

**HEALTH CARE REFORM
PAYMENT ISSUES FOR PATHOLOGY AND LABORATORY PROVIDERS**

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A. 60 Day Deadline to Report Overpayments (Effective March 23, 2010)

Requires Medicare or Medicaid overpayments to be reported and returned within 60 days after the overpayment is identified

- If a corresponding cost report is due, the deadline for reporting an overpayment is the later of the date the cost report is due or 60 days after the overpayment is identified
- Retention of an overpayment after the deadline is deemed to be an “obligation” and a false claim under the False Claims Act and to create exposure under the False Claims Act and civil monetary penalties

B. Medicare Shared Savings Program (Effective January 1, 2012)

The Medicare shared savings program is designed to promote accountability for a patient population, coordinates items and services under Medicare Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

- Two models: one-sided (shared savings only) and two-sides (shared savings and shared risk, with greater upside opportunity than the one-sided model)
- Allows providers and suppliers to work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (ACO)
- An ACO that meets quality performance standards and cost saving targets will be eligible to receive payments for shared savings
- ACO eligibility standards:
 - groups of providers and suppliers:
 - ACO professionals in group practice arrangements
 - Networks of individual practices of ACO professionals

TALKING POINTS FOR OUT OF NETWORK PROVIDERS

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Provided below are talking points that pathologists and laboratories may wish to use with clinicians who receive negative or threatening communications from payors with respect to their referrals for out of network pathology and laboratory services:

1. Only licensed physicians have the legal authority under state law to make medical decisions for patients. The selection of a pathology or laboratory provider for their patients is a medical decision. Only licensed physicians are authorized to order these services, so a payor cannot take the position that the selection of the pathology or laboratory provider is not a medical decision. If the selection of the pathology or laboratory provider was not a medical decision, then anyone could order the pathology or laboratory services, including non-physicians. Many states, such as Texas, New York and California, have strong prohibitions against the corporate practice of medicine.

2. If physicians concede to the payor with respect to the providers to whom they can refer their patients, then there is nothing that would stop the same payor from similarly restricting specialists to whom primary care physicians could make referrals. In fact, some payors have attempted to utilize the restrictive practices not only with respect to referrals out of network, but also with respect to in-network referrals. Therefore, it is important for physicians to put a stop to the payor's encroachment into their medical decision making.

3. Some payors reference concerns with respect to non-participating pathology providers laboratories who attempt to attract patients by offering to waive or cap co-payments, co-insurance or deductibles. Emphasize that your practice or laboratory does not advertise waivers in any of its billing policies in order to attract patients. Explain that your practice or laboratory does not engage in the blanket waiver of co-payments, co-insurance or deductibles.

4. Certain payors warn that the routine waiver of co-insurance, co-payments or deductibles could be a violation of the anti-kickback laws as well as the federal False Claims Act. While this is an accurate statement, violation of these laws is limited to very narrow situations. The concern under the anti-kickback law is one in which the referring clinician recognizes a financial benefit as a result of the waiver policy, and the waiver policy is utilized by the laboratory to encourage the physician to make referrals so that the physician will receive this financial benefit. A violation of the federal False Claims Act would generally require a routine waiver of co-insurance, co-payments or deductibles.

5. Physicians may wish to contact their state medical associations, state medical board and the American Medical Association to express their concern regarding payor activities, particularly as such activities encroach upon the medical decision making of clinicians, and limit the choice of physicians and their patients to select the most appropriate provider of laboratory services.

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.

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.

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 dated 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)” and a position letter dated June 23, 2005 also confirming that “in using Modifier –26 for pathology and laboratory codes 80049-87999, a written report for an individual patient is not a requirement for having performed a professional component service since it can be reported for medical direction of the tests performed.” The CPT Coding Assistant also confirms this position, explaining that no written professional interpretation is required to bill for the professional component of clinical pathology services with the -26 modifier.

