Earning your keep: succeeding in laboratory reimbursement

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The seventh Clinical Chemistry Forum of the American Association for Clinical Chemistry was held in Baltimore, Maryland, on December 4 and 5, 1997. Clinical Chemistry Forums have been oriented to addressing the management issues affecting clinical chemists and the clinical laboratory field. In this way, they complement the AACC’s targeted conferences on new technology (Oak Ridge) and applications (A.O. Beckman). The theme for the 1997 Forum was reimbursement under the difficult conditions imposed by compliance with the new regulations associated with documentation of medical necessity for provided services. The Forum brought together representatives of the government as well as the independent and hospital clinical laboratory industries.

As part of its objective of disseminating information to the many members of the AACC and other scientists who were not able to attend the Forum, the AACC is pleased to publish here a summary of the presentations delivered at the meeting. These were compiled from a transcript of the presentations as well as the handout material provided by the speakers. In addition to the 13 summaries, the full texts of the presentations by Dr. Charles Root and Dr. Thomas Hoerger are included. I accept responsibility for the summaries, which were not reviewed by the authors. They do not reflect the overall excellence of the meeting or the extensive interaction between the speakers and the audience, which created the exciting forum that was the intent of the meeting.

HCFA’s Perspective

In her presentation, Juliette Jenkins of the Laboratory Policy Division, Health Care Financing Administration (HCFA), provided the following information about how her agency is helping to implement the changes in Medicare documentation requirements mandated by the Balanced Budget Act of 1997 (BBA).

Section 1862 of the Social Security Act requires that Medicare pay only for reasonable and necessary tests and services; Section 1833e of the Social Security Act requires that no payment shall be made to any provider of services unless appropriate information has been submitted to determine the amounts due. In the past, however, in spite of these unequivocal statements, claims for laboratory services were seldom screened or reviewed for medical necessity. Consequently, almost every laboratory claim was paid, regardless of whether it was covered or needed, producing nearly $3 billion a year in Medicare expenditures. There is considerable evidence that the system was being abused, prompting several investigations and fines. The government has now recouped $1800 million in settlements from national laboratories alone. Because of the high visibility of this problem of fraud and abuse in laboratory services, HCFA has focused more resources on the development of fraud and abuse policies and medical necessity requirements.

Medical necessity documentation requirements are developed by the HCFA contractors, and many have chosen to require International Classification of Diseases (ICD)-9 codes as the preferred method for supplying the medical necessity documentation. Diagnosis codes are a more efficient and reasonable method for collecting evidence of medical necessity rather than requiring lengthy medical records to be submitted for each test that is performed. Submission of evidence of medical necessity is required when a local medical review policy (LMRP) requires such documentation. However, it is within a contractor’s au-
authority to review any claim for reimbursement at any time. Therefore, evidence for the rationale for the service should always be correctly documented in the patient’s medical record.

Before the BBA, physicians were not required to submit diagnostic information to the entities performing the services billed to Medicare; however, with the passing of the BBA, physicians and practitioners are now required to provide diagnostic information to the entity performing the service at the time a test is ordered. Another change with the BBA involves the use of Current Procedural Terminology (CPT) panels, which were developed by the American Medical Association to allow panels of clinically relevant automated multichannel tests to be grouped together to facilitate ordering and billing. However, in some instances of perceived abuse of the new panels, the contractor may review the panel and the component tests on a case-by-case basis and evaluate the need for the component level test.

HCFA is currently working on other changes as a result of the BBA; however, many are only in the formative stage. Section 4554, called “Improvements in Administration of Laboratory Test Benefit”, requires the Secretary of the US Department of Health and Human Services (HHS) to designate up to five regional carriers to process laboratory claims by July 1, 1999, with one carrier designated as a central statistical resource for such claims. The proposal is intended to simplify claims processing. Physician office laboratories would be excluded from regional claims processing if the Secretary determines that such laboratories would be unduly burdened by having to bill more than one carrier.

