

CRITICAL ISSUES IN PROFESSIONAL COMPONENT OF CLINICAL PATHOLOGY BILLING

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I. What are the professional components of clinical pathology services?

The performance of the professional components of clinical pathology services by pathologists involves the use of medical judgment and constitutes the practice of medicine. Although professional component clinical laboratory services are not the same type of face-to-face patient services that many other physicians provide, these are actual medical services, which only pathologists are educated, trained and qualified to perform. Professional components of clinical pathology services are not unnecessary or automated services, nor are they “paper-pushing” services. Pathologists devote real time and effort (often 50% of their professional time) to professional component of clinical pathology services. These services meet the recognized definition of patient care services because they contribute directly to the diagnosis, care and treatment of individual patients, and the services can be performed only by physicians with specialized training. Professional component services are medically necessary services that are separate and distinct from the hospital’s technical component of clinical laboratory services. Examples of professional component services are listed on the attached Exhibit A.

II. Do certification or accreditation requirements address professional components of clinical pathology services?

Federal and state certification standards, including, without limitation, the Clinical Laboratory Improvement Amendments of 1988, the Joint Commission on the Accreditation of Healthcare Organizations, and the College of American Pathologists, require that hospital laboratories contract with pathologists to provide professional component services. Many state license and certification criteria also require the provision of professional components of clinical pathology services by qualified pathologists.

III. How does the Medicare program reimburse for professional components of clinical pathology services?

The Medicare program provides for reimbursement for professional components of clinical pathology services to Medicare beneficiaries through Medicare Part A DRG payments to hospitals, rather than through Medicare Part B payments directly to the pathologists. When the

Medicare program shifted the reimbursement for professional component services from Medicare Part B to Medicare Part A, it allocated payment for professional component services into its DRG calculations. As explained below, the Office of the Inspector General (“OIG”) has indicated that a hospital may be in violation of the Medicare and Medicaid anti-kickback law if it does not pay the pathologists for their professional component services to Medicare beneficiaries.

IV. Can a hospital refuse to pay pathologists for their professional components of clinical pathology services for the hospital’s Medicare patients?

Remuneration between a hospital and pathologists may implicate the Medicare and Medicaid anti-kickback law, particularly if the pathologists are required to pay direct or indirect remuneration to the hospital as a condition of providing services to the hospital’s inpatients and outpatients. This issue arises most often in the negotiation of an appropriate “Part A” payment to the pathologists. If the Part A payment is below fair market value, the government could allege that the pathologists have paid a kickback to the hospital in exchange for the opportunity to provide services at the hospital.

The OIG has explained that a hospital’s demand for compensation from its hospital-based physicians is suspect under the anti-kickback law. (OIG Management Advisory Report: Financial Arrangements Between Hospitals and Hospital-Based Physicians, at pp.3-4, January 31, 1991.) This OIG report specifically discusses no, or token, reimbursement to pathologists for Part A services in return for the opportunity to perform and bill for Part B services at that hospital. The OIG’s Compliance Program Guidance for Hospitals also cautions against arrangements with hospital-based physicians that compensate the physicians less than fair market value for their services, including no or token Part A compensation for pathologists. (OIG’s Compliance Guidance for Hospitals, footnote 25, February 1998.)

By refusing to pay adequate Part A compensation to pathologists, hospitals and their individual administrators and trustees may violate the anti-kickback law, thereby subjecting themselves to criminal and civil penalties.

V. Does the hospital’s reimbursement for clinical laboratory services from private payers and patients include the pathologist’s professional components of clinical pathology services?

Reimbursement by private payors and patients for the hospital’s technical component services generally does not cover the professional medical services of pathologists with respect to the tests. The amount paid by patients and private payors to the hospital laboratory generally covers only the costs for equipment, reagents, salaries of non-physician personnel, and overhead. These technical services are distinct from the medical services of pathologists. Pathologists can bill “private” patients and payors (non-Medicare, non-Medicaid and non-TriCare patients and payors) directly for such services absent a state law or payor contract prohibition. Therefore, there is no double billing or double payment if pathologists bill and collect for their professional

components of clinical pathology services for “private” patients (patients who are not beneficiaries of the Medicare, Medicaid or TriCare programs).

If a pathologist’s Part A compensation from a hospital is not intended to cover professional components of clinical pathology services to private patients, then the hospital contract should explicitly state that the Part A compensation covers only professional components of clinical pathology services to beneficiaries of the Medicare, Medicaid, or TriCare programs.