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 States Health & Welfare Fund 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 Illinois Circuit 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.*

In *Martins v. Pekin Memorial Hospital*, Case No. 05-L-23 (Ill. Cir. 2007), the Illinois Circuit Court ruled that “*the professional component billing practice ... has been upheld in Central States Health & Welfare Fund v. Pathology Laboratories of Arkansas.*” The court held that the plaintiff’s claim that billing for professional component of clinical pathology services was improper “should not be a part of any cause of action” by the plaintiff.

In *Palmetto Pathology Services v. Health Options*, Case No. 05-4137-CA-09, the Florida Circuit Court ruled in favor of the pathologists, ordering the HMO to pay the pathologists for their professional component of clinical pathology services. The court’s ruling was based, in part,

upon Florida HMO laws, which specifically require HMOs to pay for professional and technical components of clinical pathology services. The court wrote that:

The Court finds as a matter of law that the clinical laboratory examinations conducted by Plaintiff for the benefit of Defendant's subscribers/members, for which there is potential liability by Plaintiff to each subscriber, includes the oversight and supervision of the clinical laboratory and personnel. ... Unreliable and inaccurate reports may cause unnecessary anxiety, suffering, and financial burdens and may even contribute directly to death. ... As such, the Court finds as a matter of law that the oversight and supervision of the clinical laboratory that constitutes a portion of PC-CP medical services rendered to, and for the benefit of, Defendant's subscribers is a valuable and necessary medical service that is compensable.

In *Central States, Southeast & Southwest v. Florida Society of Pathologists*, Case No. 5D01-501 (Fl. App. Ct. 2002), the Florida Appeals Court reversed the Circuit Court's 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 lower 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. This case also pre-dated the 2007 *Palmetto* case in Florida, which ruled in favor of the pathologists. 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.

On November 3, 2008, another Illinois Circuit Court ruled in favor of pathologists. In *Neighborhood Clinics v. Pathology CHP, S.C.*, No. 05 CH 2692 (Ill. Cir. 2008), the court wrote that:

This Court find 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 ensure the accuracy and reliability of the lab results needed for their diagnosis and treatment. The Court finds that it is not unfair that the patients pay for the pathologists' quality control services in assuring that the pathology lab established by the Hospital is run properly. [It] does not violate the principles of justice, equity and good conscience to allow the pathologists to retain [professional component of clinical pathology] payments they received from [the payor] on the patients' behalf.

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 Should Pathologists do to Address the *Central States* Decision?

The Florida 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. Although the *Central States* case is not binding outside of the Fifth District of Florida, 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.

MANAGED CARE CONTRACTING ISSUES

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THE PATHOLOGY/LABORATORY PROVIDER'S RELATIONSHIP WITH MANAGED CARE ENTITIES

When contracting with any managed care entity, there are four principal contracting components that every pathology/laboratory provider should keep in mind, as follows: (i) considerations prior to negotiating a managed care contract; (ii) assessing the managed care entity's program; (iii) determining the pathology/laboratory provider's negotiating approach; and (iv) evaluating and negotiating the contract's terms. This chapter provides a comprehensive roadmap of the four principal contracting components that a pathology/laboratory provider can follow when contracting with a managed care entity.

Initial Contracting Considerations

Prior to negotiating or entering into any managed care contract, a pathology/laboratory provider should ask itself two very important, but often overlooked, questions. Determining the answers to these questions, in advance of negotiating a managed care contract, will enable the provider and its negotiating team to develop an informed negotiating strategy. Having an informed strategy will ensure that the provider's critical needs and expectations are reflected in the contract.

First, a pathology/laboratory provider must determine its reasons for entering into the contract? For example, is the contract necessary to maintain the provider's current patient base or to expand its patient base? Is the contract required by an affiliated hospital or important referral source?