The regional carriers may collectively develop interim national policies effective for up to 2 years until national policies are developed. The BBA also requires carrier advisory committees to include a member representing independent clinical laboratories and other laboratories that the Secretary deems appropriate.

With implementation of the medical necessity requirements, contractors will look at trends and patterns of utilization to investigate any situations that they observe with the use of the panels to determine if there is aberrant usage; however, in general, medical necessity will be presumed.

Carrier/Intermediary Perspective

Michael Riisager of Trailblazer Health Enterprises discussed the following issues currently faced by carriers.

By October 1997, 26 model LMRPs had been developed by carriers for payment of claims for laboratory tests. These prompted considerable reaction and problems of implementation. LMRPs cause an increased operational load and a need to resolve issues with the provider community—clinical laboratories, provider specialists, specifically primary care, and within the contractor. Contractors, whether intermediaries or carriers, now receive reduced funding from the government, and a goal of their new policies is typically to simplify matters and to create cooperation and consensus.

One of the most difficult issues related to reimbursement by Medicare is the concept of screening. Physicians, as part of the proper practice of medicine, will do some tests that are screening. However, if there is no documented symptomatology or documented findings on examination, Medicare will not pay for the tests. In the absence of a documented rationale, tests are regarded as screening and therefore, by statute under the Medicare law, are not payable.

Variation in coverage between contractors is a current problem; however, this will be moot with the establishment of regional carriers for clinical laboratories. Model policies, the start of the LMRP process, have been made by informal groups of carrier medical directors, with input from clinical pathologists and internists, who have attempted to develop guidelines regarding medical usage. The carriers have held a laboratory policy summit, which has been followed by monthly telephone conferences to try to identify issues.

The carriers are trying to establish uniformity in payment policies, which makes life easier for them although not necessarily for the provider physicians.

The Commercial Laboratory Perspective

David Sundwall, President of the American Clinical Laboratory Association, discussed how new documentation requirements are impacting independent laboratories.

The clinical laboratory industry has been described recently by Ken Freeman as “tumult bordering on chaos”. The challenges facing the independent laboratory community are substantial, including downsizing, dealing with overcapacity, and consolidation. Managed care has had a dramatic impact on laboratory revenues regardless of whether it is through a contract with a staff model health maintenance organization (HMO), preferred provider organization (PPO), or an independent physicians association (IPA). Capitated payment arrangements have had a negative impact on revenues, and Medicare revenues have also decreased. The medical necessity documentation requirements, the new policies for ordering automated multichannel tests, the allegations of fraud and abuse, and ongoing investigations are of major concern to independent laboratories. The implementation of compliance plans and medical necessity documentation are big problems; however, they must be put in the context of everything else that is causing tumult.

The medical necessity documentation requirements have decreased revenues of independent laboratories across the country and have caused some friction and difficulty with their physician clients. The number of denied claims has increased, with a corresponding decrease in reimbursement. Laboratories that operate in many states must contend with multiple carriers, none of whose policies are the same. The plethora of these policies
has been costly, cumbersome, confusing, and counterproductive without improving the quality of care.

The independent laboratory companies have worked hard to comply with these new requirements. Because many have entered into settlements with the government, they have been rigorous in their efforts to comply with policies. Many independent laboratories have taken on the responsibility of educating their clients to the issues of medical necessity, because the HCFA and the carriers have not done this. For physicians, the laboratory companies have created an incentive to study their educational materials by providing continuing medical education credit where this is feasible. Another educational effort has involved explaining to patients in simple language the nuances of Advanced Beneficiary Notices. HCFA has been willing to participate in the education efforts through their endorsement of these educational materials.

It is difficult to assess the overall cost of compliance. One company has estimated that it has spent $60 million. It is possible that the costs for compliance with these policies exceeds what HCFA would have paid if it had simply paid for the tests that were ordered. Unfortunately, this extra cost does not contribute to patient benefit or patient care. Perhaps through these new requirements the government has paid less; however, it seems a disingenuous effort to cut healthcare costs, because they have been costly to all providers. Although the new model policies have not been very helpful to independent laboratories, they will probably serve as a template for developing the national rules that have been proposed.

