COLLEGE of AMERICAN PATHOLOGISTS

PC Billing Information Package

Introduction

Pathologists report denials of bills for the professional component of clinical pathology services as one of their biggest problems in dealing with private insurance companies. Many private insurance companies state that their payment policies follow Medicare payment rules but wrongly assert that Medicare does not cover professional component services. In fact Medicare provides for payment for the professional component of clinical pathology services under Medicare Part A. For non-Medicare patients, professional component billing is one of the most common methods of compensating pathologists for their services in a clinical laboratory.

The College of American Pathologists (CAP) supports professional component billing as one valid method of billing by pathologists for their clinical pathology services. This informational package provides additional explanation of this issue with copies of guidance documents from the American Medical Association, an overview of the positions of private insurance companies, and a summary of key private litigation on professional component billing for non-Medicare patients.

What Services Constitute the Professional Component of Clinical Pathology?

Pathologists, in their capacity as medical directors of clinical laboratories, provide valuable and necessary medical services for all patients for which they assume medical responsibility and legal liability. The services and responsibilities are many and varied and focus, in large part, on ensuring that the results of laboratory tests are timely, medically reliable, and clinically useful. In fact, many of these duties and responsibilities are mandated by the Clinical Laboratory Improvement Amendments.

The CAP has developed a Policy on Pathologist Professional Component Billing for Clinical Pathology Services that describes the nature and type of professional services provided by the pathologist-director of a clinical laboratory. These essential medical services include:

- 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; and
- Assuring the laboratory's compliance with State licensure laws, Medicare Conditions of Participation, Joint Commission on Accreditation of Healthcare Organizations standards, the College of American Pathologists Laboratory Accreditation Program, and Federal certification standards.

What is the Basis for Payment Denial by Some Private Insurance Companies?

Despite attempts to inform and educate private insurance companies on the nature and value of professional clinical pathology services, payment denials continue to increase. Some private insurers deny payment based on the assertion that the clinical pathology services constitute automated tests and only the technical component is reimbursed. Other private insurers claim that they follow Medicare guidelines and Medicare does not recognize these services. These assertions are simply untrue.

As an example, UnitedHealthcare does not reimburse the professional component of clinical pathology if the service is provided either manually or with automated equipment. The policy states: "The oversight of lab services is part of the facility payment. Therefore, such oversight arrangements are a matter involving the facility and the pathologist, not UnitedHealthcare and the pathologist."

In 2003 Aetna announced a new payment policy for professional clinical pathology. Aetna will now only pay for the professional component of a clinical pathology services if there is a "direct clinical interpretation of the test being performed."

Humana has also ceased reimbursing for the professional component. It states as its basis for denial: "Humana is frequently billed for professional component charges for automated clinical pathology tests, which do not require professional interpretation or intervention. These tests are automated and professional interpretation is not required."

Many private insurers deny payment for the professional component of clinical pathology services even though they assert that their payment policies are consistent with Medicare. Some insurers may cite the following Medicare policy on physician services as support for their payment policy: "Only discussions with attending physicians and analysis of results may present involvement of the laboratory physician in activities for an individual patient sufficient to qualify as physicians' services reimbursable on a reasonable charge basis" (Vol. 48 of the Federal Register, at page 8932). This Medicare rule relates to the requirements for payment of physician services under Medicare Part B. However, the professional component of clinical pathology is not reimbursed under Medicare Part B; rather, these professional services are reimbursed under Medicare Part A.

Under Part A, Medicare provides reimbursement for, among other medically necessary services, "professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility" (Vol. 48 of the Federal Register, at page 8904). The professional component of clinical pathology services is one of the types of services described by Medicare that is provided for the general benefit of all patients.

Is There Coding Guidance for Professional Component Billing?

As noted above, Medicare does recognize and reimburse for the professional component of clinical pathology services. Medicare includes payment for professional component services in the fixed amount that Medicare pays to the hospital for each patient under Medicare Part A. For each patient, Medicare pays the hospital based upon the patient's diagnosis related group, or DRG. A payment amount is assigned to each DRG, which is intended to cover a variety of services that may be received by the patient, including professional component services.

Because private insurance companies do not have a payment mechanism analogous to the DRG payments under Medicare Part A, the American Medical Association (AMA) has recognized the use of the -26 modifier as an appropriate mechanism to describe the professional component of clinical pathology services for non-Medicare patients.

The AMA recognizes that certain procedures, including clinical pathology services, are a combination of a physician professional component and a technical component. For procedures with both a technical and professional component, the AMA recognizes the use of the -26 modifier when the professional component of the procedure is being reported separately. The-26 modifier is used to describe the physician professional services in those instances when the physician is only billing for the professional component and the facility is reporting the technical component.