Second, the pathology/laboratory provider should define its contract expectations. The pathology/laboratory provider's reasons for entering into the contract should be documented and discussed with the provider's negotiating team. If the provider does not sufficiently define its expectations prior to negotiating the contract, those expectations may not be met or may not even be addressed during contract negotiations. Moreover, if the pathology/laboratory provider discusses its expectations with its negotiating team in advance of contract negotiations, the provider can determine if its expectations are realistic, or need to be revised, based on the experience of the team members in negotiating with managed care entities.

To support its financial expectations during contract negotiations, a pathology/laboratory provider should conduct a thorough financial analysis of its practice and business operations. Simply stated, a provider needs to understand, and share with its negotiating team, the financial specifics of its operation, including the fixed and indirect costs associated with its services. Having this

information will assist the provider to determine what reimbursement rates are necessary and appropriate in contract negotiations.

Third, a pathology/laboratory provider should determine how important the contract is to its business. If the contract is not important, the provider can be less flexible in its contract negotiations. If the contract is critically important, more flexibility may be required. Pathology/laboratory providers should always keep in mind that physicians who refer patients to them are usually contractually required to send managed care patients to participating providers. For convenience, such physicians may choose to send all of their referrals to participating providers. Therefore, a pathology/laboratory provider's failure to participate in a managed care contract may preclude it from receiving not only a physician's managed care referrals but also such physician's non-managed care referrals.

If a pathology/laboratory provider determines, in advance, its reasons for entering into a contract and the contract's importance to the provider's business, the provider can insure that all of its critical needs are addressed in negotiations and determine what concessions the provider can make during such negotiations.

Evaluating the Managed Care Entity

In addition to performing a self-assessment, a pathology/laboratory provider should assess the managed care entity by evaluating (i) the managed care entity's patient base, financial solvency and payment structure; and (ii) the experience of other providers who have contracted with the managed care entity.

An evaluation of the managed care entity's patient base should determine if the contract is likely to increase or maintain the provider's current patient base. Pathology/laboratory providers should request the number of members and referral sources, and determine the demographics of the members and their dependents.

The pathology/laboratory provider should assess whether the managed care entity is financially sound. This can be done by requesting specific financial information (e.g., whether and to what extent the payor has returned reserve withholds; how long it takes to pay on claims submitted; if it has ever defaulted on payments due providers; information filed with the state department of insurance).

The pathology/laboratory provider should ask other participating providers how satisfied they are with the managed care entity. It is advisable to determine whether the managed care entity's utilization management review, quality management, and peer review programs are appropriate, and whether the managed care entity engages in unreasonable denials of service.

It is critical to determine the adequacy of payment offered by the managed care entity. If payment is offered on a capitation basis, factors to consider include relevant actuarial data; the base rate; the type of population served; the services and item covered by payment; the extent of services that have to be referred outside the panel; and any additional administrative and overhead costs attributable to the managed care entity's subscribers.

If payment is on a fee-for-service basis, the important factors to consider in determining the adequacy of the payment are the base rate; the scope of covered and non-covered services; any amount of reserve withheld and the likelihood of any such reserve being returned; the deductible, copayment and coinsurance amounts; the timing of payments on claims; and any additional administrative and overhead costs attributable to the managed care entity's subscribers.

Once the pathology/laboratory provider assesses itself and the managed care entity, the provider is ready to develop its negotiating strategy.

Preparing for Negotiation of Managed Care Contract

A pathology/laboratory provider should have a plan of negotiation prior to negotiating any contract and especially contracts with managed care entities that usually employ very sophisticated and experienced negotiators.

As a preliminary matter, a pathology/laboratory provider should not assume that it must sign the standard managed care contract as there is almost always room for negotiation. Prior to negotiating a managed care contract, the pathology/laboratory provider should do the following.

- i. Assemble an appropriate contract team including provider representatives, and legal and financial representatives, among others. The importance and complexity of the contract should determine the composition of the team.
- ii. Determine who will negotiate the contract and avoid multiple contact points. The contract negotiator should be provided with written negotiating parameters.
- iii. Require that the managed care entity appoint someone to negotiate the contract on its behalf who has decision-making authority.
- iv. Identify problem areas in current managed care contracts and how they can and should be corrected and addressed in new contracts.
- v. Identify the "must have" and "deal breaker" positions in new contracts before negotiations begin and prioritize requested amendments.
- vi. Attempt to negotiate the contract on your home turf.
- vii. Set a timetable for contract completion.