Part D of Section 4554 of the BBA includes a statement concerning adoption of national policies for clinical laboratory tests. It states that the Secretary of HHS shall, by January 1, 1999, establish national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of Title 18. The national policies must promote program integrity and national uniformity and simplify administrative requirements with respect to clinical laboratory testing. The requirements must include the same beneficiary information, and the medical conditions for which laboratory testing is considered reasonable and necessary must be the same. The rules regarding bundling and unbundling of tests and the medical documentation that is required by a Medicare contractor must also be the same. Record keeping requirements for physicians, procedures for filing claims and providing remittances, and limitations on frequency coverage must be the same for tests performed on the same individual. The recommendations will be developed through the negotiated rulemaking process, involving all the groups with an interest in the outcomes; they will be published in the Federal Register, thereby enabling any physician or laboratory to comment on them before they are finalized.

HCFA has recently announced that it will encourage its contractors to consider organ and disease panels as individual tests, should they choose to develop review policies that state medical necessity requirements. This statement does not limit contractors’ authority to develop limited coverage if they choose to, based on what they determine to be excess utilization, and even enables them, in some instances of perceived abuse of the new panel codes, to deny component tests on a case-by-case basis or to evaluate the need for the component level test.

Both the American Society of Internal Medicine and the American Medical Association have called for an end to the need to demonstrate medical necessity by providing ICD-9 codes. To improve patient care, HCFA should stop prepayment review now and focus on postpayment review. The majority of physicians are honest and are being penalized by prepayment review, whereas postpayment review would catch the miscreants, allowing their exclusion from the Medicare program on the basis of the documentation of their abuse.

The payment issues raised by Medicare have made the need for the laboratory industry to promote appropriate utilization of testing apparent. Several laboratory organizations have joined to form the Laboratory Health Care Partnership, which is a coalition with the sole purpose of promoting public awareness and appreciation for clinical laboratory testing, The public, in this context, are policy makers and particularly payers, as well as physicians and the general public. The National Committee of Quality Assurance, which has developed the Healthcare Employer Data Information Sets indicators, is a primary target, and has already responded to suggestions to modify some of their indicators. Although overutilization of tests is a major concern, there is considerable underutilization of laboratory data in many areas, including the monitoring of diabetes. Many physicians have not fully adopted or used the cholesterol management practices recommended by the experts in cardiovascular medicine. The Ontario Clinical Laboratories Association has developed some excellent guidelines for iron testing, iron stores, sedimentation rate, microscopic analysis of urine, and hepatitis screening, which could well form the basis of establishing good ordering practices. Thus, there clearly are alternatives to the current method of documenting medical necessity.

The Outlook for Hospitals

Jan Steiner, Vice President of Business Development for Chi Laboratory Systems, offered the following insights into the challenges hospital laboratories face in dealing with the new medical necessity regulations.

The interesting part of the reaction of hospitals to the new medical necessity regulations is almost total inactivity. Unlike the American Clinical Laboratory Association, which is actively involved in lobbying and negotiating, the American Hospital Association has done virtually nothing. Currently the main concern of pathologists and laboratory managers is to ensure that the ICD-9 codes appear on the documentation. There appears to be a singular lack of understanding that, although the issue of
ICD-9 codes on bills is important, the real issue is that there must be congruence between the ICD-9 codes and the CPT codes or the charges to which these CPT codes are attached. It will probably take heavy penalties and actual indictments for fraud before pathologists and hospitals will wake up to the real impact of the medical necessity regulations.

The pathologist, as the medical director of the hospital laboratory, has the responsibility to see that this congruence exists; however, in most instances the director does not have the wherewithal to do it effectively. Under the Part B provision of the Tax Equity and Fiscal Responsibility Act, pathologists are supposed to receive compensation for their work in the laboratory, which is not paid for by Part B billing; however, many hospitals have reduced the compensation via Part A to the point where pathologists get very little from that source.