The AMA has published two articles with additional guidance on this issue. The first article is published in the CPT Assistant, Volume 9, Issue 5, May 1999. The AMA states that the use of the - 26 modifier is appropriate when the physician is billing separately for the professional component of a laboratory test.

Subsequently, in the CPT Assistant, Volume 15, Issue 8, August 2005, the AMA defined the professional component of clinical pathology by reference to the description in the CAP's Policy on Pathologist Professional Component Billing for Clinical Pathology Services.

As noted above, Medicare reimburses the professional component of clinical pathology services under Part A. However, there are several clinical pathology procedures that Medicare reimburses under Part B. Specifically Medicare will pay pathologists under Part B for clinical laboratory interpretation services billed with a -26 modifier for the following CPT codes:

CPT Code	Description of Service
83020	Hemoglobin fractionation and quantitation; electrophoresis (eg, A2, S, C, and/or F)
84165	Protein; electrophoretic fractionation and quantitation, serum
84166	Protein; electrophoretic fractionation and quantitation, other fluids with concentration (eg, urine, CSF)
84181	Protein; Western Blot with interpretation and report, blood or other body fluid

84182	Protein; Western Blot with interpretation and report, blood or other body fluid, immunological probe for band identification; each
85390	Fibrinolysins or coagulopathy screen, interpretation and report
85576	Platelet, aggregation (in vitro), any agent
86255	Fluorescent noninfectious agent antibody; screen, each antibody
86256	Fluorescent noninfectious agent antibody; titer, each antibody
86320	Immunoelectrophoresis; serum
86325	Immunoelectrophoresis; other fluids (eg, urine, cerebrospinal fluid) with concentration
86327	Immunoelectrophoresis; crossed (2 dimensional assay)
86334	Immunofixation electrophoresis; serum
86335	Immunofixation electrophoresis; other fluids with concentration (eg, urine, CSF)
87164	Dark field examination, any source (for example, penile, vaginal, oral, skin); includes specimen collection
87207	Smear, primary source with interpretation; special stain for inclusion bodies or parasites (eg, malaria, coccidia, microsporidia, trypanosomes, herpes viruses)
88371	Protein analysis of tissue by Western Blot, with interpretation and report
88372	Protein analysis of tissue by Western Blot, with interpretation and report; immunological probe for band identification, each
89060	Crystal identification by light microscopy with or without polarizing lens analysis, any body fluid (except urine)

In order to bill under Medicare Part B for these identified CPT codes, the services must meet the following criteria for clinical consultations:

1. the services are requested by the Medicare beneficiary's attending physician;
2. the services must result in a written narrative report included in the Medicare beneficiary's medical record; and
3. the services require the exercise of medical judgment by the consultant physician.

What has been the Outcome of Litigation over Professional Component Billing?

There are several key court cases that have established the value of and obligation of private insurance companies to reimburse for professional component services. For example, in the 1997 case of Smith v. Peoria Tazewell Pathology Group, Case No. 94-L-245, the Illinois Court for the 10th Circuit found the value of the pathologists' services indisputable. The Court stated:

"There is no genuine issue of material fact that the Pathologists provide medical services of value to all patients who have laboratory tests performed at the hospitals at which the Pathologists practice. These services include establishing test protocols, performing quality control and assurance, and remaining available to consult with laboratory technicians and treating physicians. The Pathologists are entitled to bill patients, including plaintiffs Smith and Lighter, for these services—regardless of whether the Pathologists personally perform the test or review its results."

The Court in the Smith case cites another pivotal opinion on professional component billing from the 1995 case of Central States v. Pathology Laboratories of Arkansas, 71 F.3d 1251. In this case the United States Court of Appeals for the 7th Circuit held that either the payer or the patient is obligated to pay a pathologist's charge for professional component services. In this opinion, the Court characterized professional component billing as a system that "spreads costs across all patients—and in the process it avoids the need to keep records about just which test required just which services." Additional information on the legal significance of this important case is discussed in the attached memorandum prepared by Sidley & Austin.

More recently eleven pathology groups in Florida filed suit against Health Options, an HMO and subsidiary of Blue Cross and Blue Shield of Florida, to recover reimbursement for professional component services. In the first case that went to trial, Palmetto Pathology Services v. Health Options, Case No. 05-4137 CA 09, the Florida Court for the 11th Circuit ruled in favor of the pathology group and required direct payment from Health Options to the pathologists for the professional component of clinical pathology services furnished for the HMO's subscribers.