Key Managed Care Contract Provisions

Proper Parties to the Contract/Relationship to Each Other. It is important that contract be executed by the proper party for the pathology practice. If the provider is a corporate entity (e.g., professional corporation or association, general corporation, or partnership), the contract should be with the corporate entity and not an individual. If not all members of the corporate entity (e.g., members in a group practice) do not want to participate in the managed care contract, the contract should specifically identify the participating physicians.

The managed care contract should provide that both parties are independent contractors and that the pathology/laboratory provider has no liability or responsibility for the acts or omissions of the managed care entity. In addition, the contract should specify that the managed care entity will not exercise control or direction over professional judgment. If the managed care entity owns or operates its own facilities (such as an HMO health center), the contract should provide that the provider is not liable for injuries to patients due to a defect in the facilities.

Defined Terms. The pathology/laboratory provider should review all defined terms, especially the definitions of “Payor” and “Covered Services” or their respective equivalents, because these definitions can have substantive effects upon the contractual relationship.

The term “Payor” should not extend to additional plans or payors without the provider’s prior written consent.

The term “Covered Services” should not be subject to unilateral alteration by the payor without the provider having the ability to terminate the contract on reasonably short notice. Note that the definition of Covered Services can be particularly relevant to pathology providers who wish to bill and receive payment for their professional component of clinical pathology services as well as to providers who wish to bill and receive payment for esoteric testing and molecular/genetic testing.

Some payor contracts are drafted to cover only inpatient and outpatient services, some are drafted to cover only non-hospital (outreach) services, some contracts only cover clinical laboratory services, and other contracts cover only anatomic pathology services. Some contracts cover only technical component services and others cover only professional component services. The definition of Covered Services therefore is imperative to clarify to ensure that the pathology/laboratory provider will be paid for the full range of its services.

Materials Incorporated by Reference. If the contract addresses exhibits, quality assurance guidelines, provider manuals, or any other form of reference that the pathology/laboratory provider is required to follow, a copy must be analyzed in advance and filed with the contract. If any exhibits, quality assurance guidelines, provider manuals, or any other form of reference are addressed in the contract, the contract should specify that the contract itself will control if any of these documents are inconsistent with the contract, that a copy must be given to the provider in advance if any of these documents are modified, and the provider has the right to terminate the contract prior to the effective date of any modifications of such materials..

Credentials and Qualifications. The contract should clearly set forth (i) credentials and other qualification requirements for pathologists; (ii) accreditation and/or the certification requirements for facilities; and (iii) that the managed care entity will preserve, and require employers and other third-parties to protect, the confidentiality of confidential/proprietary information, except where disclosure is required by law or third-party contract. The pathology/laboratory provider should delete requirements that are not applicable to the service being provided by the provider.

The managed care contract should specify who will have access to credentials information and the purposes for which such information will be used. The pathology/laboratory provider will want to negotiate for use of existing credentials information or a standardized credentials form.

When negotiating the terms of the managed care contract, the pathology/laboratory provider should attempt to place limitations on third-party access to confidential and proprietary information (e.g., information disclosed in credentials statements); and examine the effect of the transfer of such information upon its discoverability. In this context, the pathology/laboratory provider should be wary of provisions which require the provider to notify the managed care entity of incidents of possible malpractice. Disclosure regarding incidents of possible malpractice could be viewed as an admission of malpractice in subsequent litigation. It is important that any disclosures of possible malpractice should be reviewed with legal counsel prior to disclosure to the managed care entity.

Services Provided. To adequately assess the managed care contract, it is critical to determine what services are covered under the contract. This can be accomplished by reviewed the schedule(s) of benefits contained in the subscriber contracts. The pathology/laboratory provider should determine whether the contract requirements will require the provider to expand operational capabilities or materially alter normal business operations.

