issues, especially coverage of new technology.

Pathologists are encouraged to establish advisory relationships with insurers so that pathologists' knowledge about the practice of medicine, appropriateness of procedures, practicality of billing and claims processing requirements, and advances in new technology can be made available to insurers. Often this means that the pathologist, or state pathology society, may need to take the first step in making it known to third-party insurers that pathologists are interested in serving as advisors to the insurer.

In recent years, the Medicare and Medicaid programs and private-sector health insurers have increasingly focused on provider fraud and abuse. The Department of Health and Human Services (HHS) Office of Inspector General (OIG) has undertaken a number of enforcement activities involving clinical laboratory billing and coding practices. Pathologists are encouraged to become familiar with the basic provisions of federal fraud and abuse laws and to consult with competent legal advisors when they are unsure how such laws may affect their practice. A model compliance plan for pathology practices is available on the CAP Web site. The model plan provides basic information about fraud and abuse avoidance and includes a pathology practice compliance plan that can be used to establish an ongoing system to assist in assuring compliance with fraud and abuse rules. In addition, government fraud alerts, advisory opinions, and OIG compliance guidance for clinical laboratories, hospitals, and physician practices are posted on the CAP Web site as they become available.

A. Medicare

The federal government, through the Medicare program, insures patients 65 years or older, the disabled, and those with end-stage renal disease, for health care coverage. The original Medicare program consists of two parts. Medicare Part A covers provider services for inpatients in hospitals, skilled nursing facilities, and other institutional providers. Medicare

Part B covers the individual services of physicians and other individual health care providers to patients, outpatient hospital services, and other services not covered under Part A. Neither program covers all services provided. Under the Medicare + Choice (M+C) program (Part C), some Medicare patients are enrolled in plans that operate under different payment rules than traditional fee-for-service Medicare. These plans are paid by Medicare to provide a comprehensive range of services, using methods chosen by the plan. Although the plans are required to provide the Medicare patient at least the full range of services available through traditional Medicare, coverage of specific services may be different for Medicare patients in the same geographic area depending on whether they are enrolled in traditional Medicare or an M+C plan. M+C plans may be health maintenance organizations (HMOs), preferred provider organizations (PPOs), or other organizational configurations.

The M+C plans also may use payment arrangements and payment amounts that are very different from traditional Medicare and may contract with physicians and other providers in limiting ways. In general, M+C plans attempt to identify a network of health care providers that will guarantee services at a discounted rate. Patient access to out-of-network providers is usually limited or comes with additional cost to the beneficiary. Since the M+C plan has been paid by the program for the services, physicians and other providers are prohibited from billing the patient for most services not paid for or underpaid by the plan except to the extent that the M+C plan allows.

1. Medicare Part A Payment for Pathology Services

Medicare pays most acute care hospitals under the prospective payment system (PPS) methodology for inpatient services. Under the PPS methodology, hospitals are paid a predetermined diagnosis related group (DRG) rate for Part A services to hospital inpatients. Pathologists' services that are considered by the Medicare program to be services to the provider (eg, medical supervision and management services, autopsy services, and most clinical pathology services) are included in the DRG rate paid to the hospital, as are the Medicare program payments for clinical diagnostic laboratory tests. The only inpatient services that a pathologist may bill to the Medicare program or its beneficiaries are physician services for individual patients personally performed by the pathologist and that are identified in Medicare program instructions on Part B services. The federal regulations and instructions on payment for pathologists' services under Medicare Part A and Part B are contained in, "Instruction on Payment Conditions for Pathology Services," available at http://cms.hhs.gov/manuals/14_car/3b15000.asp#_1_10.

2. Medicare Part B Payment for Pathology Services

Medicare payment for hospital outpatient and nonhospital patient clinical diagnostic laboratory tests is made on a fee-for-service basis using the Medicare clinical laboratory fee schedules. There is some variation from state to state; but since 1986, national limitation amounts have been applied to payment for Medicare outpatient clinical diagnostic laboratory tests. Payment is 100% of the lowest of the billed charge, the carrier fee schedule amount, and the national limitation amount. The Part B deductible and coinsurance do not apply.

Assignment is mandatory for tests subject to Medicare clinical diagnostic laboratory fee schedules. Physicians and laboratories that repeatedly bill Medicare patients on an

unassigned basis are subject to monetary penalties and/or disbarment from the Medicare program. In addition to payment for the laboratory test, separate charges are allowed for specimen drawing and travel costs associated with specimen drawing, subject to certain limitations.

There is also a direct billing requirement for Medicare outpatient clinical diagnostic laboratory tests. This means that Medicare payment is made only to the laboratory that performed or supervised performance of the test, with the following exceptions.

1. Payment may be made to an independent laboratory or hospital laboratory for a test referred to another laboratory, subject to certain limitations. Unless the referring laboratory is in a rural hospital or there is an ownership relationship between the referring and reference laboratories, there is a limit to the percentage of its lab testing that a referring laboratory may refer out and bill. No more than 30% of the clinical diagnostic laboratory tests for which the referring laboratory receives requests annually may be performed by another laboratory if the referring lab wants to bill for the reference testing.
2. Payment may be made to a physician who is part of a group practice for a test performed or supervised by another physician in the group if the physicians in the group practice bill in their own names rather than in the name of the group. If the physicians bill in the name of the group practice, payment is made only to the group.

Medicare outpatient clinical laboratory tests performed in an independent laboratory or hospital laboratory for a physician or group practice must be billed directly to the Medicare carrier rather than to the physician or Medicare patient.

Laboratory tests furnished to patients with end-stage renal disease, to patients of rural health clinics, and to certain other categories of patients are subject to special rules.

Medicare payment for physician pathology services (eg, anatomic pathology) is made on the basis of a resource-based relative value scale (RBRVS) fee schedule that applies to all physician services. The RBRVS is national, but there are geographic practice cost indices (GPCIs) that cause payment to vary from state to state and, in some areas, within a state. Only services listed in the instructions to Medicare carriers as payable under Part B as physician pathology services are covered under the Medicare RBRVS. (See “Instruction on Payment Conditions for Pathology Services,” available at http://cms.hhs.gov/manuals/14_car/3b15000.asp#_1_10.)

A balance billing limitation applies to physicians who choose not to sign the Medicare Participation Agreement agreeing to accept the Medicare fee schedule amount as payment in full. That limitation is 115% of the Medicare fee schedule amount for a particular service in a specific geographic area. There are fines and other penalties for violation of the balance billing limitation. Assignment is not mandatory for Medicare Part B pathology services subject to the RBRVS fee schedule unless the pathologist or group practice has signed a Medicare Participating Physician Agreement.

Although there is no direct billing requirement for services subject to the RBRVS, there is a Medicare prohibition on a physician purchasing the professional component (such as an interpretation) of another physician and billing the Medicare program for the service under Medicare’s prohibition on reassignment of claims regulations. In addition, there is a prohibition on mark-up of a purchased technical component of a physician service.

Nonphysician providers are allowed to purchase the professional component needed to complete a service. Some states may impose additional restrictions on balance billing, which are applicable to Medicare as well as to other payers.

3. Health Care Fraud and Abuse

The term “fraud and abuse” encompasses potential liability under a variety of federal laws. These laws, as they apply to pathologists, generally prohibit: (1) the submission of false claims to the Medicare and Medicaid programs or any patient or third-party payer; (2) the use of kickbacks or other payments in exchange for referrals of patients or laboratory specimens (the Medicare and Medicaid antikickback law); and (3) the making or acceptance of referrals for laboratory services by or from a physician who has a financial interest in the clinical laboratory (the Stark self-referral prohibition law). Penalties for fraud and abuse violations include civil money penalties, criminal penalties (including possible imprisonment), and exclusion from participation in federally funded health care programs.

One of the principal concerns of any pathologist should be the avoidance of false claims. Potential false-claims violations include billing for services not rendered, upcoding, unbundling, and misrepresenting the medical necessity of laboratory services. Upcoding refers to the assignment of and billing for CPT codes that represent a more intensive or remunerative procedure than the procedure performed. Unbundling occurs when each component of a panel of tests is billed separately so that the sum of the parts is greater than the price of the panel as a whole.

False claims can be created by deficiencies in a practice’s coding and billing process. The consequences of false claims can be dire. Penalties include criminal convictions (including possible imprisonment), civil money penalties of up to \$10,000 per item or service, plus 3 times the amount claimed. Pathologists who use billing agents and consultants remain potentially liable for false-claims violations because they are responsible for assuring that bills submitted to federal programs accurately describe the services the pathologist has provided to patients.

Unlike most other federal fraud and abuse provisions, a private citizen may bring an action under the False Claims Act. “Whistleblower” actions are permitted to encourage private parties who are aware of wrongdoing to report the activity. The government retains the right to proceed with the action and has responsibility for prosecuting the action. In the event the government proceeds with the action, the individual is entitled to receive at least 15% but not more than 25% of the proceeds of the action. If the government does not proceed, the individual can prosecute the action and receive as much as 30% of the proceeds. Billing personnel and others involved in clinical laboratory operations have brought whistleblower suits that have resulted in large laboratory settlements.

Pathologists should also avoid offering or accepting kickbacks or other improper incentives for referrals. The federal antikickback statute prohibits offering or making any payments (in cash or in kind) in return for the referral of patients or medical services. The statute has particular significance for a pathologist whose practice depends upon referral of patients and laboratory specimens. Financial arrangements between hospitals and hospital-based physicians have come under the scrutiny of the Department of Health and Human Services Office of Inspector General (OIG), the federal agency responsible for investigating alleged wrongdoing in federal health care programs. Of particular concern to the OIG has

been the potential for antikickback violations when hospitals compensate physicians for less than the fair market value of the services they provide to the hospital. (See OIG regulations, “Financial Arrangements Between Hospitals and Hospital-based Physicians,” available at <http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>; and “Compliance Program for Hospitals,” available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>.)

Pathologists should also be concerned with avoiding violations of the Stark Law. The Ethics in Patient Referrals Act (commonly referred to as the “Stark Law” after its congressional sponsor, Representative Pete Stark) broadly prohibits a physician from making any Medicare or Medicaid referrals for “designated health services” to any entity with which the physician (or an immediate family member of the physician) has a “financial relationship.” The term “financial relationship” is defined so broadly that virtually all business arrangements fall within its scope. The law applies to all “ownership or investment interests” and “compensation arrangements.” The ownership or investment interest could be through equity, debt, or other means. A compensation arrangement is defined as “any arrangement involving any remuneration between a physician (or immediate family member) and an entity.” Stark defines 11 “designated health services” to which the restrictions apply, including clinical laboratory services (anatomic and clinical pathology) as well as radiology services. Therefore, physicians cannot make referrals to pathology practices and/or clinical laboratories with which they have a financial interest unless one of the numerous exceptions to the basic prohibition applies. In January of 2001, the Stark regulations were clarified so that physician group practices can independent contract with pathologists who are not members of the group practice to direct their group practice, in-office laboratories. Prior to this clarification, the regulations required physician office laboratories to be supervised by a physician who was a member of the group practice.

The Office of Inspector General (OIG) and the various United States Attorneys offices have focused much of their fraud and abuse enforcement activities on clinical laboratory services. Through its “Lab Scam” enforcement program, the OIG has recovered millions of dollars through the settlement of a number of high-profile fraud and abuse actions, attacking a wide range of laboratory billing practices. The OIG has issued Special Fraud Alerts concerning clinical laboratories as well as model compliance guidelines for clinical laboratories, physician practices, and hospitals. (See “Compliance Program for Hospitals,” available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>; and “Compliance Program for Individual and Small Group Physician Practices,” available at <http://oig.hhs.gov/authorities/docs/physician.pdf>.) These documents, model compliance plans for pathology practices, and other information are available on the College Web site, www.cap.org. Pathologists should obtain the services of qualified legal counsel when they have questions about the application of the fraud and abuse laws to their practice arrangements.

B. Medicaid

Medicaid is a program of medical assistance, funded by the federal government and the states, for impoverished persons who are aged, blind, disabled, or members of families with dependent children. The states each operate Medicaid programs according to state rules and criteria, which vary widely within a broad framework of federal guidelines. States are required to ensure that access to services is sufficient to enlist enough providers so that

care and services are available at least to the extent that they are available to the general population. However, states have the discretion to set their payment rates within their budgetary constraints and to adapt their programs to their specific circumstances. For clinical diagnostic laboratory tests, Medicaid programs are prohibited from paying more than Medicare pays for the test in their area.

Increasingly, states are seeking federal Medicaid waivers that allow them to operate innovative programs outside the federal guidelines, including programs that waive some basic requirements and allow for enrollment of Medicaid patients in state-run and private managed care plans. The states are also establishing Medicaid managed care plans, particularly for services to women and children.

Physicians are required to accept Medicaid payment as payment-in-full as a condition of participation in the Medicaid program. State Medicaid plans, in turn, are required to establish payment rates that are sufficient to enlist enough providers so that services are available to Medicaid enrollees, at least to the same extent that comparable services are generally available in the area. State Medicaid plans may also require that the enrollee satisfy deductibles, coinsurance, or co-payment requirements (except for the categorically needy and hospital inpatients).

If the Medicaid enrollee is a recipient of federally supported cash financial assistance, state Medicaid plans must make payment directly to the physician or facility providing the health care services. If the Medicaid patient is not receiving cash assistance, payment may be made to the patient at the option of the state.

Information about Medicaid eligibility, coverage, payment policies, and payment rates is best obtained at the state level. If the fiscal agent is not known, the state department of public health or welfare or a similar state department can be queried for this information.

C. TRICARE (Formerly CHAMPUS)

TRICARE (formerly CHAMPUS, the Civilian Health and Medical Program of the Uniformed Services) is a program of managed health care provided by the Department of Defense (DoD) to specific categories of persons by virtue of their relationship to the uniformed services. Although similar in structure in many of its aspects, TRICARE is not an insurance program in that it does not involve a contract guaranteeing the indemnification of an insured person against a specified loss in return for a premium paid. In addition, TRICARE is not subject to state regulatory bodies or agencies that control the insurance business generally. TRICARE is secondary to private health insurance and will pay only after the other insurance has been billed and a payment determination made.