When DRGs were introduced, HCFA made the assumption that the mean cost attributable to the laboratory as a proportion of the revenue generated by DRGs would not exceed 9.5%. Yet it appears that the average cost per day is more like 13% and 15% of the DRG revenue in many laboratories. Because there is a cap on the DRG payment, other services in the hospital suffer.

Managed care contracts limit reimbursement but have not had much effect on hospital laboratories, although many laboratories have tried to determine whether they could afford to bid on managed care contracts. Very little has been done in hospitals to control laboratory costs other than by some indiscriminate budget cutting. However, in the last 2 or 3 years much reengineering has been taking place to lower costs.

In the Medicare compliance plan, there is a little recognized statement: “Laboratories should analyze utilization of the top 30 tests for Medicare patients. If utilization increases by more than 10 percent in one year, the laboratory should determine the reason” . Insistence on the number of tests rather than the substance of the testing or the rationale for the testing is unfortunate, because a 10% increase in testing does not necessarily have anything to do with medical necessity. The medical necessity requirements are very onerous on a laboratory.

The theory of the real effect of a test is that it has an effect on the probabilities of health outcomes, such as an earlier referral. There is little documentation of the effect of laboratory tests on outcomes. Their real effect depends on the patient population being tested and on what would be done if the tests were not available. The impact of laboratory testing cannot be determined without knowing the outcomes of the treatment that follow it. The assessment of the utility of tests is in its infancy.

There are issues concerning Medicare payments. For example, Medicare does not pay for tests if proof of medical necessity is lacking. The recommended solution is to provide diagnosis and symptoms; the patient is made aware that they may have to pay for tests that are not deemed by Medicare to be appropriate. In addition, it is important to match CPT codes with ICD-9 codes to establish acceptable procedures. Billing the beneficiary is an option for noncovered tests. The prevailing denials for reimbursement are lack of proof of medical necessity (60%), invalid diagnostic code, i.e., lack of congruence between ICD-9 and CPT codes (5%), and excessive ordering of tests (35%). The latter may be addressed through the use of Advanced Beneficiary Notices. The second group is likely to comprise a larger portion of the total in the future.

There currently are no benchmarks on laboratory utilization per encounter. Chi Laboratory Systems is currently trying to gather data on current ordering practices and to develop optimum ordering practices based on the habits of best-performing physicians.

The location of testing is changing dramatically. Between 1940 and 1990, laboratory testing was split approximately 50:50 between hospitals and commercial laboratories; however, with the acquisition of practices and expansion of outreach services by hospitals, the proportion of all testing in hospital laboratories will increase. With the introduction of new technology and an increase in test volume, the cost per test has been decreasing in hospital laboratories, with an increase in productivity. Much of the increase in productivity has come through reduction of nontechnical personnel. With the introduction of additional automation into hospital laboratories the proportion of total costs attributable to labor will continue to decrease. In spite of the view that hospital laboratories are inefficient, their labor costs as a proportion of total costs typically do not differ substantially from those in large reference laboratories.

Increasingly, hospitals are being combined into regional health systems, with local rapid-response or point-of-care testing with other laboratory services consolidated in a core production laboratory with esoteric laboratories attached to it. Marketing, sales, logistics, client services, and billing are centralized, which gives the system the capability of penetrating the nursing home and physician office market. Yet these developments are occurring without proper validation of the clinical relevance of the tests or analysis of patient outcomes.

**Ambulatory Payment Classifications: What the Future Holds for Laboratories**

Janet Wellham, of the Division of Practitioner and Ambulatory Care, Health Care Financing Administration, discussed the following changes in payment for for ambulatory services.

Section 4521 of the BBA provides for the elimination of formula-driven overpayment, effective in October of 1997. The formula-driven overpayment is simply an anomaly under the current blended payment methods that are in effect for hospital outpatient payments for surgery, radiology, and other diagnostic services.