The pathology/laboratory provider should beware of and object to the following:

- i. provisions which give the managed care entity the power to unilaterally amend the schedule of covered services without giving the provider the right to terminate the contract at least on reasonably short notice;
- ii. language that requires services to be provided at a level of quality higher than that which is generally required (which could significantly increase liability exposure);
- iii. blanket requirements to provide 24-hour per day services, seven days a week;
- iv. provisions which require unreasonable turn-around time; and
- v. provisions that require the provider to continue rendering services upon the insolvency or termination of the managed care entity or the termination of the contract (in such an instance, the managed care entity should be obligated to act in good faith to promptly transfer patient care to alternative providers in the case of contract termination, and the payment obligations of the managed care entity and other payment sources should be specified).

Utilization and Peer Review. The pathology/laboratory provider should review all utilization protocols, policies, and procedures in advance of signing the contract. If any utilization protocols, policies, and procedures cannot be followed by the provider due to the type of services being provided, these items should be deleted from the contractual obligations of the provider. The pathology/laboratory provider should also determine whether the utilization and peer review protocols, policies, and procedures of the managed care entity blend with the provider's utilization management and peer review programs (e.g. claims submission deadlines, electronic claims submissions).

It is important to determine the provider's obligations regarding referrals and authorization guidelines and the pre-certification of services (i.e., how does the provider determine if necessary authorization/pre-certification is obtained, how will the pathology/laboratory provider actually obtain authorization/pre-certification, and what is the risk to the provider if necessary authorization/pre-certification has not been obtained). The provider should attempt to negotiate language that explains

that payment will not be denied due to another participating provider's or patient's violation of utilization protocols, policies or procedures (e.g., failure to meet a billing deadline).

The contract should specify the provider's rights for alleged violations of policies and procedures, including appeal rights. Appeal to an outside arbitration panel is preferred.

The pathology/laboratory provider should consider the provider's potential liability exposure under the contract. The provider should beware of utilization programs which shift all responsibility for services rendered to the provider. The managed care entity also has responsibility because of its utilization review and quality assurance functions.

Participation in peer review and disclosure of records is tied to a reasonableness standard. If the contract requires the provider to participate in peer review functions, the provider should also confirm that there is coverage for utilization review/peer review activities under the provider's malpractice insurance. It is advisable to obtain the carrier's response in writing. The provider should also consider confirming whether there is coverage under the managed care entity's insurance program. The provider should confirm that the peer review program of the managed care entity complies with federal and state statutory requirements for participants in peer review to qualify for statutory immunities.

Membership Verification. The contract should explain how a patient's eligibility for covered services is to be verified.

The contract should also address the payment source for services provided to patients who are designated as being covered but are later determined to be ineligible by the payor. It is preferable from the pathology/laboratory provider's standpoint that the managed care entity pay for services to ineligible patients, at least to the extent the error was the fault of the managed care entity. Otherwise, the patient should remain responsible for payment.

Capitated Payment Terms. If payment is made to the pathology/laboratory provider on a capitation basis, the contract should specify the payment rate, the payment schedule/timeframe, and any exceptions to or limitations on payment. The rate should be subject to renegotiation upon specified events. The managed care entity should not be able to unilaterally reduce the payment rate unless the provider has the right to terminate the contract on short notice.

Under capitated contracts, it is also critical to specify the "stop-loss limit." The stop-loss limit is the limit of liability of the provider, and is usually tied to a set dollar amount per member, per year. The pathology/laboratory provider should negotiate an annual aggregate stop-loss limit for all members assigned to the provider to protect against numerous expensive individual cases.

For capitated payment contracts, the pathology/laboratory provider should also consider negotiating a "safety net" provision, whereby payment is made on a capitation basis, but with a guarantee that the aggregate capitation payment will be "no less than" a specified discounted fee-for-service amount.