VI. *Is it ethical to bill for professional components of clinical pathology services?*

Billing private payors and patients for professional components of clinical pathology services is clearly recognized as being professionally and ethically appropriate. Both the American Pathology Foundation and the College of American Pathologists recognize professional component billing. Since at least 1993, the American Medical Association, which develops and publishes all CPT codes, has informed payors that pathologists may bill for professional components of clinical pathology services using the –26 modifier. The American Medical Association issued a position letter on December 9, 2004, reaffirming that “the use of the –26 modifier is appropriate to describe physician professional services associated with CPT codes 80048-8799 when the physician is only billing for the professional component of the laboratory test (i.e., medical direction, supervision, or interpretation).”

VII. *Is it legal for pathologists to bill for professional components of clinical pathology services for private patients?*

The legality of billing non-government payors and patients for professional components services for “private” patients is well-established.

In *Central State v. Pathology Laboratories of Arkansas*, 71 F.3d 1251 (7th Cir. 1995), the United States Court of Appeals held that either the payor or the patient is obligated to pay a pathologist’s charge for professional component services. The Supreme Court of the United States denied certification in this case, effectively upholding the appeals court’s ruling in favor of the pathologists.

Similarly, in *Smith v. Peoria Tazewell Pathology Group*, Case No. 94-L-245 (Ill. Cir. 1997), the court ruled:

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 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 for these services** - regardless of whether the Pathologists personally perform the test or review its results.

The *Central States* case in Florida is discussed below.

VIII. *How can billing for professional components of clinical pathology services for private patients be reconciled with the Medicare program's reimbursement methodology for such services?*

Billing for the professional components of clinical pathology services for “private” patients is consistent with the policy of the Medicare program with respect to reimbursement for professional component services provided to Medicare beneficiaries. Congress has authorized reimbursement for professional component services to Medicare beneficiaries. Since 1983, reimbursement for the professional components of clinical pathology services of pathologists is made through the Medicare Part A DRG payments, rather than Medicare Part B. Prior to this date, reimbursement for these services was made through Medicare Part B. The switch in Medicare reimbursement from the Part B fund to the Part A fund was for accounting purposes, and did not affect the Medicare program’s recognition of professional components of clinical pathology services as a covered, reimbursed service. Private payors generally do not have such separate funds for reimbursement.

Furthermore, the OIG has explained that hospitals risk violating the Medicare and Medicaid anti-kickback law if they do not pay pathologists for their professional component services to Medicare beneficiaries. Therefore, the Medicare program does provide dollars to compensate pathologists for these services, and may impose criminal and civil penalties for the failure of a hospital to pay a portion of the Medicare DRG amount to the pathologist for professional components of clinical pathology services for Medicare patients.

Billing for professional components of clinical pathology services for “private” patients does not involve the submission of any claim to any government payor, thereby avoiding many of the claims submission compliance issues that affect health care providers. Payors have the ability to decline to cover reimbursement for professional components of clinical pathology services, but this does not mean that pathologists cannot bill for the services. Physicians, hospitals, and other health care providers routinely bill patients for non-covered services.

IX. *What was the ruling in the Florida Central States case?*

On July 12, 2002, the Fifth District Court of Appeals of the State of Florida (the “Appeals Court”) announced its decision in *Central States, Southeast & Southwest, etc. vs. Florida Society of Pathologists, etc., et al.* The Appeals Court reversed the Ninth Circuit Court’s (the “Trial Court”) February 2001 grant of an injunction banning Central States, Southeast & Southwest Areas Health and Welfare Fund (“Central States”) from advising patients that bills they receive from pathologists for professional components of clinical pathology services are “fraudulent” and should not be paid. The Appeals Court’s ruling against the pathologists was based primarily upon the Appeals Court’s position that the pathologists had not established that a contractual relationship existed with the patient that would obligate the patient to pay for the professional component services.

The Appeals Court wrote that the record from the Trial Court case did not show an existing or prospective legal or contractual right on the part of the pathologists. The Appeals Court further explained that the pathologists had not cited a contract obliging the patients to pay a professional component fee. The Appeals Court examined the admission form that patients receive when they are admitted to the hospital, and explained that “*some of the small print in these forms mentions that the patients may receive bills from pathologists, anesthesiologists, and other professionals, but we (the Appeals Court) see nothing in these forms that obliges a patient to pay a pathologist or anesthesiologist in the absence of a professional relationship with the pathologist or anesthesiologist. We see no mention of a professional component, and no mention of the nature of any bills the patient may receive from pathologists. Certainly we see nothing that obliges a patient to pay for what might be characterized as the pathologists’ overhead and/or a pro rata share of hands-on pathology services performed for another patient.*”

The Appeals Court did not address specifically the findings in prior cases, more particularly the *Central States* case in Arkansas and the *Tazewell* case in Illinois, which found that the patients have an implicit contractual obligation to pay for professional components of clinical pathology services. It appears as though the Florida Appeals Court wanted to find a reason to rule against the pathologists, and because it was not able to find that professional components of clinical pathology services were medically unnecessary, fraudulent, or duplicate services, the Appeals Court instead relied upon the lack of a contractual relationship.