Section 4522 changes payment for hospital outpatient services. For some years, hospitals have experienced a
reduction of 5.8% of operating costs that they incur and a 10% reduction off the top of capital costs. Those reductions were scheduled to expire at the end of 1998. This provision extends those reductions and has the effect of keeping the reduced target amount in determining outpatient prospective payments.

Section 4523 implements a prospective payment system for hospital outpatient services for the facility part of hospital payments. It does not affect physician services for hospital outpatients. This prospective payment system will go into effect for all hospitals on January 1, 1999, except for cancer centers. The prospective payment system is still under development, and the ultimate goal is to have all patient services under some form of prospective payment system. The system will also include inpatient services that are furnished to beneficiaries under Part B when they exhaust their Part A coverage. The outpatient prospective payment system will exclude ambulance services and therapy services—physical therapy, occupational, and speech therapy—that are addressed separately. Clinical laboratory diagnostic tests will continue to be paid under the clinical laboratory fee schedule; however, pathology services will be included in the system. Payment for durable medical equipment, orthotics and prosthetics, and end-stage renal disease dialysis services will remain as now.

Ambulatory payment classifications (APCs) form the basis of the new payment system. APCs were developed from the ambulatory patient groups of 3 M. Medical visits and ancillary services are assigned to groups. Within each APC or group the services are similar both clinically and with respect to resource use. The overall plan is to have a fairly unpackaged system; however, it is possible to make a single payment for a clinic visit, which would include all the ancillary services that are furnished. It is possible that different payers will have different payment rates.

There are ~300 APCs; however, the exact number has not been decided on yet. The packaging of individual services will be minimal; if a person had a clinic visit, laboratory test, and an x-ray, three different group payments would be made. This minimal packaging is a way to get the system started without too much confusion. The system will require no changes in the billing form, and the codes that are being collected currently will be adequate to process the bills.

Relative weights for services are being calculated. By multiplying the weight by the national conversion factor dollar amount, a payment will be developed for a particular group. By law, the payments must be budget-neutral, so that under the new system the same amount would be paid in 1999 as would have been paid under the current system.

By law HCFA has the ability to periodically revise the groups, the weights, and geographic wage adjustments. This will allow the addition of new services, new codes, and relative distribution of cost groups. An annual increase in payments has been mandated by law. The law also requires the development of ways to control for unexplained increases in volume.

APCs will be used to pay free-standing ambulatory surgical centers. The system would basically change their prospective payment system from 8 groups to ~100 surgical groups; however, those surgical groups will have some clinical coherence rather than just being resource-based as they are now. The outpatient prospective payment system also deals with beneficiary co-insurance, with a goal of bringing the beneficiary co-insurance rate back to 20% from the close to 50% that it has become now.

Details of the system are expected to be issued in April or May of 1998, with final regulations issued by October 1, 1998, so that the system can be implemented on January 1, 1999.

Medicare Part B Reimbursement

In her presentation, Anne Marie Lynch, a staff member, of the House Ways and Means Health Subcommittee discussed some of the changes in Medicare reimbursement mandated by the BBA.

President Clinton’s healthcare reform package put healthcare in the public eye. At the same time, Congress was working toward the BBA. In 1995, in an effort to balance the budget, Congress capped overall Medicare spending. In 1996, Congress realized that the public did not readily accept change to the structure of Medicare but determined that Medicare spending had to be reduced by $115 billion over 5 years if the goals of the BBA were to be met. The House and Senate joint committee, to work out the details as to how this reduction might be achieved, seriously looked at relating Part B payments to income, increasing the age of Medicare eligibility to 67 years, and adding a $5 co-payment for home health services. However, none of these were included in the Act that was finally passed.

While the BBA was being worked on, Congress was made aware that HCFA would be unable to pay its Part A bills by the year 2001; therefore, extension of the solvency of the Part A Trust Fund for at least another 10 years became an integral requirement for the BBA. To ensure this, payment for home health expenditures was shifted to Part B, and the part B premium was set at 25% of the cost, with tax-payers picking up the other 75%. In addition, managed care payments were reformed and hospital outpatient co-insurance payments were reduced. Other major objectives were to increase choice and to increase the participation of private health plans in Medicare.