The pathology/laboratory provider should watch provisions which permit the managed care entity to adjust deductibles, coinsurance, and copayments downward without an appropriate adjustment upward in the capitation rate. Lower deductibles, coinsurance, and copayments mean higher utilization).

Fee for Service Payment Terms. If payment is made to the pathology/laboratory provider on a fee-for-service basis, the contract should clearly identify the fee schedule to be utilized. The fee schedule proposed by the managed care entity may be based upon schedules developed nationally or in other states, and may not be appropriate in all areas. The fee schedule should be subject to regular renegotiation. The managed care entity should not be able to unilaterally reduce the fee schedule unless the provider has the right to terminate the contract on short notice.

The discount rate, if any, should be specified in the contract and should not be subject to mid-term downward adjustment, unless the provider has the right to terminate the contract on short notice. The provider should watch volume pricing provisions, and assess whether the figures are realistic and how accessible the volume is (i.e., is the volume widely scattered or not from existing referral sources).

The contract should address whether payment will be made for the professional and/or technical components of all services. If the pathology/laboratory provider performs both components, the contract should confirm that payment will be made for both components.

Caution should also be given to language that could permit the managed care entity to impose unilaterally payment edits, similar to Medicare's correct coding initiative edits, that could limit the number of reimbursable units of service, or impose other payment restrictions such as rebundling edits.

If pathology/laboratory providers expect payment for professional component of clinical pathology services, they should specify the payment terms in the contract.

The method of billing the managed care entity should be reasonable and compatible with the current system. The pathology/laboratory provider should review the specific information that must be disclosed for billing purposes and the specific billing forms.

It is important to remember that prompt payment is part of the consideration for the provider's agreement to accept discounted fees. Payment by the payor to the provider should be tied to the date the properly completed bill is submitted and not the "approval" date (the latter is largely up to the managed care entity). The agreement should specify when a claim will be considered "properly completed" (i.e., what form must be used and what information must appear on it). The pathology/laboratory provider may wish to negotiate late payment penalties.

If significant administrative responsibilities are assumed with respect to a managed care contract, such as substantial credentials review or utilization management, the provider may want to seek compensation for these services from the managed care entity.

The pathology/laboratory provider should attempt to delete "most favored nation" clauses. A "most favored nation" clause requires the provider to give the managed care entity the more favorable financial terms agreed upon between the provider and any other payor. Generally, a "most favored nation" clause should only be triggered by financial arrangements with substantially similar plans (e.g., same type of plan, same patient volume, and same geographic area).

If a reserve withhold is utilized, it is important for the contract to specify: (i) the cost items to be subtracted from the withhold; (ii) the obligation of the managed care entity to return the withhold; (iii) the payment schedule therefor; and (iv) which party is entitled to the interest on reserves. The

pathology/laboratory provider should beware of agreements which give the managed care entity discretionary power to return the reserve balance even when cost targets are met. The provider should request regular financial reports regarding withhold accounts, and the right to audit such accounts.

Other payment considerations include the determining if there is a default reimbursement for new codes and test that may be added in the future and if the managed care entity can down code or bundle claims unilaterally. The pathology/laboratory provider should also review restrictions on billing for non-covered services, and confirm that such services be billed to the patient without the necessity for a signed advance beneficiary notice.

Liability Insurance. The pathology/laboratory provider should confirm that the insurance or self-insurance requirements under the managed care contract are fair and can be met without significant additional expense. If the provider is self-insured, the contract should specifically permit self-insurance. The pathology/laboratory provider should beware of contracts which limit insurance to “occurrence” policies. Claims-made insurance should also be an option.

The provider should not agree to insure against all losses and liabilities. Instead, coverage requirements should be subject to standard policy exclusions and limitations. The pathology/laboratory provider should also ensure that it does not agree to insure individuals or situations that are not covered under its policy.

The contract should not give the managed care entity the unilateral right to eliminate self-insurance or determine insurance limits. Initial limits should be set in advance and the provider should have the right to terminate the contract before the effective date of any new insurance limits.