X. *Is the Florida case binding upon all pathologists?*

It is important to note that the Appeals Court’s decision in *Central States* is only binding in the Fifth District of Florida, and only with respect to the specific circumstances involved in the case. It is not binding in other jurisdictions. In fact, in states such as Arkansas and Illinois, there is existing legal precedent that firmly establishes the right of the pathologists to bill professional components of clinical pathology services. Nevertheless, for pathologists in other areas of Florida and in the remaining states where there is no specific guidance from state courts, this case offers guidance for pathologists to strengthen their legal position with respect to professional component billing.

XI. *What should pathologists do to address the Central States decision?*

The Appeals Court in *Central States* was concerned that the admission materials provided to the patients upon admission to the hospital did not specifically explain the nature of the pathologists’ professional components of clinical pathology services, or the fact that the patients would receive a bill for these services. Therefore, pathologists should review the admission and outpatient registration materials utilized by their hospitals and other facilities at which they practice and discuss modifications or supplements to these materials in order to address the decision of the Appeals Court.

Many pathologists have fairly thorough written explanations of the nature of and charges for professional components of clinical pathology services, and include these materials to patients with the professional component bill. If these materials clearly explain that the patient

may receive bills for professional components of clinical pathology services, and the patient is financially responsible for these services, then the pathologists may wish to include these materials, with a signature line for patient acknowledgement, in the hospital admission/outpatient registration form. If a much shorter description is required, then the following language could be used:

“While you are in the hospital, you may receive anatomic or clinical laboratory tests directly performed by a pathologist. You may also receive clinical laboratory tests that will be performed under the supervision and direction of the pathologists but are not personally performed by the pathologists. Although a pathologist may not perform these tests or personally review their results, the pathologist is responsible for the supervision and direction of the laboratory. You may receive a bill for these different types of pathologist services. By signing this form, you agree to pay the pathologist’s charges for these services if your health plan does not cover all of the pathologist’s charges.”

Language also should be added to the contracts between hospitals and pathologists that obligates the hospitals to include this type of form in the hospitals’ admission packages for patients. In addition, the hospital contract should state that compensation received by the pathologists from the hospital for professional components of clinical pathology services is for specific patient categories (such as Medicare and Medicaid patients), and the pathologists have the right to bill and collect for professional components of clinical pathology services for all other patient categories.

The hospital contract should prohibit the hospital from negotiating with payors to receive compensation for any professional services provided by the pathologists. Pathologists also should review their own payor contracts carefully to ensure that the contracts do not prohibit the pathologists from billing for professional components of clinical pathology services.

EXHIBIT A

The professional components of clinical pathology services that pathologists provide to the patients include, without limitation, the following:

- (i) The consideration of appropriate test methodology, instrumentation, reagents (agents used in laboratory testing), standards, and controls;
- (ii) The establishment of test reference values and levels of precision, accuracy, specificity, and sensitivity;
- (iii) The direction of laboratory technical personnel and advice to such personnel concerning testing;
- (iv) Assurance that tests, examinations and procedures are properly performed, recorded, and reported;
- (v) Interactions with members of the medical staff regarding issues of laboratory operations, quality, and test availability;
- (vi) The design of test protocols and the establishment of parameters for the performance of tests;
- (vii) Recommendations regarding appropriate follow up diagnostic tests when appropriate;
- (viii) The direction, performance and evaluation of quality assurance and quality control procedures;
- (ix) The evaluation of clinical laboratory data and the establishment of a process for review of test results prior to the issuance of patient reports;
- (x) The determination of the effects of medication on tests;
- (xi) The determination of the effects of other analytes on test results;
- (xii) The effects of other disease states on test results;
- (xiii) The establishment of turnaround times;
- (xiv) The criteria for “stat” (emergency) applications;
- (xv) The prioritization of testing and testing sequences;

- (xvi) The application and response of “critical values” (values which require immediate medical consideration);
- (xvii) The determination of formats for reporting;
- (xviii) The establishment of referral criteria for review by pathologists and subsequent examination;
- (xix) The determination of the type of data collection and storage criteria that will be used for particular tests;
- (xx) The prevention of overuse and improper application of tests; and
- (xxi) The assurance that the hospital laboratory complies with state licensure laws, certain accreditation standards, and certain federal certification standards.

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