The overall impact of the changes will be to reduce the rate at which Medicare spending increases over the next 5 years. Congress is well aware of the delicate balance needed to reduce costs while maintaining quality. The Prospective Payment Assessment Commission has predicted that even with freezing the DRG rate in 1998, hospital margins will remain positive and substantial through 2002. During its reexamination of Medicare spending, Congress noted the uncontrolled growth of

A radical departure from prior Medicare practice was the expansion of preventive coverage. Deductibles for Pap smears and prostate and colorectal cancer screening were waived, and support for self-management was introduced. Congress also asked the Institute of Medicine to look at additional benefits that should be provided as part of a disease prevention approach, specifically requesting feedback on dental care, immunosuppressive drugs, and nutrition therapy.

Congress also carved out the cost of graduate medical education from the payments to hospitals. There will be a transition over 5 years, with teaching hospitals eventually receiving a completely separate payment for all residency training. Although there is currently a system to voluntarily restrict the number of residency positions, with the incentive of a lower reduction in payment than would normally be associated with the reduction in numbers of trainees, Congress has asked the Prospective Payment Assessment Commission to develop a system to examine all aspects of residency training, including the appropriate number of positions nationally.

Congress, through the BBA, has developed a program called Medicare+Choice. This is basically a reform of the old Tax Equity and Fiscal Responsibility Act or HMO program but makes privatization of Medicare a priority for HCFA. Privatization may involve a traditional HMO, a PPO, a provider-sponsored organization, or a medical savings account. However, traditional Medicare fee-for-service coverage would also remain an option. It is estimated that within 5 years, 25% of all Medicare beneficiaries will be in such a program, with 38% in 10 years. The BBA broke the link between county-specific fee-for-service spending and managed care rates. It also requires the Secretary of HHS to develop risk adjusters to allow for the complexity of the diseases in patients in managed care programs.

Congress has appointed a “Baby Boom Commission” to look at the long-term future of Medicare. It is likely that the Commission will look at many creative solutions, such as aggregate spending caps, defined contributions, higher Part B payments by beneficiaries, income-related payments, and higher cost-sharing payments for home care and laboratory tests. In the near future, Congress is likely to monitor HCFA carefully to determine if it is following its directives. Congress will continue to focus on fraud and abuse of Medicare. It is probable that Congress will take an increasing interest in all aspects of the confidentiality of medical information.

Congress has asked the Institute of Medicine to study payments under Part B and to report to it by August 1999 with regard to changes in the current system of payments.

The Institute of Medicine has been specifically asked to examine the impact of the current system on access to high-quality laboratory tests and new technology. The BBA also seeks to improve the administration of Part B payments by reducing the number of carriers to five. The Secretary of HHS has been asked to develop a national policy for coverage and administration of payments for laboratory services by January 1999.

The New ICD-10 Codes: What You Need to Know
Norbert I. Goldfield, Medical Director of 3M/Health Information Systems, gave the following preview of the soon-to-be-completed ICD-10 system.

The ICD-10 system is nearing completion after a 3-year contract to develop a new procedure classification system that is to be used potentially by HCFA to replace ICD-9, volume 3. ICD-9, volume 3, is used for inpatient purposes only and is used particularly for procedures and the development of procedure-based DRGs. An independent contractor is currently evaluating the ICD-10 codes that have been developed to date.

Some of the essential characteristics of the new code follow. The ICD-10 system is hierarchical to enable data from individual codes to be aggregated into larger categories, thus differentiating the new codes from previous codes such as CPT and Snowmed. It is expandable, with the flexibility to incorporate new procedures and technologies. It can be periodically updated. It is comprehensive to enable all possible procedures to be classified. The AACC and other professional societies have been actively involved in the development of codes in the areas of their greatest interest to ensure their pertinence. The codes are designed not to overlap, for ease of use, and for being provider-neutral. The coding system is in the public domain. “LOINC” codes have been used as the basis for laboratory test descriptions. However, LOINC is essentially a test ordering system, and a software map has had to be constructed from LOINC codes to ICD-10 codes so that the two codes combined provide both an ordering and a results system.