TRICARE offers eligible persons several options for coverage, and enrollees may move in and out of options at varying frequencies, with individual family members enrolled in different options at different times. TRICARE Standard most closely resembles the old CHAMPUS program. The Standard option shares most of the costs of care provided by civilian hospitals and doctors based on the DoD perception of acceptable charges and medically necessary care. A health care provider must be authorized or certified by the regional TRICARE contractor to provide care to TRICARE enrollees in order for the government to share the cost of the care. "Authorization/certification" is not the same as "participation," which involves agreement to the TRICARE Standard fee schedule.

TRICARE Extra involves voluntary use of a network of health care providers who provide services at a discount.

TRICARE Prime is an HMO option in which the enrollee agrees to receive care from a military treatment facility (usually a military base hospital or clinic) or from the TRICARE network of civilian providers. Out-of-network services are covered only with referral by the enrollee's Primary Care Manager and with authorization from a Health Care Finder. Prime also allows enrollment in a point-of-service option, which allows more flexibility in TRICARE coverage of out-of-network services, but includes greater enrollee cost sharing.

TRICARE for Life allows persons enrolled in Medicare Part B who wish to receive care from civilian providers to use their TRICARE benefit as their secondary insurer. TRICARE will pay eligible out-of-pocket costs similar to the secondary insurance plans available to non-TRICARE Medicare beneficiaries.

Although TRICARE is a worldwide program, much of the day-to-day implementation in the United States is delegated to the DoD TRICARE Service Regional Office in which the care is provided. Contact information for the service regions, as well as detail about the program benefits, can be found at www.tricare.osd.mil.

D. Private Insurance Plans

Many private insurance plans are in operation—many across state lines. Some private plans also serve as the contractor to the Medicare program to administer their claims processing operations in the local area. Private and Medicare plan operations are separate, however, and the rules and procedures under the private plan often do not follow those of the Medicare program. Within the constraints imposed by the state insurance commission, and subject to market conditions in the area, BlueCross BlueShield (BCBS) and other private plans are free to establish their own coverage, policy, coding, and public communication rules. Plans established under the Employment Retirement and Income Security Act (ERISA) are exempt from most state regulations that govern other private insurers. Some private plans publish periodic bulletins describing changes in payment policy or payment amounts, which can be helpful to physicians in keeping abreast of program requirements. Others are silent in this regard. Some BCBS plans will make information on these issues available upon request by physicians, whereas with other plans it can be more difficult to ascertain coverage and payment policy rules and amounts. Experience in claims processing with these private insurance plans may be the only way to identify and track their payment policies and payment amounts. A billing agent or consultant who is familiar both with the local insurers and with pathology billing issues may have valuable information in this regard. If a private plan in an area also serves as the Medicare carrier, and a positive working relationship has been established with carrier representatives, it may be possible to use that as a building block for establishing such a relationship with the private side of the BCBS business.

Private plans may offer participation contracts to physicians in the state(s) in which they operate. Before signing, contracts should be carefully reviewed for any restrictions in balance billing or in billing for noncovered services.

Some plans do not offer participation contracts to all physicians and will not pay claims for nonemergency care from physicians who are not contracted.

E. Managed Care Plans

Pathologists increasingly are being asked—in some cases required—to enter into arrangements with private insurance plans, often called managed care plans. Managed care plans take many different names and structures. They may feature total health care for a fixed prepaid fee or for discounted fees-for-service and may involve risk sharing between the physician and the insurance plan. Some of the principle types of managed care plans are described below.

Health maintenance organizations (HMOs) offer comprehensive health care to voluntarily enrolled subscribers for a prepaid fixed fee. The subscriber is guaranteed a defined set of benefits, usually without regard to specific type or frequency of service. HMOs often require that the health care be provided in an HMO-owned centralized facility or in a facility designated by the HMO, except in emergency circumstances. In staff-model HMOs, physicians are salaried to the HMO plan. Alternatively, the HMO may establish contracts with physicians who agree to provide services to plan enrollees for a capitated payment (a fixed amount per enrollee) or on the basis of a fee schedule negotiated with the HMO. Rigorous utilization review is a hallmark of HMOs.

Independent practice associations (IPAs) and physician service organizations (PSOs) are forms of managed care in which physicians form a partnership, association, or other legal entity with which they in turn contract to provide services to subscribers. An IPA/PSO may accept either a fee-schedule payment or a capitated rate, and usually involves some degree of risk if service utilization exceeds expectations. IPA/PSO physicians generally practice in their usual practice site and may continue to see patients who are not covered by the specific HMO plan. Although capitation to laboratories or pathologists for clinical or anatomic pathology services is rare, capitation of other providers, which includes incentives to limit diagnostic testing or restriction of referrals to a defined network, can significantly affect pathology practices.

Preferred provider organizations (PPOs) are health care providers, usually physicians, hospitals, or hospitals and physicians in partnership, that contract with employers, insurance carriers, or third-party administrators to provide comprehensive medical services on a negotiated fee-for-service basis to subscribers. The PPO providers accept a discount from the employer or insurer in return for an enlarged or assured patient referral base and prompt payment of claims. Alternatively, a managed care plan may form a PPO that consists of all physicians/hospitals willing to accept its payment terms, but in which the health care providers have no organizational relationship among themselves.

Generally, the patient is not required to use PPO hospitals or physicians but will be required to pay additional co-payments and deductibles if the patient obtains services from providers or physicians who are not contracted with the PPO. Some PPOs rely on pre-authorization of services, strict utilization review, and retrospective data analysis to control utilization and cost. Other PPOs are merely lists of providers that have agreed to accept a discounted payment in exchange for online prompt claims processing.

Managed care plans seek to reduce their cost by: (1) selectively contracting for medical services at discount rates; (2) monitoring, controlling, or reducing utilization of medical services; and (3) shifting some of the risk of high cost patients to physicians, hospitals, and other providers. Selective contracting for clinical laboratory services results in the exclusion of qualified clinical and physician office laboratories from the managed care plan's network

of providers. A few states have enacted legislation that requires managed care plans to contract with “any willing provider” if the provider accepts the price and other contract terms applicable to those providers already in the network. Physicians and other providers have sought enactment of “any willing provider” laws in other states. The managed care industry, however, opposes “any willing provider” requirements, saying such requirements increase cost to the managed care plan by making it more difficult to negotiate large volume discounts. Instead, managed care plans have widely adopted “point of service” options that allow the patient to select a provider outside the network at an additional cost to the patient. Some providers also oppose “any willing provider” requirements because such requirements interfere with managed care contracts that they have negotiated.

Entering into an arrangement with a managed care plan raises a number of issues for pathologists. The following section provides an overview of a number of those issues. The section also discusses possible contract provisions for the pathologist’s contract with the hospital where the hospital seeks to require the pathologist to contract with or perform services for a managed care plan.

1. Reimbursement

Managed care plans use a handful of basic methods to determine payments to physicians. A managed care plan may negotiate a discount from the physician’s usual and customary charges. This is the method primarily used by PPOs and by independent practice associations (IPAs) to compensate specialists and consulting physicians. The pathologist’s ability to minimize the discount factor depends on relative bargaining power. Of course, a pathologist who is forced by the hospital to contract with a particular plan may have little bargaining ability.

A managed care plan may compensate physicians according to a fixed fee schedule that lists payments for all covered services. The schedule is developed by the plan. If compensation under the fee schedule is inadequate, the pathologist can either refuse to contract with the plan or attempt to negotiate a more realistic payment scheme.

A managed care plan may pay the physician a negotiated fee for services, minus a risk-sharing holdback. Under this risk-sharing model, a managed care plan withholds a certain percentage (eg, 20%) of all payments to the physician. At the end of the year, if the managed care plan income exceeds expenses, the risk-sharing holdback is distributed to the physicians. If not, the risk-sharing fund is used to make up the difference, with any remaining funds distributed to the physicians on a pro-rata basis. A risk sharing withhold generally is not attractive for pathologists. They have little or no ability to control the volume of tests ordered. In most cases, the pathologists may want to resist this type of arrangement.

If, however, the pathologist must accept a risk-sharing withhold, the contract should contain reasonable protections. For example, the contract could specify a date for repayment of the risk-sharing holdback so the pathologist is not providing an interest-free loan to a managed care plan. In addition, the pathologist could seek the right to audit managed care plan calculations of costs and risk-sharing contributions to ensure that the pathologist is treated fairly. Finally, the pathologist could try to restrict the scope of the risk-sharing fund to expenses over which the pathologist may have some control so the pathologist is not unfairly penalized for the inefficiency of others.

Some managed care plans (usually staff-model HMOs) may employ physicians for a fixed salary to treat managed care plan patients at their facilities. These physicians may also receive bonuses if medical costs fall below budgeted levels. Salaried physicians should negotiate the terms of vacations, overtime, and other benefits, such as payment of malpractice premiums and membership dues in medical societies. It should be noted that employed physicians might not be permitted to treat non-HMO patients or to have a private practice.

Some managed care plans have proposed capitation arrangements under which the services of the pathologist are packaged, perhaps with hospital services or certain other physician services, for a single price. Another variation could be a package price for physician and hospital services for each type of discharge. Capitation is a prime example of how the risks traditionally assumed by the insurer have been shifted to the provider. For this reason, pathologists must develop an understanding of the risks they are assuming before entering into a capitation agreement. In many ways, capitation is similar to a salary, ie, capitation is a fixed payment per month per patient for covered laboratory services, while a salary is a fixed payment per month for providing services to all patients. The difference is financial risk. Under capitation, if the volume of services goes up, the pathologist has provided a volume discount; if the volume goes down, the pathologist has made more profit.

Before reaching an agreement with a managed care plan under any of these compensation models, a pathologist should:

1. Obtain reasonable estimates of the total expected payments under the managed care plan proposal.
2. Know how much it will cost in money, time, and resources to provide the expected level of service. The cost can be better estimated by knowing the utilization history of the plan for the services you will be expected to provide. Knowledge of the number of persons enrolled in the program and the demographics of the enrolled population will aid in determining the costs the pathologist will incur.
3. Understand the philosophy of the managed care plan.
4. Find out about the sponsoring company, eg, reputation, stability, frequency of change in providers, disenrollment rate.
5. Look at the managed care plan's financial status, eg, net worth, profit margin, ratio of current assets to current liabilities, health care expense ratio.
6. State in the contract by name and CPT code exactly what services will be included for the payments made.
7. Establish an upper and lower limit on utilization at the negotiated capitation rate.

The pathologist should then weigh the value of expected revenues against the time commitment and the services to be performed. If unsure about the ultimate level of reimbursement, the pathologist might seek a guaranteed minimum payment from the managed care plan. In any case, the pathologist may want to seek the right to renegotiate compensation if there are changes in costs, number of enrollees, or the profitability of the managed care plan. It also is useful to include a provision requiring the managed care plan

to reimburse the pathologist promptly for services. Otherwise, late payments from the managed care plan could cause cash-flow problems. As discussed below, it also is useful to have the right to terminate if the managed care plan gets behind in payments.

Sign managed care contracts with the same care exercised in signing a contract with a general contractor to build a home. Contractual clauses may go unnoticed until much later, when the significance of those few words buried in mountains of fine print are put into effect. It may be advisable to obtain help from an attorney who has had experience in this area. An attorney may be able to point out significant risks that might be buried in a lengthy contract.

2. Liability Provisions

a. Liability for Required Methods of Practice or Administration

Many managed care plan agreements provide that physicians shall conform their practice to the standards or practice parameters of the managed care plan. The restrictions imposed on physicians might include pre-procedure review, utilization review, or certain practice guidelines. If the methods of practice prescribed by the managed care plan are not consistent with good medical practice in a particular case, the physician following those methods may be held liable for malpractice.

Therefore, pathologists who contract with a managed care plan should ask for the practice standards of the managed care plan to be described in specific terms. If the terms are not consistent with good medical practice, the pathologist may well have serious doubts about contracting with a managed care plan. Furthermore, the pathologist should determine whether the contractual provisions and the quality care provisions are consistent. For example, a managed care plan requirement that the physician deliver “cost-effective care” or “preauthorized care” may be inconsistent with the requirement that services be of the “highest quality.”

There is a risk that a pathologist may be held accountable for certain failures of the managed care plan in administering its plan. For example, a managed care plan’s failure to promptly process requests for referrals or authorization for treatment may adversely affect a particular patient. A patient who is injured may seek to recover not only from a managed care plan, but also from individual physicians affiliated with the managed care plan who have provided medical services. Therefore, before affiliating with a managed care plan, the pathologist should determine whether or not the managed care plan procedures will adversely affect the delivery of good medical care.

b. Liability Insurance

Many managed care plan agreements specify the amount of liability coverage physicians must maintain. Before signing a managed care plan contract, a pathologist should make sure that the required coverage limits are available and not prohibitively expensive. The pathologist also may want to include a provision requiring the managed care plan to carry adequate liability insurance so the pathologist will not become the “deep pocket” in cases of joint and several liability.

c. Hold-harmless Clauses

Some managed care plan agreements provide that the physician is solely responsible for the quality of care performed for managed care plan enrollees and must indemnify and hold the managed care plan harmless for any liability arising from the physician's services. In addition, these agreements often provide that the physician shall hold the managed care plan harmless from any liability arising from the overall care and treatment of managed care plan enrollees. These clauses often are quite broad.

The pathologist should have any hold-harmless agreement reviewed by counsel. In many cases, the pathologist should seek to eliminate or at least limit these hold-harmless clauses. Many clauses are so broad that they would apply to decisions made by the physician at the direction of the managed care plan or to other cases where the managed care plan is at fault. Most importantly, pathologists should discuss the implications of the clause with their professional liability insurance carrier. Because indemnification is contractual in nature, it generally is not covered by professional liability insurance policies in the absence of a specific rider.