In reaching this conclusion, the Florida Court noted that the professional component of clinical pathology "directly benefits each and every patient needing laboratory services." The opinion also recognizes that the professional component of clinical pathology constitutes a valuable and necessary medical service that is separate and distinct from the technical component of a laboratory test. Health Options challenged the Court's ruling. The CAP filed an amicus brief in support of the pathologists. On appeal, the District Court of Appeal of Florida (3rd Dist.), the court affirmed the trial court's ruling in all respects in Health Options, Inc. v. Palmetto Pathology Services, PA, Case No. 3D07-1453. Health Options then appealed to the Florida Supreme Court which on October 15, 2008 denied Health Options' request for a hearing representing the judicial conclusion in favor of the pathologists. As a matter of law, therefore, Florida's HMOs must make direct payment to pathologists for the professional component of clinical pathology.

In 2008 and 2009, Illinois courts upheld professional component billing rulings in favor of pathologists billing for these services. In November 2008, the Circuit Court of Cook County in Neighborhood Clinics, LLC v. Pathology CHP et al, Case No. 05 CH 2692, upheld the validity and fairness of professional component billing indicating "The evidence is overwhelming that patients and not just the hospitals benefit from the pathologists' quality control services billed under the professional component of clinical pathology which insure the accuracy and reliability of the laboratory result for their diagnosis and treatment." Neighborhood Clinics had contracts with numerous HMOs and health plans, such as Blue Cross Blue Shield, Humana, and others. The CAP submitted an amicus brief in favor of the pathologists in this case.

In October 2009, pathologists in Illinois again prevailed, this time at the Illinois state appellate court level in Richard Martis v. Pekin Memorial Hospital Inc, et. al, Case No. 2-08-0543. The court held the practice of professional component billing not actionable. Professional component services included the pathologist's supervision of the laboratory to make sure results are timely and medically reliable and the pathologist's availability – seven days a week, 24 hours a day – to review any result that is questionable and to discuss various medical issues that might be raised about test results.

There has been an unfavorable ruling on the issue of professional component billing, which came in 2002 in Central States v. Florida Society of Pathologists, 5D01-501, July 12, 2002, District Court of Appeal of the State of Florida (5th Dist.). This case did not directly address the nature and value of professional component services; rather, the case involved the ability to bill patients for the services. The Florida Society of Pathologists filed a complaint against Central States for unfair trade practices and interference with business relationships after Central States communicated to its plan members that pathologists had inappropriately billed the professional component of the clinical pathology services received by the members. The letters to the plan members instructed them not to pay any bills for professional component services. The court ruled against the pathologists finding that there was no contractual commitment on the part of the members to pay for the pathologist's bill for the professional component.

It is important to note that the Central States case did not rule against the practice of professional component billing but required that patients in Florida contractually agree to be obligated to pay for the service before a pathologist could submit a bill. One of the key facts cited by the court was the lack of clear reference to the professional component in patient brochures. The brochure given to the patients included the following statement:

"The pathologist's bill will cover his or her professional services in examining and analyzing your blood, cells, tissue or other specimens, reporting the findings, and consulting with your physician when it is appropriate."

While the patient brochure created a contractual obligation, the Court found that the brochure suggested that the bill would only include patient-specific services. The Court also stated that because the pathologist did not furnish direct services for the patients, the patients did not contractually agree to pay for the professional component.

Lessons Learned from Professional Component Litigation

The nature and value of professional component services has been well established under these and many other private litigation matters. While the case opinions may not be directly applicable or binding on private insurers in your area, the favorable characterizations of professional component

services in these cases may be persuasive as you attempt to negotiate for, or resolve a dispute regarding, reimbursement for your professional services.

Another important lesson from both the successes and setbacks from the litigation is the need to establish the appropriate contractual obligation for payment of the professional component of clinical pathology services. Pathologists may need to establish contractual relationships with private insurers, hospitals and patients regarding professional component billing.

In the case of contracts with private insurers, you need to document the insurer's position on reimbursement of clinical pathology services. If the insurer does not include the professional component of clinical pathology as a covered medical service, you need to ensure that your contract with the insurer does not require you to give up the right to bill health plan participants and collect for professional component services as a condition of participation. If the insurer believes that payment for your professional services is included as part of the facility fee and covered by the contract between the insurer and the hospital, you need to discuss this issue with the hospital.

There are often regional variations in the payment by private insurers of the professional component of clinical pathology. While an insurer may have adopted a national policy on clinical pathology services, some pathologists have been successful in negotiating for payment as part of their local participation agreement. You should ensure that the payment terms of your contract cannot be unilaterally amended by virtue of a policy announcement by the insurer and inquire whether hospital agreements can be amended in this fashion.