ICD-10 is based on a seven-character alphanumeric code. The digits used are 0 through 9, with letters A through H, J through N, and P through Z. The numerical codes apply to medical and surgical, obstetrics, placement, administration, measurement and monitoring, imaging, nuclear medicine, radiation oncology, osteopathy, diagnostic audiology and rehabilitation, extracorporeal assistance and performance, laboratory, mental health, chiropractic, and miscellaneous.

For medical and surgical conditions, the first of the seven characters pertains to the section, such as kidney or cardiovascular. An attempt has been made to define every medical or surgical procedure but without the use of eponyms. Of the hundreds of procedures that exist, essentially 25–27 root operations have been created, such as excision or extraction, or resection or destruction.

Within the laboratory there are several different sec-
tions, including the blood bank, toxicology, and chemistry. The second character refers to this section, or analyte class. Each section has a different alphanumeric code. Subsequent numbers refer to the specific analyte, the specimen, its source, and the analytical method. The third and fourth characters refer to the analyte or the test that is being performed. The fifth and sixth characters specify the the specimen for analysis, e.g., blood or cerebrospinal fluid. Character seven indicates the method used for the analysis. The system allows for ~900 analytes, 900 specimen sources, and 32 or 33 methods.

It is anticipated that the ICD-10 diagnosis codes will be implemented in the year 2000 or 2001. Within the next 3 months, there will be a HCFA web site from which the 1000 pages of ICD-10 diagnosis codes can be downloaded. The Health Insurance Portability Act mandates a single classification system for virtually every aspect of medical care. At present, the ICD-10 code does not meet the standard. Once ICD-10 PCS is finalized, which is anticipated to occur in March 1998, HCFA will have to decide whether it will adopt the system, which will constitute the only coding system that could be used for both inpatient and outpatient services.

**How to Bid, Evaluate, and Implement a Capitated Contract**

Philip Beard, President of ProSTAT Resource Group, offered the following guidelines on negotiating capitated contracts. Much of what Mr. Beard discussed is contained in the book, *How to Negotiate Capitation (Without Losing Your Head)*, available from the AACC National Office. The book is oriented to costing and contracts for the laboratory.

Although there are many myths about capitation and how it works, there really is a logical basis to it. The basic process for analyzing a capitation proposal includes:

- identifying the services to be included in the contract;
- comparing the laboratory’s current data with those in the proposed contract;
- calculating an average allowable and average cost for each procedure;
- arraying patients by sex and age; ideally this requires actuarial utilization data;
- obtaining specific actuary-based utilization data on the procedures;
- combining the laboratory’s fee-for-service historical data with the utilization data to calculate a “raw” capitation equivalent and comparing it to cost to estimate profitability;
- refining the data to ensure that the laboratory receives the per-member-per-month calculated rates to maintain current income; and
- comparing the offered rates to the laboratory calculated rates.

It is vitally important to identify the services to be included in the contract. Details must get to the level of the CPT and modifier-specific codes that are being capitated. This is essential to protect the laboratory. Ideally a contract should be based on claims history, and often the contractor has the data but does not want to share its past experience.

A laboratory should search its own data to find out what typically has happened in its own environment; however, unless it has had an exclusive fee-for-service contract, it is impossible to calculate its true capitation rates because the amount of work that went elsewhere is unknown. It is necessary to look at the activity over the whole population, including all of the sources that provided those laboratory services. If the laboratory has had an exclusive contract and is the sole source for all of those laboratory services, it is possible to calculate the capitation rate if the number of member months is known. “Member months” is a better defined term than covered lives, because the number of covered lives can vary markedly from month to month. If a laboratory has an exclusive contract, it collates all the CPTs by month and has a record of all the member months. It is thus possible to derive the actual utilization of individual laboratory tests.