The managed care entity should be required to maintain adequate professional liability insurance, general liability insurance and, if a risk bearing entity, reinsurance.

Indemnification and Hold Harmless Provisions. The pathology/laboratory provider should carefully review any indemnification provisions with its insurer. Most insurance policies do not cover contractual indemnification provisions. Possible substitute language is: “Each party shall be responsible for its own acts and omissions to the extent it would be responsible under statutory or common law, and nothing contained in this Agreement shall impute or transfer responsibility for the acts or omissions of one party to the other party.”

The pathology/laboratory provider should beware of provisions that impose liability on the provider beyond that which would exist under applicable law (e.g., liability for acts/omissions of third parties). In addition, the pathology/laboratory provider should avoid provisions which shift liability to the provider or make the provider solely responsible for medical care decisions (e.g., unduly shift all responsibility for patient care decisions to the provider).

Reporting, Record Retention, Disclosure and Facility Inspection. The contract should specify what information and records have to be maintained and disclosed (e.g., internal financial information). Record disclosure should be made subject to all applicable laws, regulations and ethics codes. The provider should not be required to maintain records longer than the provider’s standard retention period.

The pathology/laboratory provider should ensure that record disclosure is limited to those records of subscribers of the managed care entity unless broader disclosure is required by law or by federal or state agencies. The provider should not be required to disclose proprietary business information, or, if such information must be disclosed, the managed care entity should be required to protect its confidentiality and refrain from using such information except where disclosure is required by applicable law. The contract should also specify that the records are the property of the provider.

If the provision of records to a managed care entity will be routine and substantial, the contract should specify that the managed care entity will bear the photocopying costs and other costs related to disclosure.

If the pathology/laboratory provider operates a laboratory, the contract should explain that laboratory inspections may occur only upon reasonable notice and at reasonable times.

The pathology/laboratory provider also should confirm that the managed care entity or provider has proper release forms in place before releasing a copy of any patient records to a managed care entity.

Use of Name. The contract should explain the managed care entity's policy regarding the use of the provider's name in the managed care entity's marketing and promotional materials. If the pathology/laboratory provider operates a laboratory, it is beneficial to commit the managed care entity to referencing the provider and its laboratory services in all general circulation marketing and promotional materials. The pathology/laboratory provider may wish to request the right of prior review and, preferably, the right of prior approval, of marketing and promotional materials which reference the provider.

Termination of Contract. It is important for the pathology/laboratory provider to identify how the contract can be terminated. If the contract can be terminated "without good cause", the provider should confirm that the termination rights are reciprocal and balanced. Similarly, "with cause" (or for "good cause") termination language should be reciprocal and balanced between the parties. If there is a provision for "with cause" or "good cause" termination, the term "with cause" or "good cause" should be defined.

The pathology/laboratory provider should obtain the right to terminate the contract upon a certain amount of notice, preferably not to exceed 90 days, so that a "bad" contract can be terminated quickly. The provider should watch for provisions which permit such notice termination only at the end of a term.

The managed care entity should not be permitted to terminate the contract for the acts or omissions of a single professional. The contract should provide for termination action only against the individual professional.

The pathology/laboratory provider should obtain the right to terminate the contract immediately if the managed care entity fails to make payment, files for bankruptcy, or becomes insolvent.

Dispute Resolution. The contract should the procedure for resolving disputes and the venue for resolution of disputes. The provider should have the right to present its argument, and to hear the opposing arguments/evidence. The provider should also have at least one level of appeal to an independent third party.

The pathology/laboratory provider should beware of dispute resolution procedures where the managed care entity has final authority to resolve disputes. Instead, the provider should push for the right to submit disputes to an independent body such as an arbitration panel. The provider should also avoid restrictions on the provider's ability to litigate against the managed care entity or engage in a class action or arbitration. It is advisable to delete provisions which state that the contract is governed by the laws of another state, or that the venue for dispute resolution is in another state.