If the hospital accepts that their contract with the insurer covers both the professional and technical component of the service, then you should ensure that the hospital understands their obligation to pass-through payment to you or your group. If the hospital does not agree with the insurer then the hospital may serve as an ally in negotiating appropriate contract language with the insurer that expressly covers the professional component of the service. If you have a separate medical director agreement with your hospital, you need to review the language to determine what professional component services are included in the compensation. The terms of your medical director agreement should be specific to Medicare and non-Medicare patients to distinguish the different payment methodologies for your services.

In the case of contracts with patients, you may need to work with the hospital to include appropriate billing disclosures to be provided to patients as part of the registration or admission process. You should also check for requirements under your State law for obtaining patient consent for payment purposes. The CAP has prepared sample language (located at the end of this document) that may be used as part of a patient brochure to inform patients and serve as an agreement to pay for professional component services. There is a one-page patient consent statement and a shorter version depending on your State requirements.

For more information and practical tips for pathologists who engage in professional component billing, please read the article, "Ten Commandments of Professional Component Billing March 2003", CAP Today, prepared by Jack Bierig of Sidley Austin Brown & Wood, LLP, and published in CAP Today, March 2003.

For additional information on professional component billing for non-Medicare patients, please visit www.cap.org, or contact the Division of Advocacy for the College of American Pathologists at (800) 392-9994 or (202) 354-7100.

COLLEGE of AMERICAN PATHOLOGISTS

AGREEMENT TO PAY FOR

PROFESSIONAL COMPONENT

AND OTHER PATHOLOGY SERVICES

If your doctor orders testing of a specimen of your blood, urine, or other tissue, the specimen will be sent to the medical laboratory for analysis. The laboratory is directed by a pathologist, a physician who specializes in laboratory medicine. The pathologist is responsible for assuring that the results of your laboratory tests are clinically reliable and are reported to your doctor in a timely manner.

It is important for you to understand what pathologists do for you in the laboratory. Sometimes, pathologists review biopsied tissue under a microscope to determine whether or not the tissue indicates the presence of disease and, if so, what specific kind of disease. They will report their findings to your doctor. These services are known as anatomic pathology services.

Where a specimen of your blood, urine, stool, or similar material is sent to the laboratory, a pathologist many not have to review the specific specimen. Rather, in these situations, pathologists are responsible for quality assurance and quality control. They provide medical supervision of the technicians and technologists who work in the laboratory. They must be available to address problems that arise in the laboratory regarding specific results. Moreover, they must be available to answer any questions that your doctor might have about your laboratory results. Pathologists' services in directing the medical laboratory to assure the timeliness, reliability, and usefulness of your test results are referred to as the "professional component" of clinical pathology services.

If you have laboratory work done while at this hospital, you will receive a separate bill for the pathologist's services. The bill will include charges for the pathologist's direct, anatomic pathology services with respect to your biopsied tissue. It will also include charges for the pathologist's professional component services relating to your specimens that were tested in the laboratory. **YOU WILL RECEIVE A BILL FOR PROFESSIONAL COMPONENT SERVICES EVEN IF THE PATHOLOGIST DID NOT PERSONALLY PERFORM THE TEST OR REVIEW ITS RESULTS**.

By signing this Agreement, you agree to be responsible for the pathologist's anatomic and professional component charges as described above to the extent that those charges are not paid for by your insurer or managed care plan. These charges are made so that we can continue to offer the quality laboratory work that is essential to the proper diagnosis and treatment of your condition. If you have any questions about pathology services or the bills for

such services that you receive from the pathologist, please call _____ at _____.

AGREEMENT TO PAY FOR PROFESSIONAL COMPONENT PATHOLOGY SERVICES

When a specimen of your blood, urine, stool, or similar material is tested in the laboratory while you are in the hospital, the testing will be performed under the supervision of the pathologist who directs the laboratory. The pathologist may not perform the test or personally review its results. However, the pathologist is responsible for supervising the laboratory to assure that the results of all of your tests are clinically reliable and are reported to your doctor in a timely manner. **YOU WILL RECEIVE A BILL FROM THE PATHOLOGIST FOR THESE SUPERVISORY SERVICES FOR EACH TEST EVEN IF THE PATHOLOGIST DID NOT PERSONALLY PERFORM THE TEST OR REVIEW ITS RESULTS.** By signing this Agreement, you agree to be responsible for the pathologist's bill to the extent that it is not paid for by your insurer or managed care plan.

Disclaimer

THE INFORMATION PROVIDED IS FOR GENERAL INFORMATION PURPOSES ONLY AND DOES NOT CONSTITUTE LEGAL ADVICE AND MAY NOT BE RELIED UPON FOR ANY PURPOSE. The information provided on these pages summarizes federal laws applicable to health care providers, but does not address potential legal issues under state law. You should consult legal counsel on specific legal questions. If you are in need of legal counsel there are a variety of lawyer referral services, including those through your state and local bar associations and the American Bar Association.