3. Term and Termination Provisions

The most advantageous term and termination provisions will depend on individual circumstances. In general, the pathologist may desire a shorter duration of affiliation if the future and profitability of the managed care plan are uncertain or if there is concern over the adequacy of compensation. Where there is less uncertainty and the level of reimbursement is more attractive, a longer term may assist the pathologist in planning for the future.

Regardless of the contract's duration, the contract should give the pathologist the right to terminate the agreement under certain circumstances. These would include material breach by the managed care plan, the insolvency of the managed care plan, the failure of the managed care plan to pay claims in a timely manner, or any liability imposed on the pathologist for actions of the managed care plan. In addition, the pathologist may want to consider termination if there is a material change in the number of providers or enrollees in the plan. Pathologists should also consider negotiating for a provision which limits the managed care plan's right to assign the contract to another managed care plan. Without a limitation on assignability, such as a physician's right to refuse the assignment, the physician may be forced to affiliate with an entity that is undesirable.

4. Noncompete Provisions

Managed care agreements may attempt to limit the pathologist's ability to affiliate with a competing managed care plan. Some of these provisions may apply both during the term of the contract and for a period following termination of the contract as well. Pathologists should weigh the disadvantages of such clauses with the overall desirability of the contract. In addition, the pathologist should weigh the opportunities offered by the contracting managed care plan against the potential opportunities of a new managed care plan that must be foregone under the noncompete provision. The pathologist should seek to modify noncompete provisions that are overly burdensome.

Instead of using a nonaffiliation clause, a managed care plan may attempt to limit the physician's ability to contract with another managed care plan by including a "most-favored-

nation” clause in the contract. This provision compels the pathologist to give the contracting managed care plan the benefits of any more favorable arrangements negotiated with other managed care plans. While not as restrictive as a noncompete provision, the most-favored-nation clause substantially limits the pathologist’s options and should therefore be carefully considered prior to the execution of the contract. If a pathologist has already agreed to a most-favored-nation clause with a particular plan, the pathologist should consider the implications of that clause on every other managed care contract. A discount offered to a single plan may inadvertently increase the discount to other plans covered by a most-favored-nation clause.

Finally, some managed care agreements prohibit the pathologist from any activity that competes with the managed care plan for a specified period of time after leaving the managed care plan. Although the law varies from state to state, most courts generally uphold these provisions if they are strictly limited in time and area. Thus, most courts would tend to enforce a provision that applied for 1 year after the pathologist left a managed care plan and that covered a limited geographic area. In contrast, a clause that applied for 5 years and covered a whole state or region would most likely be struck down.

5. Miscellaneous Provisions

A managed care contract may include other provisions that could limit the professional freedom of pathologists. One such provision is a confidentiality clause that prohibits physicians from disclosing certain information designated as confidential to any person without the consent of the managed care plan. The pathologist should be wary of overly broad provisions, which may prohibit formal consultations with other physicians or disclosures that the pathologist may have a legal duty to make, such as providing information needed to defend a lawsuit.

Another contract provision that warrants special consideration deals with the procedures for handling complaints among subscribers, physicians, and providers. Pathologists should obtain a copy of these grievance procedures, if not fully outlined in the contract, and make sure there is some provision for a hearing by an impartial panel composed of representatives of the managed care plan, physicians, providers, and subscribers.

Finally, if there is a utilization review or quality assurance program within the managed care plan, the contract should clearly outline those mechanisms. The pathologists may want to have the contract expressly describe the manner of appointment and composition of the review committee, the frequency of the review committee meetings, general standards for quality of care and treatment, and appeal procedures that allow the physician to challenge the decisions of the review committee. The pathologist also may want to seek the right to have at least one review committee member appointed by physicians.

6. Special Provisions for Hospital-based Physicians

The pathologist should also be concerned about provisions in the hospital-physician contract which seek to bind the pathologist to particular arrangements between hospitals and managed care plans. Some hospitals have attempted to bind pathologists to payment terms negotiated by the hospital with third-party payers. Other hospitals seek to require pathologists to designate the hospital or the local physician hospital organization as their

agent for purposes of negotiation with third-party payers. Hospitals have also sought to include provisions that: (1) require the pathologist to agree to the same discount as the hospital with respect to certain third-party payers; (2) require the physician to enter into contracts with each of the third-party payers with which the hospital contracts; or (3) permit the hospital to terminate its relationship with the pathologist if the pathologist does not reach agreements with certain managed care plans. Moreover, managed care plans have attempted to require participating hospitals to control the terms or participation of the hospital's pathologists or to exclude the hospital's pathologists entirely by utilizing nonhospital, discount pathology groups or laboratories.

Needless to say, these hospital and third-party-payer tactics erode pathologist compensation. Moreover, these tactics undermine the professional freedom of pathologists. Pathologists may be forced to participate in undesirable managed care plans. Also, any arrangements that erode the pathologist's ability to make independent decisions with regard to third-party payers may undermine the pathologist's status as an independent contractor. On the other hand, pathologists who do not reasonably accommodate the needs of the hospital and third-party payers may lose a substantial source of business. Indeed, hospitals or managed care plans may enter into contracts with discount, nonhospital laboratories to provide all of the services ordinarily performed by the hospital-based pathologist.

There is no "right" approach to these issues. The most appropriate contract terms in a particular case will depend on the number and quality of managed care plans in the area, the demands of the hospital, and the relative bargaining position of the parties. This section is intended to offer suggestions and options for consideration by each pathologist.

Often the best time to resist onerous arrangements with managed care plans begins with the terms of the contract the pathologist negotiates with the hospital. Attention to seemingly small details in the hospital contract can avert large problems with managed care plan arrangements. The pathologist may find that the "window of opportunity" is past when the hospital begins negotiations with these plans if the pathologist's contract with the hospital is not in order. The best strategy depends on the situation and the extent of the pathologist's bargaining power. Aggressive tactics to avoid large discounts may work in some instances. In other cases, the tactics may lead to the managed care plan utilizing discount, non-hospital laboratory services.

If the pathologist seeks to avoid being forced to contract with a particular plan, there are a number of arguments that can be made. The pathologist can stress that the lack of pathologist discretion with respect to payer contracts may threaten the independent contractor status of the pathologist. Alternatively, the pathologist could argue that a forced managed care arrangement appears to make the pathologist and the hospital partners in the provision of services to managed care patients. Such a characterization could increase liability risks to both the pathologist and the hospital.

The pathologist also can argue that the decision to participate in a managed care plan creates liability risks for the pathologist. As long as the pathologist is responsible for professional liability insurance premiums, the pathologist should have the right to determine with whom to contract. The pathologist should try to negotiate a provision that permits opting out of a managed care plan that poses unacceptable liability risks. Alternatively, the pathologist could ask the hospital to indemnify the pathologist for any

claims that might arise in connection with a managed care plan in which the hospital required the pathologist's participation.

It also is reasonable for the pathologist to request the right to refuse to contract with a managed care program that is financially weak. Without that protection, the pathologist runs the risk of not being paid. If the hospital wants to require the pathologist to accept a financially weak payer, the pathologist could ask for a guarantee from the hospital that the payer will make timely payments.

The pathologist may want to propose alternative contract provisions to the hospital seeking to require arrangements with managed care plans. For example, the pathologist could ask for a contract provision that increases Part A compensation if the hospital's arrangement with a managed care plan materially increases the physician's workload. Or, the pathologist could seek a contract reopener in the event that the hospital enters into an agreement with a managed care plan. Another possibility is a clause that requires the pathologist to bargain with the payer in good faith, to consider certain discounts, and to consider the reputation of the payer and network for quality, solvency, and prompt payments. Finally, a contract provision could give the pathologist discretion to reject any payer but, in exchange, give the hospital the right to contract with other pathologists to serve particular managed care plans.

Appendix A

College of American Pathologists Policy: Retention of Laboratory Records and Materials

The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). It may be appropriate for laboratories to retain records and/or materials for a longer period of time when required for patient care, education, quality improvement, or other needs. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA '88 regulations; therefore any applicable state or federal laws should be reviewed carefully when individual laboratories develop their record retention policies.

Material/Record	Period of Retention
<i>General Laboratory</i>	
Accession log records	2 years
Maintenance/instrument maintenance	2 years
Quality control records	2 years
<i>Surgical Pathology (Including Bone Marrows)</i>	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
<i>Cytology</i>	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine-needle aspiration slides	10 years
Reports	10 years
<i>Non-Forensic Autopsy Records</i>	
Wet tissue	3 months after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years

Material/Record	Period of Retention
<i>Forensic Autopsy Records</i>	
Wet stock tissue	3 years
Wet tissue of whole organs	3 months
Paraffin blocks	20 years
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log records	Indefinitely
Serum/CSF/Urine	2 years
Whole blood	6 months
Dried blood stain or frozen tissues for DNA	Indefinitely
Frozen tissue for toxicology	6 months
<i>Clinical Pathology Records</i>	
Patient test records	2 years
Serum/CSF/Body fluids (except urine)	48 hours
Urine	24 hours
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides—microbiology (gram, trichrome, etc)	7 days
<i>Cytogenetics Records</i>	
Slides	3 years
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized or negatives)	20 years
<i>Blood Bank</i>	
Donor records	10 years
Patient Records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipients protection (eg, those donors that are Hepatitis B Core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from blood donors units and recipients	7 days post-transfusion

Revised May 2001

Appendix B

Form Letter and Policy on Requests for Pathology Material

Department of Pathology
Hospital ABC
Anywhere, USA

Date: _____

To Whom It May Concern:

We have recently received your request for _ a copy of our report(s), _ slides, _ blocks, _ wet stock and/or _ other material pertaining to your client, _____.

Note that _ we will need OR _ you already have submitted (1) written explanation for the purpose of this request AND (2) a properly executed release form.

We do not send original slides, blocks, or wet tissue, but may submit a copy of our report(s) and recut duplicates of the original slides to you. Pathologists normally send recut duplicates to colleagues when requesting a consultation, and accept “recuts” when requesting slides for review. Please let us know if that will be satisfactory.

There is a total of _____ slides on the case(s), to which we have assigned number(s)

_____.

You may not really want or need all of those slides and cases. If you will telephone us, we can discuss what you need. Alternatively, you might focus your request based upon copies of our reports, which you have in the patient’s chart.

The hospital has set its fee at \$_____ to retrieve the appropriate material from storage, review it for completeness and suitability, and copy the report(s); plus \$_____ per slide for recuts. The total fee for your request therefore is \$_____. Please enclose a check for the amount indicated with your request for the pathology materials. That check should be payable to Hospital Anywhere, USA, and sent to the pathology department’s attention at the address below.

It is our policy to retain our original and irreplaceable pathology material (including original slides, paraffin blocks, wet tissue, cytology, FNA slides, and hematological smears) at this hospital to allow for possible review. We can make our original and irreplaceable material available for inspection and review by a physician or other consultant of your choice, BUT ONLY ON THE PREMISES OF THE HOSPITAL. The time and terms for such inspection must be agreed upon between the parties, and we will bill you for time, efforts, expenses, and expertise.

Very truly yours,

Pathologist

Surgical Pathology Policies

Attorney Requests for Pathology Reports and Slides

1. If a written request for pathology reports and slides is received from an attorney, the pathology department will first respond by sending the standard letter requesting (a) the reason for the request and (b) the specific case accession number requested, and (c) stating the policy that only recuts of slides may be sent. Additionally, the letter will state the charges for preparing the recuts and submitting them.
2. If the attorney insists on receiving only the original slides or blocks, inform the attorney that the requested original materials will be available for examination by the attorney's expert **ONLY** on our premises and under our direct supervision.
3. An attorney who has written a letter of request in the absence of a subpoena cannot compel the submission of original materials.
4. If a subpoena is received in a case where a formal lawsuit has been filed involving a member of the department of pathology or the hospital, the pathology reports and corresponding slides will be brought to the pathologist who signed out the case. It is the responsibility of the pathologist who signed out the case to review the case. The professional liability insurer must be notified and a determination made on whether to file a motion in court to limit discovery.
5. Original slides will be submitted **ONLY** if a court so orders, in which case there is no alternative but to comply. However, if the original material is subsequently broken or lost, the pathology group will be operating under the protection of the court.

Appendix C

Guidelines for the Delineation of Clinical Privileges in Pathology

I. Professional Privileges: General Statement

To maintain high standards of care and service, and to provide to the greatest extent possible that each member of the medical staff provides only those patient services he or she is qualified to perform, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that privileges be delineated for every hospital medical staff member. Each pathologist should be required to apply for and obtain an appointment to the medical staff of the hospital, in the same manner as do all other physicians. They should assume individual responsibility for abiding by the bylaws and rules and regulations of the medical staff.

The degree of complexity and specificity required for delineation of professional privileges is influenced by the size of the hospital and by the services and skills available. Although most physicians requesting privileges in anatomical or clinical pathology will be diplomats of the American Board of Pathology, the granting of privileges should be based on evidence of current licensure, education, experience, and current competence, not solely on the basis of board certification. Fellowship in the College of American Pathologists (CAP) or in the American Society for Clinical Pathology (ASCP), membership in other scientific organizations, or the physician's rank or tenure are relevant only to the extent that they are indicative of education, experience, or competence.

The JCAHO guidelines state that delineation of privileges should be reasonably comprehensive and should not be stated in general terms such as "family medicine" or "general surgery," unless such terms have been specifically defined in staff documents. The most common methods of classification of privileges are by (1) illness/condition/procedure specific, (2) designation by specialty, and (3) categorical designations. None of the methods is suitable by itself for pathology. Rather, in most instances, the granting of privileges to hospital staff members in pathology will combine a specialty (pathology) and intraspecialty designation (anatomical pathology, clinical pathology, etc), coupled with specific authorization for any invasive patient procedure.