Typically, the dispute resolution procedures of the American Health Lawyers Association are preferred over the American Arbitration Association.

Other Provisions. The contract should specify how notices have to be sent under the contract (e.g., by certified mail). It is preferable to require notice to be sent in a format in which receipt is confirmed (such as certified mail or overnight courier delivery), rather than regular mail, general mailings or website notices. Managed care contracts increasingly are specifying websites as permissible means of providing notice, which can be problematic for the pathology/laboratory provider. No provider has time to constantly review a managed care entity's website.

Amendment and modification to the contract should be mutually agreed, in writing, and with prior notice. At a minimum, the contract should contain the right to terminate if key terms are amended or modified.

The contract should explain the parties' rights, if any, to assign the contract. The pathology/laboratory provider should avoid provisions which permit the managed care entity to assign the contract without the provider's consent. The provider may wish to have the right, however, to assign the contract to its affiliates or successors without the managed care entity's consent.

- Partnerships or joint venture arrangements between hospitals and ACO professionals
 - Hospitals employing ACO professionals
 - Such other groups of providers of services and suppliers as the Secretary determines appropriate
 - Mechanism for shared governance
 - Accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it
 - Agreement with the Secretary to participate in the program for at least three years
 - Formal legal structure allowing distribution of payments for shared savings to participating providers and suppliers
 - Sufficient primary care professionals to serve the number of Medicare fee-for-service beneficiaries assigned to the ACO (in no event fewer than 5,000 beneficiaries)
 - Leadership and management structure that includes clinical and administrative systems
 - Processes to promote evidence-based medicine and patient engagement, report on quality and cost measures and coordinate care (e.g., through telehealth, remote patient monitoring, and other such enabling technologies)
 - Meets patient-centeredness criteria to be specified by the HHS Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans
- Establishes measures to assess the quality of care furnished, such as measures of clinical processes and outcomes, patient and caregiver experience of care, and utilization (e.g., rates of hospital admissions for ambulatory care sensitive conditions)
- Establishes quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing quality of care.
- Providers who participate in other shared savings programs or in the independence at home medical pilot program are not eligible to participate in the ACO shared savings program
- Medicare beneficiaries are assigned to an ACO based on utilization of primary care services provided by an ACO professional
- Reimbursement:
 - Providers and suppliers participating in the ACO continue to receive payment under the regular Medicare part A or B fee-for-service program
 - Participating ACO is eligible to receive pay for a portion of the shared savings if:
 - The ACO meets the quality performance standards; and
 - The estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for

beneficiary characteristics, is at least the percent specified by the HHS Secretary below the applicable benchmark

- The HHS Secretary may impose sanctions, including termination from the shared savings program, if an ACO takes steps to avoid at risk patients in order to reduce the likelihood of increasing costs

C. Medicare Bundled Payment Program (Effective January 1, 2013)

A national Medicare pilot program to pay a single bundled payment for all providers participating in a single inpatient episode for all care beginning three days before admission and ending 30 days after discharge.

- Four payment models: retrospective acute care hospital stay only; retrospective acute care hospital stay plus post acute care; retrospective post acute care only; and acute care hospital stay only
- Participation is voluntary – over 500 participants as of January 2013
- Goal: improve the coordination, quality and efficiency of health care services
- An entity comprised of providers and suppliers, including a hospital, physician group, skilled nursing facility, and a home health agency, may apply to participate in the program
- The program applies to 48 episodes of care/conditions specified by the HHS Secretary
- Services:
 - Acute care inpatient services
 - Physicians’ services
 - Outpatient hospital services, including emergency services
 - Post-acute care services, including home health services, skilled nursing service, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital
 - Other services determined by the HHS Secretary
- “Episode of care” is defined as the period beginning three days prior to the inpatient admission, including the length of the patient’s stay in the hospital, and continuing for 30 days after discharge
- Bundled payment is for all services during the episode of care