Most pathologists practice both anatomical and clinical pathology. They are usually certified by the American Board of Pathology. Pathologists certified by the American Board of Pathology in Clinical Pathology or having equivalent qualifications are generally granted privileges in clinical pathology and all its subdisciplines, including immunohematology, blood banking, hematology, hematopathology, clinical microbiology, etc. Pathologists certified by the American Board of Pathology in Anatomic Pathology or having equivalent qualifications are generally granted privileges in surgical pathology, autopsy pathology, and cytopathology. Pathologists qualified to perform invasive biopsy techniques (needle or surgical), chemotherapy, in vivo nuclear medicine, or other special diagnostic or therapeutic procedures should be approved by the medical staff on a procedure-specific basis (see the following).

An initial appointment to the medical staff should be based on a thorough review and verification of the pathologist's credentials. The appointment should include a designated classification of privileges and a provisional period of established duration (for example, 6 months to 1 year). An appointee found to be professionally competent at the end of the provisional interval should be granted regular staff membership, with an appropriate classification of privileges.

As noted, there are a number of methods used for delineation of specific medical staff privileges. This does not release each department within the hospital—or the hospital staff—from establishing its own specific regulations according to local need and professional resources available.

In any event, the pathologist should be certain to have privileges that allow consultation, making entries on patient charts, ordering medication from the hospital pharmacy, etc.

II. Procedure for Delineation of Initial Clinical Privileges in Pathology

- A. Clinical privileges are requested by the physician on a form approved by the hospital medical staff.
- B. The Hospital Credentials Committee should review the requested privileges. If the hospital staff is small and not organized on a departmental basis, the Credentials Committee should pass the privilege request form to the Chief of the Medical Staff, who will recommend approval or disapproval. Subsequently, the hospital governing board approves or disapproves.
- C. If the hospital is organized along departmental lines, the Chairman of the Credentials Committee should pass the request for privileges, after initial review, to the Chief of the Department of Pathology for examination. After the form has been returned to the Chairman of the Credentials Committee, it will be processed as noted above.

This recommended procedure indicates that privilege delineation begins with the credentials committee and then proceeds to the medical staff or to the various departments within the hospital, and finally to the governing board. It is entirely acceptable for the credentialing process to begin, in those hospitals organized along departmental lines, within the individual departments, and thence to the credentials committee, medical staff, and governing board.

III. Staff Reappointment and Reappraisal of Privileges

Clinical competence of each staff member should be documented continually. JCAHO standards require the reappointment or reappraisal of clinical privileges at least every 2 years. Ordinarily, the function of the Credentials Committee is to carry out this periodic review. The file should contain evidence of the pathologist's health, continuing medical education, professional recognition, participation in staff activities, and professional performance. If found competent, according to the bylaws of the institution, the pathologist should be reappointed. If any question of competence exists or other irregularity arises, a defined mechanism should be in place to resolve these issues in a fair way. This mechanism should include an opportunity for a hearing and appellate review in accordance

with due process requirements when recommendations of the initial or periodic credentialing procedure are adverse to the pathologist.

IV. Cross-specialty Concerns

Pathologists complete a long and specialized residency training program. In their daily practice, they acquire a breadth and depth of experience in pathology, which other physicians generally lack. Consequently, nonpathologists ordinarily do not have the expertise and competence in all areas of pathology that pathologists have. It is particularly unlikely that the nonpathologist will request privileges in anatomic pathology, although there are exceptions (eg, dermatopathology, bone marrow aspiration, and biopsy). Clinical imaging, radioisotopic pathology, and clinical pathology consultations are areas where overlap may occur. As noted previously, privileges should be granted on the basis of education, experience, and demonstrated competence. Demonstrated competence should remain the benchmark. Where education, experience, and competence are comparable, all eligible physicians should be considered by the Credentials Committee and Medical Staff for privileges.

A. Example Privilege Delineation Form

The following example privilege delineation form is offered by the College of American Pathologists as a satisfactory method of privilege delineation for individuals in pathology. The College recognizes, however, that other adequate methods are in current use or will be devised in the future.

I. CERTIFICATION OR EQUIVALENT

Specialty	Subspecialty(ies)
_____	_____

Primary specialty certification (Anatomical Pathology and/or Clinical Pathology) and date(s)	
_____	_____
_____	_____

Subspecialty or areas of special competence (Forensic Pathology, Immunopathology, Dermatopathology, etc) and date(s) of certification	
_____	_____
_____	_____

If you claim either primary or subspecialty competence in pathology by virtue of equivalent education, experience, or demonstrated competence, please document these on a separate sheet and submit with this request for privileges.

II. REQUEST FOR PRIVILEGES (request privileges in the following areas)

A. General Privileges

(check lines that apply)

- To admit
- To have consultation
- To order controlled substances
- To interpret diagnostic studies
- To perform history and physical
- To interpret history and physical
- To diagnose from history and physical examinations
- To discharge
- To order medication
- To order diagnostic studies
- To order treatments
- To consult
- To order drugs

B. Anatomic Pathology

- Yes No Surgical Pathology
- Yes No Autopsy Pathology
- Yes No Cytopathology
- Yes No Frozen Section
- Yes No Clinical Chemistry
- Yes No Clinical Microbiology

C. Clinical Pathology (administration and interpretation)

- Yes No Immunochemistry/Blood Banking
- Yes No Clinical Immunology/Immunopathology
- Yes No Radioisotopic Pathology
- Yes No Hematology/Hematopathology
- Yes No Clinical Microscopy

D. Invasive Procedures

- Yes No Venous Phlebotomy, Routine
- Yes No Arterial Puncture
- Yes No Bone Marrow
- Yes No Aspiration
- Yes No Biopsy
- Yes No Venous Injection of Contrast Dyes, Isotopes
- Yes No Apheresis
- Yes No Fine-needle Aspiration

E. Other

Yes No _____
 Yes No _____
 Yes No _____

III. APPROVAL

 Signature of Applicant _____
 Date

 Signature of Approval _____
 Date

B. Example Privilege Categorization Delineation Form

The following example privilege categorization delineation form is offered by the College of American Pathologists as a method of privilege delineation for individuals in pathology. The College recognizes, however, that other adequate methods are in current use or will be devised in the future.

Privileges in Pathology LEVEL I

CODES	CHECK PRIVILEGES REQUESTED
<p>Level 1.00</p>	<p>In order to be granted LEVEL I privileges, the physician must demonstrate:</p> <ul style="list-style-type: none"> • current licensure • completion of an approved postgraduate training program of at least 3 progressive years • current clinical competence • professional liability insurance in accordance with requirements established by the Board of Directors • freedom from any impairment which may adversely affect performance
<p>1.01</p>	<p><input type="checkbox"/> CORE ANATOMIC PATHOLOGY PRIVILEGES Core privileges in Anatomic Pathology include patient diagnosis, ordering, consultation, and quality assurance in the following disciplines: Surgical Pathology, Intraoperative Consultation, Autopsy Pathology, and Cytopathology.</p>
<p>1.02</p>	<p><input type="checkbox"/> CORE CLINICAL PATHOLOGY PRIVILEGES Core privileges in Clinical Pathology include patient diagnosis, ordering, consultation, and quality assurance in the disciplines of clinical chemistry, clinical microscopy, hematology, immunology, immunochemistry, and microbiology.</p>

1.03 SPECIAL TYPE I PRIVILEGES INCLUDE THE FOLLOWING:

- 1.04 Venous Phlebotomy
- 1.05 Bone Marrow Biopsy
- 1.06 Bone Marrow Aspiration
- 1.07 Arterial Puncture
- 1.08 Venous, Intramuscular, and Subcutaneous Medication Injections

Level 2.00 In order to be granted **LEVEL II** Anatomic Pathology privileges, the physician must demonstrate all requirements for Level I and demonstrate requisite training and experience in the Level II privileges requested.

- 2.01 Neuropathology
- 2.02 Fine-needle Aspiration and Diagnosis
- 2.03 Forensic Pathology
- 2.04 Electron Microscopy Diagnosis
- 2.05 Hematopathology
- 2.06 Pediatric Pathology
- 2.07 Other _____

2.10 In order to be granted **LEVEL II** Clinical Pathology privileges, the physician must demonstrate all requirements for Level I and demonstrate requisite training and experience in the Level II privileges requested.

- 2.11 Flow Cytometry Diagnosis
- 2.12 Cytogenetic Pathology
- 2.13 Nuclear Medicine Pathology
- 2.14 Molecular Pathology
- 2.15 Reproductive Pathology
- 2.16 Medical Informatics
- 2.17 Other _____

Appendix D

Suggested Outline of Rules and Regulations for a Hospital Laboratory

The following outline provides a skeletal table of contents for hospital laboratory rules and regulations. Hospital laboratory circumstances vary substantially; the following outline will need to be modified to apply to each laboratory.

A. Organization of Department

1. *Table of Organization*

This probably is best prepared in chart form. It should clearly delineate responsibility and function so that members of the staff clearly understand how their positions relate to others.

2. *Hours of Operation*

Hospital laboratories are required to provide 24-hour emergency service. The rules and regulations should include a list of available emergency tests and how and by whom coverage will be provided. Regular working hours should be stated, and a schedule, published in advance, should ensure that appropriate services are available and provided at necessary times.

3. *Job Qualifications and Descriptions*

The rules and regulations should include job descriptions for each technical and clerical position and should specify the desired qualifications, even if these cannot always be obtained. For pathologist colleagues, it may be sufficient to specify board certification or its equivalent. Responsibilities and limits of authority should be delineated for all.

4. *Departmental Meetings*

A regular schedule of departmental, sectional, and supervisor-employee meetings should be specified. These meetings will provide valuable feedback of information at all levels and will often permit the pathologist to identify potential problems at an early stage of development. Minutes of such meetings should be kept for future reference.

B. Liaison With Medical Staff and Hospital Departments

1. *Medical Staff*

Liaison with the medical staff is best accomplished by the presence of the departmental chief on the executive committee of the staff and by associates serving on appropriate medical staff committees.

Frequent attendance at and participation in hospital educational conferences by departmental pathologists will prove valuable in anticipating the needs of the medical staff,

especially in the consideration of new procedures. When appropriate, other departmental personnel may also attend, if this is the desire of the medical staff.

2. Hospital Departments

The department of pathology is a major component of the hospital administrative structure and should have a mechanism for close liaison with other departments. The rules and regulations should specify how this is to be accomplished and, in each case, who is the individual responsible. The nature of the liaison required will usually determine whether it will be most effectively managed by the pathologist, as the Department Chairman and Medical Director, or by the laboratory administrative director. A comprehensive laboratory manual or other means of retrieving information should be prepared and furnished to the department of nursing as a guide for meeting the requirements for submission of specimens for analysis. Format and content of this manual will depend on local circumstances, but the following basic information should be included: (1) laboratory hours of operation—weekdays, weekends, and holidays; (2) special preparation of patients for certain tests; (3) responsibility for initiating and preparing request slips; (4) method and time for obtaining the specimen; (5) method of transportation to the laboratory; (6) special rules for “stat,” nighttime, and nonroutine requests; (7) laboratory reporting procedures; and (8) whom to contact in case of difficulty.

C. Personnel Policies

Laboratory rules and regulations may simply state that all employees will be governed by hospital policies. Amplification of hospital policies may, however, be desirable to accommodate the special requirements of a laboratory. If so, care should be exercised to ensure that special rules do not infringe on employee rights as established by the hospital administration and the law. If the laboratory staff is employed directly by the pathologist rather than by the institution, the rules and regulations should contain a detailed personnel policy, or reference should be made to a separate document; in this case, every effort should be made to make departmental and hospital policies compatible.

D. Anatomic Pathology

1. Surgical Pathology

Rules and regulations governing the operation of a surgical pathology laboratory are best devised after discussion among all pathologists in the department. Individual preferences and techniques should be recognized, but a certain uniformity of behavior is desirable to ensure a harmonious relationship with the medical staff, residents, and technical personnel. The rules and regulations should touch on many of the following points.

Surgeons should be required to provide appropriate clinical and operative data upon submission of a specimen for examination. The pathologist, in conjunction with hospital administration and appropriate medical staff departments, should develop a written policy that addresses the limited number of specimens that do not need to be submitted to pathology and which specimens may not routinely require a microscopic exam. The policy should state that a microscopic exam will be performed whenever there is a request by the attending physician, or at the discretion of the pathologist when such an examination is

indicated by the gross findings or clinical history. The policy should be individualized for each institution and take into account the diagnostic needs of the medical staff, the reliability of procedures to ensure proper handling of specimens in surgery, and potential medicolegal implications.

Copies of the pathology report should be dispatched to the patient's chart and to the surgeon within acceptable time frames. If a delay occurs, a preliminary report may be issued, or the surgeon should be contacted and informed. Opinions given on the basis of an operating room consultation should be included in the patient's chart. CLIA '88 regulations establish minimum retention periods for reports, records, slides, and specimen blocks (available at <http://www.phppo.cdc.gov/clia/regs2/toc.asp>). In addition, certain states have laboratory regulations that establish retention requirements that may differ from CLIA '88 requirements. Consideration should be given to retaining specimens for future research projects. The procedures for safe and sanitary disposal of discarded specimens should be specified, including those for amputated limbs. The rules and regulations should not fail to address issues of mislabeled, unlabeled, and lost specimens.

The responsibility for cross-indexing diagnoses should be fixed and an attempt made to ensure some uniformity of diagnostic terminology. The Systematized Nomenclature of Medicine (SNOMED-CT®) is now the recommended system of nomenclature.

The distribution of reports should be restricted to laboratory files, the hospital chart, the attending physician, the surgeon, and such committees or departments as may be called for by the rules and regulations of the medical staff (eg, department of radiology, tumor registry). Requests for reports and slides from another hospital should be honored, preferably when a written release is provided by the patient. Reports should be supplied upon written release by the patient or in response to a legal subpoena. As a courtesy, the attending physician should be notified when patient reports are released.

With minor modifications, most of the rules for surgical pathology can be applied to the cytopathology laboratory. It must be understood that most cytopathological preparations are unique and cannot be duplicated if lost.

2. Cytopathology

The regulations implementing the Clinical Laboratory Improvement Amendments of 1988 include specific requirements for cytology services. Proficiency testing of individuals involved in screening and interpreting gynecologic preparations is required, as are workload limits on the number of cytology slides screened during each 24-hour period.

The laboratory must ensure that diagnostic interpretations are not reported on unsatisfactory smears, and that all cytology slide preparations are evaluated on the premises. The technical supervisor must establish the maximum workload (based on capability/ documented performance evaluation) for each individual examining slides, and the limit must be reassessed at least every 6 months. The maximum workload of 100 slides can be completed/examined in no less than an 8-hour workday. Part-time employees' workload must be prorated based on screening time and an 8-hour day. If a full-time cytotechnologist has duties other than screening slides, the workload limit must be prorated to the number of hours spent screening.

3. Autopsy Service

General autopsy guidelines and special procedures should be established by the pathologist. An administrative department should be responsible for the release of all bodies. The attending physician should sign the death certificate. Local laws and customs should be considered carefully.

Care should be taken to ensure that the legally responsible individual has signed the autopsy permit. It is convenient to supply clinicians with a list that ranks relatives in descending order of kinship, consistent with local law. The autopsy permit should provide space for notation of restrictions and for authorization of retention or donation of organs. The procedure to be followed in removing donated tissues should be developed in conjunction with the appropriate clinical departments and, in certain circumstances, with local funeral directors. Special permits may be desirable. (See Appendix E, “Sample Autopsy Consent and Authorization Form.”)

The rules should clearly state the hours during which autopsies are normally performed and should provide for timely notification of the attending or resident physicians. In many communities, agreement has been reached between the local pathologists and funeral directors regarding various aspects of autopsy performance. This agreement should be incorporated into departmental rules and regulations.

Rules should be established for the safe performance of autopsies that might present a hazard to those involved. Such cases would include patients with uncontrolled infectious disease or in whom radioactive exposure might be expected. The Centers for Disease Control and Prevention (CDC) “Recommendations for Prevention of HIV Transmission in Health Care Settings” can be consulted. The CDC guidelines call for “universal blood and body fluid precautions” for the autopsy and include special requirements for protective eyewear, gloves, masks, gowns, and waterproof aprons.

Emergency physicians or other medical staff members may request a pathologist to perform an autopsy upon a patient who has died before or shortly after arrival at the institution. The following guidelines are suggested to avoid overwhelming the pathology department with cases of this type.

- The great majority of emergency room deaths are sudden, unexpected, or of a violent nature and hence fall under the jurisdiction of the medical examiner or coroner. If the medical examiner or coroner orders an autopsy, the ME/coroner should either perform the examination or authorize the autopsy and payment of its costs.
- When the request for an autopsy is from the family of the deceased rather than from the physician in attendance, it may be appropriate that the family requesting the autopsy be responsible for payment to the pathologist and the institution for the provision of this service. Alternatively, the pathologist may elect to perform autopsy examination only on written order of the attending physician.
- Individual circumstances should be considered when a patient has been previously hospitalized at the institution and the attending physician requests an autopsy.
- The pathologist should have the ultimate responsibility for determining whether an autopsy will be performed.

The postmortem diagnosis and presumptive cause of death based on the gross findings should be made available to the attending physician promptly.

E. Clinical Pathology Laboratories

1. Specimen Collection

The rules should specify when and who will obtain specimens. They should emphasize the importance of correct identification of the patient. Technologists should understand their responsibilities regarding difficult venipunctures, arterial punctures, and patients suffering from infectious disease. Centers for Disease Control and Prevention (CDC) recommendations for prevention of HIV transmission state that blood and other bodily fluids from all patients should be considered infective and that standard precautions be taken. The CDC recommends additional precautions for health care workers in clinical laboratories. The NCCLS document, *Occupationally Acquired Infections; Approved Guideline, 2nd Edition*, should be consulted. In addition, OSHA regulations on occupational exposure to bloodborne pathogens as delineated by the Bloodborne Pathogens Standard and the Needlestick Safety and Prevention Act should also be incorporated into rules, particularly the use of appropriate personal protective equipment, the evaluation and implementation of safer needle devices, the maintenance of a log for recording injuries from contaminated sharps, and the implementation of engineering and work practice controls. More detailed information can be found in the CAP publication, *So You're Going to Collect a Blood Specimen: An Introduction to Phlebotomy, 10th Edition*.

Rules should clearly outline the procedure for receipt and handling of specimens, such as body fluids and 24-hour urine specimens, especially when these are delivered to the laboratory at other-than-regular working hours. Rules concerning packaging and shipment to reference laboratories should be defined. Guidelines should be provided on specimen stability and acceptability and on issues of handling mislabeled, unlabeled, and lost specimens.

2. Reports

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported on a timely basis. Expected turnaround time should be established for all routine and “stat” requests. A policy should be established regarding critical value reporting. A procedure should be established for notifying the medical staff and nursing stations if unexpected delays occur due to instrument breakdown or other causes, such as submission of an inadequate specimen. The importance of establishing specific responsibility for answering questions and investigating complaints cannot be overstressed. Copies of reports should be retained in the laboratory as required by CLIA '88 regulations and as required by state law, if applicable.

3. Safety Policies

Laboratory rules should clearly describe the manner of handling and disposing of infectious, radioactive, and toxic materials, and the safe preparation of reagents. The OSHA Hazard Communication, the Bloodborne Pathogens Standard, and the Needlestick Safety and Prevention Act should be consulted. OSHA regulations establish special requirements for clinical laboratories handling hazardous chemicals and for all persons at risk of exposure to blood or other potentially infectious materials.

The laboratory should adopt specific measures for the detection and control of fire, with special attention given to storage of flammable materials and to potential electrical hazards. The fire control regulations of the laboratory should be coordinated with those of the hospital.

4. Quality and Inventory Control

Laboratory rules should include an outline of the quality control program, including assignment of responsibility for the measures involved. Similarly, responsibility should be assigned for control of inventory and the purchase of supplies.

5. Quality Assessment and Improvement

Clinical laboratory activities contribute substantially to patient management. Therefore, pathologists and other administrative leaders in the laboratory must develop and implement plans for improving the quality of that aspect of care which the laboratory provides. These are most effective when they are integrated with activities of other departments so that desirable patient outcomes are achieved.

Appendix E

Sample Autopsy Consent and Authorization Form

The College of American Pathologists offers this sample form to assist pathologists and hospitals in developing their own forms for use in securing consent for the performance of autopsies. This sample form should not be adopted without careful consideration of applicable state law, institutional policies, and local practice. It should be tailored to reflect all of these considerations as well as the drafting style of the particular pathology group and hospital. The College also recommends that each pathology group have a list of next of kin, in order of authority by state statute, available for reference by appropriate hospital staff.

Please note that this sample does not cover obtaining consent for the removal of organs or tissue for transplantation. A separate form is required for that purpose. In any event, the College recommends that, prior to adoption, any autopsy consent form be reviewed by an attorney knowledgeable about governing law and sensitive to local practice.

SAMPLE

Consent and Authorization for Autopsy

 Service

 Attending physician

 Date of death

 Time of death

Addressograph
 or Patient Name / Hospital Number

The College recommends that each pathology group develop its own specific consent form tailored to applicable law, institutional policies, and local practice. This autopsy consent form is offered as a starting point. Prior to adopting a specific form, the pathology group should have the form reviewed by an attorney knowledgeable about applicable law and sensitive to local practice. The group should also have the form reviewed by appropriate individuals within any institution in which autopsies will be performed.

I, (printed name) _____, the (relationship to the deceased) _____ of the deceased, _____, being entitled by law to control the disposition of the remains, hereby request the pathologists of (name of hospital) _____ to perform an autopsy on the body of said deceased. I understand that any diagnostic information gained from the autopsy will become part of the deceased's medical record and will be subject to applicable disclosure laws.

Retention of Organs/Tissues:

I authorize the removal, examination, and retention of organs, tissues, prosthetic and implantable devices, and fluids as the pathologists deem proper for diagnostic, education, quality improvement and research purposes. I further agree to the eventual disposition of these materials as the pathologists or the hospital determine or as required by law. This consent does not extend to removal or use of any of these materials for transplantation or similar purposes. I understand that organs and tissues not needed for diagnostic, education, quality improvement, or research purposes will be sent to the funeral home or disposed of appropriately.

I understand that I may place limitations on both the extent of the autopsy and on the retention of organs, tissue, and devices. I understand that any limitations may compromise the diagnostic value of the autopsy and may limit the usefulness of the autopsy for education, quality improvement, or research purposes. I have been given the opportunity to ask any questions that I may have regarding the scope or purpose of the autopsy.

- Limitations: None. Permission is granted for a complete autopsy, with removal, examination, and retention of material as the pathologists deem proper for the purposes set forth above, and for disposition of such material as the pathologists or the hospital determine.
- Permission is granted for an autopsy with the following limitations and conditions (specify):

Signature of person authorizing the autopsy	Date	Time
Signature of person obtaining permission	Printed name of person obtaining permission	
Signature of witness	Printed name of witness	

- Permission was obtained by telephone.

The above statements were read by the person obtaining permission to the person granting permission. The person granting permission was provided the opportunity to ask questions regarding the scope and purpose of the autopsy. The undersigned listened to the conversation with the permission of the parties and affirms that the person granting permission gave consent to the autopsy as indicated above.

Signature of witness	Date	Time
Printed name of witness		

Appendix F

Uniform Anatomical Gift Act

A. Individual Authority to Donate

The Act grants authority to any individual of sound mind and 18 years of age or older to give all or part of their body for autopsy, anatomical studies, research, transplantation, or placement in a tissue bank.

B. Mechanism of Gift by Donor

1. Wills

A gift specified in a will is effective immediately upon death, without waiting for probate.

2. Other Written Instructions

An anatomical gift may be made only by a document of gift signed by the donor. If the donor cannot sign, another individual and two witnesses, all of whom have signed at the direction and in the presence of the donor and each other, must sign the document of gift. Because a gift document may not be discovered for a considerable time after death, the Act specifically provides that a properly executed card carried on the donor's person or in the person's effects will suffice.

C. Authority of Next of Kin to Donate

The next of kin may donate the body or parts of the deceased for any purpose described in (A). The Act specifies an order of priority for next of kin, beginning with a surviving spouse (followed by adult son or daughter, parent, adult brother or sister, and continuing in order of descending kinship). A legal guardian is authorized to donate the body of a minor. Permission granted by an individual in a higher order of kinship cannot be superseded by a countermand from an individual of lower kinship.

D. Mechanism of Gift by Next of Kin

The Act eliminated the requirements for witnesses, although many permission forms still retain this feature as an added precaution. Consent may be given by telegraphic, recorded telephonic, or other recorded message, which is contemporaneously reduced to writing and signed by the recipient.

E. Conflict Between Donor and Next of Kin

The Act provides that a donation by the deceased is paramount to the wishes of the next of kin and cannot be countermanded.

F. Donees

The Act is comprehensive in granting the right to act as donees to licensed hospitals, accredited medical schools and dental schools, and tissue banks, as well as specified persons. The donee is not required to accept a gift. Following removal of organs or completion of the authorized examination, the donee is required to return the remaining parts to the next of kin or other persons under obligation to dispose of the body according to law.

If a donee is designated but unavailable at the time and place of death, the hospital may accept and use the gift.

G. Purposes of Donation

The purposes of donation include medical and dental education, research, advancement of science, therapy, and transplantation.

H. Physician Liability

Under the Uniform Act, physicians or other persons who harvest an organ after receiving informed consent are not liable for their acts if they have acted in good faith.

I. Time of Death

A physician who is not involved in a proposed transplantation procedure must determine the time of death, and the attending physician cannot be a member of the transplant team.

J. Revocation of Donation

The donor may revoke or modify an anatomical gift at any time. If an anatomical gift is made by means other than a will, it may be amended or revoked only by a signed statement, an oral statement in the presence of two witnesses, any communication during a terminal illness to a physician, or by a signed statement to a specified donee. A donor of an anatomical gift made by will may also amend or revoke the gift by properly altering the will.

K. Authorization for Autopsy (See Appendix E)

The Uniform Anatomical Gift Act, which provides the legal basis upon which authorization for an autopsy may be granted, is remarkably clear and uncomplicated. Nevertheless, experience has shown that occasional problems in interpretation and administration of any autopsy service still arise. Some of these will be considered in this section.

1. Next of Kin

Two problems commonly arise with respect to establishing the next of kin. The first concerns the status of an estranged spouse. While it is quite clear that divorce severs all ties of kinship, this is not the case in marital separation, legal or otherwise. Under these circumstances, the separated spouse remains the next of kin. The status of a common-law spouse has not been clarified, but he or she would probably be accepted as the next of kin provided the common-law marriage was in effect before the date such arrangements became illegal in that particular state.

The second problem concerns disagreement between individuals of the same order of kinship (eg, between two sons). Under these circumstances, it is probably wise to refuse to perform an autopsy.

2. Medical Examiner or Coroner Cases

When death is known or suspected to be from other-than-natural causes, the medical examiner or coroner, in most jurisdictions, has authority to perform any necessary postmortem examination. Under these circumstances, the medical examiner or coroner is authorized to take immediate physical possession of the body and retain it until the investigation is complete. Notification of next of kin may be required. It is the responsibility of the pathologist to notify the appropriate authority if it is determined death is from other-than-natural causes.

When a medical examiner or coroner decides to release a body from custody without performing an autopsy, control of the body immediately reverts to the next of kin, from whom permission for a postmortem examination may be obtained. A medical examiner or coroner may permit the removal of a part from a body in custody for transplantation or therapy only under certain limited circumstances defined by state law.

3. Limitation on Autopsy

Every care should be taken to avoid any mutilation of a body during performance of an autopsy. The "Authorization for Autopsy" form should provide space for specification of the extent of the examination permitted, and any restriction(s) should be meticulously observed. The permission form should also be phrased in such a way as to permit retention of organs, or parts of organs, for further study. If such a statement does not appear, the next of kin is entitled to presume that all organs will be replaced in the body before it is released for burial. Most religious faiths accept the autopsy as consistent with their beliefs. Some, however, do not. Others have restrictions regarding time of burial, which may necessitate performance of an autopsy at an hour not always convenient to the pathologist.

L. Authority for Transplantation

Pathologists generally will not be concerned with obtaining permission for donation of organs for transplantation, but they may have occasion to review permission forms for completeness and validity. Pathologists may also have occasion to work closely with surgeons involved in removing organs for transplantation, especially if a postmortem examination is also authorized.

Techniques should be developed so that removal of organs interferes as little as possible with the autopsy. When interference is inevitable, accurate notes and descriptions should be made by the surgeons. To encourage donation of corneas, it may be advisable to include a specific authorization on the autopsy permission form.

Appendix G

College of American Pathologists Policy: Direct Access Laboratory Testing

The College of American Pathologists holds that patients are best served when laboratory tests are ordered by a qualified physician where such a physician directs the course of the diagnostic and therapeutic care of the patient, and that a physician should determine which clinical and anatomic laboratory services are appropriate.

The College also holds that each individual pathologist or pathology group should make its own determination whether to accept requests for diagnostic laboratory studies from patients. This determination should be based on a laboratory's assessment of the interest of the patient, potential legal exposure of the laboratory, applicable state law, medical staff bylaws, and other relevant considerations. A pathologist or pathology group retains the right not to offer direct-access testing as a policy, unless state law requires such testing.

When a pathologist or pathology group decides to permit direct access by patients to laboratory testing, then the following issues should be considered in the formulation of the policy:

1. Is a physician, or other appropriate health care provider, available to assist the patient in the proper interpretation of tests results, particularly when the test results fall outside an expected range? Has the patient designated, in advance and in writing, an appropriate health care provider who should be informed of test results at the same time as the patient?
2. Is the director of the laboratory able to order appropriate tests and assist the patient with interpretation of results? Has the laboratory developed a policy that ensures appropriate access to necessary additional diagnostic testing or therapeutic intervention? Policies which give the laboratory responsibility for ordering additional tests could have legal implications; therefore, it is recommended that the laboratory director consult appropriate insurance and legal counsel about the risks of such involvement.
3. Have provisions been made for compensation for direct-access testing? Medicare restricts reimbursements to tests ordered by "physicians" (as defined in section 186(r) of the Social Security Act), and health insurance policies may not cover non-physician ordered laboratory testing or interpretation of test results.
4. Does the laboratory have a policy specifying the levels of testing or particular tests that will be available by direct access?
5. Do the laboratory's policies comply with legal requirements governing informed consent, confidentiality of patient information, and mandated reporting of test results?

Reaffirmed November 2000

Appendix H

College of American Pathologists Policy: Guidelines for Review of Pap Tests in the Context of Litigation or Potential Litigation

The Pap test is the most effective cancer screening test in medical history and remains the most effective screening method for the identification of pre-malignant cervicovaginal conditions. The Pap test has been associated with a 70% or greater decrease in the United States death rate from cervical cancer.

If the Pap test is to continue as an effective cancer screening procedure, it must remain widely accessible and reasonably priced for all women, including those economically disadvantaged and those at high risk for cervical cancer. There must also be an understanding of the inherent limitations of this screening test.

The Pap test is a screening test that involves subjective interpretation by a cytotechnologist or pathologist of the thousands of cells that are present on a typical gynecologic cytology specimen. Studies indicate an irreducible false-negative rate of approximately 5%. Although rescreening can reduce the false-negative rate, zero-error performance cannot currently be attained. Many factors, including the subjectivity involved in interpreting difficult cases and sampling problems with specimen collection, prevent zero-error performance.

In the context of litigation and potential litigation, there should for these reasons be an unbiased and scientific method for review of questioned cases that is fair to both the patient and the laboratory. To help attain this objective, the College offers the following guidelines for use by courts and attorneys:

- The finding of a false-negative in a gynecologic cytology sample is not, by itself, proof of practice below the standard of care. A false-negative gynecologic cytology finding can occur—without any negligence—as a result of the subjectivity involved in evaluating difficult cases or as a result of the inadequacy of the specimen.
- Atypical cells of undetermined significance represent an equivocal interpretive category with poor inter- and intra-observer reproducibility. Therefore, most cases of atypical squamous cells and atypical glandular cells do not represent consistently identifiable abnormalities or a reasonable basis for allegations of practice below the standard of care.
- One asserting a violation of the standard of care should first have the Pap test slides assessed by qualified reviewers without knowledge of clinical background and in an environment that simulates normal screening practice. Specifically, such slides should be subjected to an unbiased screening process that includes the contested case material as one or more of a substantial number of normal and abnormal gynecologic cytology samples. The best process is to have the review process conducted by several qualified reviewers. Negligence should not be inferred unless

there is a consistent finding by the reviewers that the laboratory failed to identify clinically significant abnormalities.

- The standard of care should be that of the reasonable and prudent practitioner. Focused review, or review with knowledge of subsequent development of carcinoma, biases the objectivity of the review. Unless the review is blinded, it cannot establish a deviation from the standard of practice.
- Professional expert witnesses who do not have significant experience in cytopathology are not qualified to express an expert opinion on the standard of care. Instead, a court should rely upon the testimony of expert, physician witnesses who have, at a minimum, the following qualifications:
 - Maintains a current and unrestricted license to practice medicine in his/her state of practice;
 - Is certified in anatomic pathology by the American Board of Pathology or by an equivalent Board; and
 - Is knowledgeable in the practice of cytopathology as indicated by years of practice experience, current up-to-date continuing education, and active engagement in the practice of gynecologic cytopathology.

To adjudicate the performance of a cytotechnologist, the court may alternatively rely upon the testimony of expert cytotechnologist witnesses who have, at a minimum, the following qualifications:

- Maintains a current and unrestricted license to practice if licensure is required in the state in which the cytotechnologist practices;
 - Is certified as a cytotechnologist by the ASCP Board of Registry; and
 - Is knowledgeable in the practice of cytotechnology, as indicated by years of experience, currently up-to-date continuing education, and active engagement in the practice of cytotechnology.
- Compensation of the witness should reasonably reflect the time and effort expended in preparation, depositions, and trial. Compensation of an expert witness contingent on the outcome of the case introduces the possibility of bias and should not be permitted.
 - The parties should also strongly consider mediation or non-binding arbitration by a panel of individuals trained and having experience in cytopathology before proceeding with civil litigation relating to a Pap test. Such panels could be developed through national societies with interest and experience in gynecologic cytology.

Revised November 2001

Appendix I

College of American Pathologists Policy: Pathologist Professional Component Billing for Clinical Pathology Services

Quality laboratory services are essential to the diagnosis and treatment of patients. Pathologist-directors of hospital laboratories spend a significant amount of time and effort in fulfilling their responsibility to the patient for quality laboratory services. The pathologist is professionally responsible and legally accountable for laboratory results. To prepare for this responsibility, the pathologist must complete a lengthy medical residency program. Moreover, Federal certification standards and Joint Commission on Accreditation of Healthcare Organizations standards require certain professional, organizational, and administrative services be provided in the clinical laboratory to assure quality laboratory services to patients. The pathologist-director of a hospital clinical laboratory provides professional services in:

- Assuring that tests, examinations, and procedures are properly performed, recorded and reported;
- Interacting with members of the medical staff regarding issues of laboratory operations, quality, and test availability;
- Designing protocols and establishing parameters for performance of clinical testing;
- Recommending appropriate follow-up diagnostic tests, when appropriate;
- Supervising laboratory technicians and advising technicians regarding aberrant results;
- Selecting, evaluating, and validating test methodologies;
- Directing, performing, and evaluating quality assurance and control procedures;
- Evaluating clinical laboratory data and establishing a process for review of test results prior to issuance of patient reports;
- Assuring the hospital laboratory's compliance with state licensure laws, Medicare conditions, Joint Commission on Accreditation of Healthcare Organizations standards, the College of American Pathologists Laboratory Accreditation Program, and federal certification standards.

A variety of valid and accepted methods for payment for the above professional services of the pathologist in the hospital clinical laboratory are available.

These physician services may be billed by the pathologist to the patient (or the patient's insurer) or to the hospital as the pathologist and hospital may agree. Medicare rules require pathologists to seek payment from the hospital for the professional component of clinical pathology services to Medicare patients because the hospital's Medicare payment rate includes payment for these physician services. Pathologists and hospitals often negotiate a

different billing arrangement for the pathologist's professional services for non-Medicare patients. The pathologist may bill a professional component for clinical laboratory services to the patient, and the hospital may bill the technical component.

Professional component billing is one valid method of billing for the professional services of pathologists in the clinical laboratory. In many communities the standard practice is for the pathologist to direct bill patients for the professional component of clinical laboratory services. When the pathologist bills a professional component to a non-Medicare patient, no payment is made by the hospital to the pathologist for this service. The hospital's bill for the technical component covers hospital costs for laboratory equipment, supplies, and non-physician personnel; it does not cover the professional services of the pathologist.

Reaffirmed February 2002

Appendix J

College of American Pathologists Policy: Criteria for Autopsies

The College of American Pathologists advocates the autopsy as a valuable medical procedure and resource for assessing the quality of patient care, evaluating clinical diagnostic accuracy, determining the effectiveness and impact of therapeutic regimens, discovering and defining new and/or changing diseases, increasing the understanding of biological processes of disease, augmenting clinical and basic research, providing accurate public health and vital statistical information and education as it relates to disease, and obtaining medical-legal factual information.

The College of American Pathologists recommends that a request be made for autopsy on every death. It is, however, recognized that performing an autopsy on every death may not be possible. Deaths in which an autopsy should be especially encouraged are:

- Deaths in which autopsy may help to explain unknown and unanticipated medical complications to the attending physician.
- All deaths in which the cause of death or a major diagnosis is not known with reasonable certainty on clinical grounds.
- Cases in which autopsy may help to allay concerns of the family and/or the public regarding the death, and to provide reassurance to them regarding same.
- Unexpected or unexplained deaths occurring during or following any dental, medical, or surgical diagnostic procedures and/or therapies.
- Deaths of patients who have participated in clinical trials (protocols) approved by institutional review boards.
- Unexpected or unexplained deaths which are apparently natural and not subject to a forensic medical jurisdiction.
- Natural deaths which are subject to, but waived by, a forensic medical jurisdiction such as (a) persons dead on arrival at hospitals, (b) deaths occurring in hospitals within 24 hours of admission, and (c) deaths in which the patient sustained or apparently sustained an injury while hospitalized.
- Deaths resulting from high-risk infectious and contagious diseases.
- All obstetric deaths.
- All perinatal and pediatric deaths.

- Deaths at any age in which it is believed that autopsy would disclose a known or suspected illness which also may have a bearing on survivors or recipients of transplant organs.
- Deaths known or suspected to have resulted from environmental or occupational hazards.

The College of American Pathologists' position on autopsies is provided for information purposes. While the CAP makes general recommendations as to when autopsies are desirable, every institution should establish their specific recommendations by means of consultation between the pathologist and the rest of the medical staff. Proper personnel and other resources must be committed in support of this activity.

Reaffirmed May 2000

Appendix K

College of American Pathologists Policy: Payment and Performance of the Autopsy Service

The autopsy is a medical procedure and service performed by physicians specializing in pathology. The autopsy is of value to medicine as an educational tool, a measure of performance and outcomes, and a resource for research. The autopsy is used to assess the quality of patient care, to evaluate diagnostic accuracy, to monitor effectiveness of new technologies, and to determine the efficacy of therapeutic regimens. The autopsy also provides the decedent's family valuable information about familial, genetic, and communicable diseases and provides the greater community critical data regarding prevalent or emerging infectious or environmental disease.

The Joint Commission on Accreditation of Healthcare Organizations and the CAP state that autopsy information should be used as a source of clinical information in the quality assessment and improvement programs of the hospital. Collaboration between pathologists and clinicians to translate autopsy data into correlated information useful in a total hospital quality management framework can lead to improved organizational systems and processes as well as clinical performance and, therefore, error reduction and improved patient safety.

Pathologists should be compensated for their professional autopsy services. A variety of methods for payment for the autopsy services of the pathologist are available. The hospital should be responsible for payment for the autopsy in the case of hospital-related autopsies. Such payment can be made in various ways. The pathologist may seek a per-autopsy payment from the hospital. Alternatively, the pathologist may negotiate a fixed amount for a package of designated services that includes the autopsy (eg, providing hospital medical staff requested autopsies, serving on committees, providing education programs).

When the autopsy service is provided at the request of the family of the deceased, the pathologist who performs the autopsy may bill the family of the deceased for the professional service. The amount of the fee and the manner of payment should be discussed with the family in advance. Similarly, when the autopsy is provided at the request of law enforcement officials or other third parties, the pathologist who performs the autopsy may bill the requesting entity. Once again the amount of the fee and manner of payment should be discussed in advance.

Pathologists who perform autopsies must practice in a safe medical environment. Autopsy suites should be compliant with all applicable federal, state, and local standards.

Numerical standards or minimum autopsy rates for hospital deaths are inappropriate. Instead, the hospital medical staff should develop criteria that identify deaths in which an autopsy should be performed. The appropriate focus should be the use of autopsy data to measure performance in a quality assurance or improvement context so that autopsies are not performed on an unselective basis simply to meet a hospital autopsy rate requirement.

Adopted August 2000

Appendix L

College of American Pathologists Policy: Surgical Specimens to be Submitted to Pathology for Examination

The College of American Pathologists has developed the following recommendations to help in determining what specimens should routinely be submitted to the pathology department for examination. These are intended only as suggestions and are not mandatory or a requirement for CAP accreditation.

Each institution, in conjunction with the pathologist and appropriate medical staff departments, should develop a written policy that addresses which specimens do not need to be submitted to the pathology department and which specimens may be exempt from a requirement for microscopic examination. This policy must be individualized for each institution and should take into account the diagnostic needs of the medical staff, the likelihood of significant findings in otherwise unremarkable specimens given the clinical situation, the reliability of procedures to ensure proper handling of specimens in surgery, and potential medicolegal implications. According to JCAHO standards and CAP guidelines, this policy must be jointly determined by the pathologist and the institution's clinical staff.

The policy should clearly state that all specimens not specifically exempted must be submitted to the pathology department for examination. It should also state that a microscopic examination will be performed whenever there is a request by the attending physician, or when the pathologist determines a microscopic examination is indicated by the gross findings or clinical history. A pathology report should be generated for every specimen submitted to the pathology department for examination.

Creating two lists may be useful. One list should designate those specimens (if any) that are exempt from routine submission to the pathology department. A second list should specify those specimens that are to be submitted to pathology for gross examination but which are exempt from mandatory microscopic examination, ie, gross only examination.

The following are specimens that an institution may choose to exclude from routine or mandatory submission to the pathology department. There should be an alternative procedure for documenting the removal and disposition of any specimens or devices not submitted to pathology for examination. This is particularly important for any failed medical devices that may have contributed to patient injury, any failed device for which litigation is pending or likely, and for devices subject to tracking under the Safe Medical Devices Act of 1990 (see Addendum).

- Bone donated to the bone bank.
- Bone segments removed as part of corrective or reconstructive orthopedic procedures (eg, rotator cuff repair, synostosis repair, spinal fusion).
- Cataracts removed by phacoemulsification.
- Dental appliances.

- Fat removed by liposuction.
- Foreign bodies such as bullets or other medicolegal evidence given directly to law enforcement personnel.
- Foreskin from circumcisions of newborns.
- Intrauterine contraceptive devices without attached soft tissue.
- Medical devices, such as catheters, gastrostomy tubes, myringotomy tubes, stents, and sutures, that have not contributed to patient illness, injury, or death.
- Middle ear ossicles.
- Orthopedic hardware and other radio-opaque mechanical devices, provided there is an alternative policy for documentation of their surgical removal.
- Placentas that do not meet institutionally specified criteria for examination.¹
- Rib segments or other tissues removed only for purposes of gaining surgical access, provided the patient does not have a history of malignancy.
- Saphenous vein segments harvested for coronary artery bypass.
- Skin or other normal tissue removed during a cosmetic or reconstructive procedure (eg, blepharoplasty, cleft palate repair, abdominoplasty, rhytidectomy, syndactyly repair), provided it is not contiguous with a lesion and the patient does not have a history of malignancy.
- Teeth when there is no attached soft tissue.
- Therapeutic radioactive sources.
- Normal toenails and fingernails that are incidentally removed.

It is recommended that the following specimens should be submitted to the pathology department for examination. These specimens often require only a gross examination. However, exceptions are at the pathologist's discretion.

- Accessory digits.
- Bunions and hammertoes.
- Extraocular muscle from corrective surgical procedures (eg, strabismus repair).
- Inguinal hernia sacs in adults.*
- Nasal bone and cartilage from rhinoplasty or septoplasty.
- Prosthetic breast implants.²
- Prosthetic cardiac valves without attached tissue.
- Tonsils and adenoids from children.*
- Torn meniscus.
- Umbilical hernia sacs in children.*
- Varicose veins.

*Each institution should determine its own specific age requirements.

Addendum

The complete list of devices required for tracking under the Safe Medical Devices Act of 1990 follows.³

1. Permanently implantable devices:
 - Vascular graft prostheses
 - Vascular bypass (assist) devices
 - Implantable pacemaker pulse generator
 - Cardiovascular permanent pacemaker electrode
 - Annuloplasty ring
 - Replacement heart valve
 - Automatic implantable cardioverter/defibrillator
 - Tracheal prosthesis
 - Implanted cerebellar stimulator
 - Implanted diaphragmatic/phrenic nerve stimulator
 - Implantable infusion devices
2. Life-sustaining or life-supporting devices:
 - Breathing frequency monitors (apnea monitors)
 - Continuous ventilator
 - CD-defibrillator and paddles
3. FDA-designated devices:
 - Silicone inflatable breast prosthesis
 - Silicone gel-filled breast prosthesis
 - Silicone gel-filled testicular prosthesis
 - Silicone gel-filled chin prosthesis
 - Silicone gel-filled angel chik reflux valve
 - Electromechanical infusion pumps

References

1. Althshuler G, Deppisch LM. CAP Conference XIX on the examination of the placenta: report of the working group on indications for placental examination. *Arch Pathol Lab Med.* 191;115:701-703.
2. Revised CAP guidelines for prosthetic breast implants. *CAP Today.* April 1995;9:58.
3. Medical devices; device tracking. *Fed Reg.* May 29, 1992;57:22966-22981.

Revised August 1999

Appendix M

College of American Pathologists Policy: Expert Review of Histologic Slides in the Context of Litigation

Departure from the standard of care in the practice of medicine is defined as conduct that falls below that which a reasonable physician would practice under similar circumstances. Finding a deviation from the standard of care in surgical pathology is in sharp contrast to a difference of opinion, which may not represent an error on the part of the original pathologist.

When histologic slides are reviewed in the context of litigation, several issues must be considered before determining whether the standard of practice has been met or whether negligence has occurred. Such issues include:

- The clinical information available to the pathologist at the time of the original review;
- Whether more than one diagnostic interpretation is valid;
- The evolution of scientific understanding and diagnostic criteria between the time of the original diagnosis and the time the slides are reviewed;
- Whether the reviewing pathologist has reviewed the same slides as the original pathologist; and
- Whether the expert has been biased either by knowledge of subsequent clinical developments (hindsight bias) or by a presumption of an unfavorable outcome (context bias).

The following recommendations have been prepared by the College of American Pathologists to help ensure accuracy and fairness in expert testimony when histologic slides are reviewed for reasons of litigation, potential litigation, or disciplinary action.

1. Individuals performing slide review in the context of litigation must have significant experience examining and reporting the disease and type of specimen under consideration. Those lacking such experience are not qualified to render an expert opinion on whether the original pathologist met the standard of care. Instead, the court should rely upon the testimony of expert witnesses who have, at a minimum, the following qualifications:
 - A current and unrestricted license to practice medicine in his/her state of practice;
 - Completion of an appropriate training program in pathology;
 - Active engagement in the practice of anatomic pathology;
 - Up-to-date continuing medical education; and
 - Expertise with the specific disease and type of case under consideration as shown by the number of similar cases reviewed in the expert's own practice and through a record of publications and/or conference presentations.

2. The standard of care should be that of a reasonable and prudent practitioner following normal practices at the time the original diagnosis was rendered. Finding a deviation from the standard of care requires showing that the diagnosis was inappropriately based on examination of the original slides and clinical information that was available to the pathologist. This finding should not be based on clinical outcome or subsequent changes in diagnostic criteria.
3. To reduce the effect of hindsight bias, histologic slide review should be done without knowledge of clinical outcomes or the specifics of the claim. Disclosing a subsequent recurrence, metastasis, or other significant development to the reviewing expert witness before he or she has reviewed the slides introduces the possibility of bias into the review.
4. Review should occur in an environment that, as closely as possible, approaches a normal practice environment. This may be in the reviewing pathologist's own office or laboratory but can occur in other settings.
5. When slides are reviewed for the purposes of litigation or the determination of negligence, the same slides that were the basis for the original interpretation must be the subject of the review.
6. Fair and impartial review of histologic slides must not discriminate between defendant and plaintiff.
7. Compensation of the physician-witness should reasonably reflect the time and effort expended by the witness in preparation, depositions, and trial. Compensation of a physician-witness must not be contingent on the outcome of the trial as this introduces the possibility of bias and the appearance of possible impropriety.

Adopted February 2000

Appendix N

College of American Pathologists Policy: Licensure Requirements for Interstate Diagnosis, Including Interstate Telemedicine Practice

The College of American Pathologists supports the right of each state, through licensure, to regulate the practice of medicine in order to protect the health and welfare of its citizens. The CAP believes that a pathologist who engages in the interstate practice of pathology (including telepathology) and issues a pathology diagnosis that is contained in the patient's medical record should have a full unrestricted license to practice medicine from the state in which the patient presents for diagnosis or where the specimen is taken or image is made.

Definitions

The *interstate practice of pathology* occurs whenever a patient specimen, including a specimen slide or a specimen image, is sent through interstate commerce or an interstate communication system, from the state in which the patient presents for diagnosis to another location outside the state. The patient is deemed to have presented for diagnosis within a state from which the specimen is obtained.

Telemedicine is the practice of medicine whereby diagnosis is achieved through digital or electronic communication technology whenever the physician is not in the physical presence of the patient.

Telepathology is the practice of anatomic or clinical pathology whereby diagnosis is enabled through digital or electronic communication technology whenever the pathologist is not in the physical presence of the patient's specimen. Telepathology is the practice of the pathology component of telemedicine.

Explanatory Note

Intra-specialty consultation from an out-of-state pathologist should not require in-state licensure provided that the consultation is at the request of a in-state pathologist licensed within the state and if the consultation is reflected in a pathology report issued by a in-state pathologist. Similarly, pathologists examining specimens and/or slides from a case that has been previously reported, such as might occur when a patient is referred to a treatment center in another state, need only to be licensed by the state within which the examination occurs.

Revised February 2003

Appendix O

Internet Resources: Documents

College of American Pathologists (CAP)

- Laboratory Accreditation Program Checklists
<http://www.cap.org/html/ftpdirectory/checklistftp.html>

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

- CLIA Requirements for the Preservation of Materials and Reports in the Laboratory
- CLIA Laboratory Director Responsibilities for High Complexity Laboratories
<http://www.phppo.cdc.gov/clia/regs2/toc.asp>

Medicare Carriers Manual

- Instruction on Payment Conditions for Pathology Services
http://cms.hhs.gov/manuals/14_car/3b15000.asp#_1_10

Office of Inspector General, Department of Health and Human Services

- OIG Regulations
<http://www.oig.hhs.gov/authorities/regulatory.html>
- Financial Arrangements Between Hospitals and Hospital-based Physicians
<http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>
- Compliance Program for Hospitals
<http://oig.hhs.gov/authorities/docs/cpghosp.pdf>
- Compliance Program for Individual and Small Group Physician Practices
<http://www.oig.hhs.gov/authorities/docs/physician.pdf>

Title 42 – Public Health, Part 415

- Services Furnished by Physicians in Providers, Supervising Physicians in Teaching Settings, and Residents in Certain Settings
 - Subpart B: Fiscal Intermediary Payments to Providers for Physician Services
 - Subpart C: Part B Carrier Payments for Physician Services to Beneficiaries in Providers
http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr415_02.html

Internet Resources: General Information

College of American Pathologists (CAP)

www.cap.org

American Association of Blood Banks (AABB)

www.aabb.org

American Association of Clinical Chemistry (AACC)

www.aacc.org

American Board of Pathology (ABP)

www.abpath.org

American Medical Association (AMA)

www.ama-assn.org

Association of Directors of Anatomic and Surgical Pathology (ADASP)

www.panix.com/~adasp

Centers for Disease Control and Prevention (CDC)

www.cdc.gov

Centers for Medicare & Medicaid Services (CMS)

www.cms.hhs.gov

Clinical Laboratory Management Association (CLMA)

www.clma.org

COLA

www.colas.org

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

www.cms.hhs.gov/clia

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

www.jcaho.org

NCCLS

www.nccls.org

Occupational Safety and Health Administration (OSHA)

www.osha.gov

Office of Inspector General, Department of Health and Human Services

www.oig.hhs.gov

United States Government Printing Office

www.access.gpo.gov

US Department of Health and Human Services (HHS)

www.hhs.gov

World Health Organization (WHO)

www.who.int/en

Definitions

Glossary

Administrative/Supervisory Services to Provider: Those services furnished to a hospital by a physician benefiting patients generally or indirectly. Examples include, but are not limited to, personnel scheduling, quality control, medical supervision and administration of the clinical laboratory, and autopsy services.

Allocation Agreement: A written understanding between the physician and the provider, making a reasonable estimate of the time the physician spends rendering services for direct (Medicare Part B) patient care and services (Medicare Part A) to provider. The agreement must be filed annually by the provider along with the Medicare cost report. It must be supported by adequate documentation.

Benchmarking: Under quality improvement programs, the process of identifying and implementing “best” practices to achieve continuing quality improvement. Benchmarking is sometimes utilized by managed care organizations to evaluate physician performance.

Bloodborne Pathogens: Defined under the Occupational Safety and Health Administration Bloodborne Pathogens Standards as pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Bundling: The use of a single payment for a group of related services.

Capital-related Costs: Costs other than operating costs that are not included in the DRG rate. These costs include (1) depreciation expense, (2) lease and rental payments, (3) interest expense, and (4) insurance and taxes related to assets used to provide patient care.

Capitation: A method of payment where a fixed amount per person per time period is paid to cover specified services. Capitation payment rates are usually expressed in payment per member per month (PMPM) and may be adjusted by such factors as age and sex.

Carrier: An insurance company authorized by Medicare to reimburse a physician for direct patient care under Medicare Part B.

Carve Out: Services and procedures contractually defined apart from those included in a capitation rate and generally paid for on a fee-for-service basis. Laboratory services carved out frequently include anatomic pathology, cytopathology, and molecular diagnostics.

Case Mix Index: The average DRG weight for all cases paid under the prospective payment system (PPS). The case mix index is a measure of the relative costliness of the patients treated in each hospital or group of hospitals. See Diagnosis Related Groups (DRG).

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88): Revised the regulation of clinical laboratories by imposing certification, proficiency testing, quality control and personnel standards, and sanction and enforcement requirements on all laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The CLIA regulations became effective September 1, 1992.

CMS-1500: Formerly HCFS-1500, this is the form used for billing actual charges for Part B physician services to patients. It is used to identify specific charges for specific services. Providers also use the form to bill for physicians' services when the provider compensates the physician for Part B services. It is also used by physicians who accept assignment and by beneficiaries whose physicians do not accept assignment.

Coinsurance: A type of cost sharing where the insured party and insurer share payment of the approved charge for covered services in a specified ratio after payment of the deductible by the insured.

Copayment: A fixed dollar amount paid for a covered service by a health insurance enrollee.

Cost Sharing: A general term referring to payments made by a health insurance enrollee for covered services. Examples of cost sharing include deductibles, coinsurance, and copayments. See Coinsurance, Copayment, and Deductible.

Covered Lives: All persons who are entitled to health care benefits managed by a third-party insurer, including indemnity and managed care plans.

Combined Billing: Procedure in which a hospital submitted a single bill that did not distinguish between the institutional and professional elements of pathology services. Combined billing was eliminated by the provider-based physician regulations.

CPT: The physician Current Procedural Terminology is a listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. CPT was developed by the American Medical Association (AMA) and is updated annually.

Deductible: A type of cost sharing where the insured party pays a specified amount of approved charges for covered medical services before the insurer will assume liability for all or part of the remaining covered services. See Coinsurance, Copayment, Cost Sharing.

The Deficit Reduction Act (DRA) of 1984 (P.L.98-369): The legislation established Medicare carrier-wide fee schedules for clinical diagnostic laboratory tests effective July 1, 1984.

Diagnosis Related Group (DRG): The system used by CMS for classifying Medicare discharges. The system was developed by Yale University for classifying patients into groups that are clinically homogeneous with respect to resource consumption.

Direct Billing: Provider-based physicians direct bill for professional services when they bill individual patients (or their insurers) in their own name. The physician bears the risk of nonpayment and incurs billing costs. The physician is not direct billing when the provider compensates the physician for professional services, and the physician reassigns the right to bill to the provider.

Fee For Service (FFS): A payment method in which a charge is made and payment received for each service or procedure provided. FFS is the payment method employed by traditional indemnity health insurance plans.

Full-time Equivalent: This is the standard of 2080 work hours per year (40 hours per week x 52 weeks) used by CMS in determining the reasonable compensation equivalent (RCE) by specialty. The RCE is adjusted upward or downward based on actual hours worked.

Gatekeeper: A physician or other health care professional who coordinates, manages, and authorizes all health care services provided to a patient. Primary care physicians often fulfill the role as a gatekeeper for managed care organizations.

Health Maintenance Organization (HMO): A type of managed care plan that acts as both insurer and provider of a comprehensive set of health care services to an enrolled population. Benefits are typically financed through capitation with limited copayments, and services are furnished through a system of affiliated providers. See Independent Practice Association, Managed Care, Staff-model HMO.

HEDIS (Health Plan Employer Data and Information Set): A survey methodology devised and used by the National Committee for Quality Assurance (NCQA) that standardizes the quality performance data supplied by managed care organizations to NCQA. HEDIS allows NCQA to compare managed care organizations and provide “report cards” based on the quality of services provided.

Hold-harmless Clause: A contracting provision in which one party agrees to assume legal and financial responsibility for any liability arising out of the arrangement and agrees to indemnify the other party for liability claims. Managed care organizations often try to include such liability avoidance clauses in their provider agreements.

Hospital/Provider-based Physician: A physician who furnishes services in a provider and generally is compensated by or through the provider for Part A services. The physician may bill patients directly for Part B services. Alternatively, the physician may receive compensation for Part B services from the hospital and reassign the right to bill for these services to the hospital.

Independent Practice Association (IPA): A provider organization that contracts with individual physicians to provide services to enrolled members at a negotiated per capita or fee-for-service rate. Physicians maintain their own offices and can contract with other managed care plans and see other fee-for-service patients. IPAs are often affiliated with a hospital through a contractual arrangement that allows the hospital and physicians to jointly contract for the provision a full range of physician and hospital services. See Health Maintenance Organization.

Intermediary: An insurance company or fiscal agent authorized by CMS to make Part A payments to hospitals, nursing facilities, and comprehensive outpatient rehabilitation facilities on behalf of the Medicare program.

Laboratory: Defined under CLIA as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both), or only serving as a mailing service and not performing testing, are not considered laboratories.

Laboratory Services Organization (LSO): An entity formed to provide administrative management and support services by a group of participating laboratories with the objective of cost savings based on augmented volume. LSOs frequently own facilities and equipment, and employ staff. LSOs usually provide marketing, contracting, information system coordination, and courier services to member laboratories.

Lease/Concession Agreement: A relationship with the provider under which the physician furnishes services in the provider and assumes some or all of the operating costs of the department in which the services are rendered.

Managed Care: Any system of health service payment or delivery arrangements where the health plan attempts to control or coordinate the use of health services by its enrolled members to contain health expenditures, improve quality, or both. Arrangements often involve a defined delivery system of providers with some form of contractual arrangement with the plan. See Health Maintenance Organization, Independent Practice Association, Preferred Provider Organization.

Management Service Organization (MSO): An organization providing practice management and other operational needs to physicians. MSOs may operate as service bureaus, providing a menu of services from which the practice may choose, or as a turnkey operation, providing all practice needs.

Most-favored-nation Clause: A contractual term that requires the health care provider to charge the managed care or other payer the most favorable rate charged to any other payer for the same service.

National Committee for Quality Assurance (NCQA): An independent review and accreditation organization for managed care organizations. NCQA standards focus on quality improvement, utilization management, credentialing, peer review of medical records, preventative health services, and member rights.

Office of Inspector General (OIG): Office within the US Department of Health and Human Services (HHS) charged with the responsibility for enforcement of federal fraud and abuse laws with respect to Medicare, Medicaid, and other federal HHS programs. The OIG has issued separate guidelines for voluntary fraud and abuse compliance plans for independent clinical laboratories, hospitals (including their laboratories), physicians, and billing companies.

Outcome Reporting: Reporting on the consequence of a medical intervention on a patient. Outcomes effectiveness research attempts to identify and understand the clinical outcomes (including mortality, morbidity, and functional status) of the delivery of health care.

Occupational Exposure: Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials, which may result from the performance of an employee's duties.

Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard: Requires employers of all employees who have occupational exposure to blood or other potentially infectious materials to develop and implement procedures to reduce and prevent occupational exposure to bloodborne pathogens. The regulation is generally effective March 6, 1992.

Part A: This is the Medicare Hospital Insurance Program which covers inpatient hospital services. Most hospitals are paid for their inpatient services on the basis of a prospectively determined price for each Medicare discharge classified by diagnosis related group (DRG).

Part B: This is the Medicare Supplemental Medical Insurance Program under which physicians are reimbursed for approved medical and other health services provided directly to beneficiaries.

Per Member Per Month (PMPM): The payment method used in determining capitation payments for health care services consisting of a monthly payment amount for each member registered with the health care provider.

Physician Hospital Organization (PHO): The joint venture of a hospital or hospital group with participating members of its medical staff(s) as a vertically integrated bargaining entity.

Physician Compensation: For Medicare, there are 2 types: physician services to individual patients and physician services to a provider. Services to individual patients must be personally performed by the physician and contribute directly to the diagnosis or treatment of an individual patient. Such services are reimbursed on a reasonable-charge basis under Medicare Part B. Physician services to a provider, such as administrative and supervisory services of general benefit to provider patients, are reimbursed only to the provider under Medicare Part A.

Point of Service Plan (POS): A managed care plan that combines the features of both prepaid and fee-for-service insurance. Health plan enrollees decide whether to use network or non-network providers at the time care is needed and usually are charged sizable copayments for selecting the latter.

Practice Guidelines: An explicit statement of what is known and believed about the benefits, risks, and costs of particular courses of medical action. Practice guidelines are intended to assist decisions by physicians, patients, and others about appropriate health care for specific clinical conditions.

Preferred Provider Organization (PPO): A managed care health plan that contracts with networks or panels of providers to furnish services and be paid on a negotiated fee schedule. Enrollees are offered a financial incentive to use providers on the preferred list but may use non-network providers as well.

Primary Care Physician: A physician, usually in Family Practice, General Internal Medicine, or Pediatrics, who provides care to a patient on initial contact, usually occurring in the outpatient setting. These physicians may act as “gatekeepers” in managed care health plans.

Professional Component: The professional component includes the gross and microscopic examination of the specimen by the physician and interpretation. See Technical Component.

Prospective Payment System (PPS): The Social Security Amendments of 1983 (P.L.98-21) established a Medicare prospective payment system (PPS) for hospital inpatient services. The PPS regulations were effective October 1, 1983. The unit of payment is the Medicare discharge; payment varies according to the DRG classification of the discharge.

Quality Assurance: The process and procedures used to review, assess, correct, and improve the quality and appropriateness of services provided to patients.

Reasonable Compensation Equivalent (RCE): A limitation on Medicare reimbursement for administrative and supervisory services furnished by physicians to providers. The RCE limits do not apply to inpatient services when the hospital is paid under the prospective payment system. The RCE limits continue to apply to outpatient services because they are paid on the basis of reasonable cost. The RCE levels vary according to physician specialty, geographic location, and number of hours worked. The RCE levels may be adjusted upward

for the cost of continuing education, professional society membership, and malpractice insurance.

Reasonable-cost Reimbursement: Medicare's method of determining payment to hospitals prior to the adoption of the prospective payment system on October 1, 1983. Reasonable-cost reimbursement continues for outpatient services. It also continues for those hospital units that are exempt from the PPS. Some non-Medicare payers continue to use the reasonable-cost reimbursement formula.

Relative Value Scale (RVS): A listing of physician procedures with a numerical weighing factor to indicate physician time and effort on a common scale. A relative value scale requires a conversion value to derive a fee schedule. Medicare adopted a resource-based relative value scale (RBRVS) for payment for physician services on January 1, 1992. RBRVS weighting factors are periodically updated, as are conversion factors.

Risk Contract: A managed care contract in which the health care contractor has a risk of financial loss due to excessive use of health resources. Compensation methods include capitation, fixed rate, and percent of premium.

Risk Parameters or Bands: Clauses in at-risk contracts that are used to provide limitations on financial exposure of contractees providing services under managed care contracts.

Safety Net: The provision in an at-risk contract that limits the assumed risk by the health care provider. Such contractual clauses usually include minimum volumes, minimum fee guarantees, and rate adjustment initiated by utilization in excess of originally specified levels.

Separate Billing: The provider-based physician regulations require separate item-by-item billing for Part B services to provider patients. If the hospital compensates the physician, the hospital separately bills for the physician services. If the provider-based physician is not compensated by the hospital, the physician separately bills. Physician services must be billed on the CMS-1500 claim form.

Staff-model HMO: A managed care organization where physicians are salaried to the HMO.

Teaching Hospital: A hospital with an approved graduate medical education program in which physicians provide services to individual patients, as well as research, educational, and related supervisory services.

Technical Component: The technical component includes the preparation of the slide for interpretation by a physician and other usual pre-slide preparation items and services, such as nonphysician personnel clinical activities, medical supplies, and medical equipment. See Professional Component.

TEFRA: The Tax Equity and Fiscal Responsibility Act of 1982 (P.L.97-248) Section 108 contains the provisions relating to reimbursement of provider-based physicians.

Third-party Administrator (TPA): A third-party organization that does not provide health insurance, but handles payment, contract administration, utilization review, and data collection for the health care services provided.

Unbundling: The Medicare PPS regulations prohibit billing under Part B for nonphysician services to hospital inpatients. Inpatient clinical laboratory services (that do not meet the definition of physician services to individual patients) must be billed under Part A by the hospital and paid through the predetermined DRG rate.

Utilization Management: The concurrent and prospective process of monitoring, assessing, and controlling the utilization of health care services to promote efficiency and quality. Usually included are review of length of stay (LOS); patient admission practices; coordination of physician and nonphysician services; utilization of ER, laboratory, x-ray, and pharmacy services; as well as the concurrent and retrospective review of the specific health care provided.

Utilization Review (UR): A retrospective method of health care assessment to ensure that enrolled members have received appropriate quality medical services. Medical service reviews are conducted by health care professionals to assess appropriateness of hospital admission, length of stay, and use of other medical services.

Withhold: The proportionate share of a provider's payment in an at-risk contract that is withheld to finance overutilization of services. Distribution of withheld funds not needed to pay for excess utilization is primarily based on the provider's contribution but is sometimes adjusted to reflect predetermined standards for provider efficiency, quality, patient satisfaction, and other factors.

Abbreviations and Acronyms

Note: Items With Asterisks (*) are Defined in the Glossary

ABN	Advanced Beneficiary Notice
AMA	American Medical Association
APC	Ambulatory Payment Classification
CAC	Carrier Advisory Committee
CAP	College of American Pathologists
CCI	Correct Coding Initiative
CLIA	Clinical Lab Improvement Amendments of 1988*
CMD	Carrier Medical Director
CMS	Centers for Medicare and Medicaid Services (formerly HCFA)
CPT	Current Procedural Terminology*
DRA	Deficit Reduction Act of 1984*
DRG	Diagnosis Related Group*
FFS	Fee for service*
FTE	Full-time equivalent*
HCFA	Health Care Financing Administration (now called CMS)
HEDIS	Health Plan Employer Data and Information Set*
HIAA	Health Insurance Association of America
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization*
ICD-9	International Classification of Disease, 9th Edition
IDS	Integrated Delivery System*
IPA	Independent Practice Association*
LLC	Limited Liability Company
LMRP	Local Medical Review Policies
LSO	Laboratory Services Organization*
MFS	Medicare Fee Schedule
MSO	Management Service Organization*
NCQA	National Committee for Quality Assurance*
NLA	National Limitation Amounts
OIG	Office of Inspector General*
OSHA	Occupational Safety and Health Administration
PCP	Primary Care Physician*
EAC	Economic Affairs Committee (of the CAP)
PHO	Physician Hospital Organization*

Definitions

PMPM	Per Member Per Month*
POS	Point of Service
PPO	Preferred Provider Organization*
PRM	Professional Relations Manual (of the CAP)
QA	Quality Assurance*
QC	Quality Control
RBRVS	Resource-based Relative Value Scale
RCE	Reasonable Compensation Equivalent*
RUC	Relative Value Update Committee (of the AMA)
TEFRA	The Tax Equity and Fiscal Responsibility Act of 1982*
TPA	Third-party Administrator*
UR	Utilization Review*

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