Laboratories should calculate an average allowable payment. Capitation produces a dollar figure, usually cents not dollars per member per month. It is necessary to assign a monetary value to a service. Payers historically take what they have paid in fee-for-service and devalue the fee-for-service historical payments by 25–30% to roll into their calculations, based on their assumption that utilization will decrease. In reality, utilization may increase when capitation hits, because the gatekeepers will not get concerned if it is no longer their problem.

To derive market rates, it is necessary to divide all of the laboratory’s fee-for-service business into categories based on its residual HMO fee-for-service business as well as the PPO, Medicare, and Medicaid business. The top CPT codes that account for revenue throughout the laboratory should be reviewed and then averaged by CPT code.

It is probable that there will be many Medicare risk contracts with fee-for-service until 5000 covered lives are reached, which is when capitation contracts will take over. This is extremely risky because, without stop loss, re-insurance, or some kind of risk controls, one or two patients could completely decimate a capitation rate on 5000 covered lives. Risk contracts with 20 000–25 000 or more covered lives provide more security, and at 100 000 covered lives, the population is predictable. A plan should be required to make the capitation payment early. This improves cash flow. The laboratory should automatically recalculate the capitation rate if there is a shift in age and sex distribution.

A laboratory should try to negotiate an exclusive arrangement; however, this is becoming increasingly difficult. Every capitated contract should have some carve outs. For the laboratory, possible carve outs are as follows: Pap smears, cytogenetics, molecular diagnostics, surgical
pathology, and other services that are low volume and high cost. Risk contracts should contain incentives, with the opportunity for increased payments. A systematic approach should be developed to review managed care contracts and determine whether they are worthwhile.

**Practical Tips for Surviving under Managed Care**

Dan Follas, President of Follas Laboratories, offered the following advice to independent laboratories negotiating contracts with managed care groups.

The laboratory business is highly competitive, and it is particularly difficult for the small- or medium-sized reference laboratory that must compete against the large national reference laboratories. In selecting a managed care group with which to work, it is important to look at the various PPOs, HMOs, or physician- or hospital-based organizations wishing to contract out their laboratory tests and work only with those that appear to provide benefits for the laboratory. There is merit in actively avoiding capitation. The critical questions to be asked in negotiating a capitation contract involve the number of members per month and what type of testing is required. If it does not look as if a laboratory could make money, a capitated contract should be avoided.

In the independent laboratory, although not in a hospital, it is possible to limit the amount of Medicare testing performed, because the expense in billing patients for the part of the fee not covered by Medicare is typically greater than the amount likely to be recovered. Medicare demands that the patient's portion of the charge be billed. Thus, the only way to avoid losing money or potential charges of Medicare abuse is to eschew tests for Medicare patients.

An opportunity to do testing under favorable conditions arises with new PPOs and HMOs. When these organizations are first established, they look for providers, and if the financial opportunities look appropriate, it is a good time to participate because it is more difficult to join a program later.

When reviewing contracts it is important to watch for exclusionary language, which might be as simple as demanding that the laboratory is College of American Pathologists-accredited. It is equally important to look for unrealistic obligations. Such an obligation might require the laboratory to open a phlebotomy station convenient for patients but totally outside the laboratory's usual service area.

An opportunity for a laboratory lies in networks and niche markets. Niches are often services not covered by insurance, which facilitates billing, which must be done directly to the patient. It is important to understand the networks and subnetworks that operate in the laboratory’s geographic location, and it may be necessary to have a subnetwork agreement so that the laboratory can do the testing. It is necessary for a laboratory to develop a strategy for interacting with the networks in the local area to protect its niche market. The laboratory may need to become a full service provider doing all the common tests. To differentiate itself from other laboratories, the niche laboratory should still attempt to carve its specialty tests out of the contract. The concept of special carve outs must be sold to the insurance carriers.

The requirement of explanation of benefits (medical benefits or Medicare benefits) creates considerable work, and the language is often vague, misleading, and difficult to understand. Yet it is worthwhile to try to read these carefully because many insurance carriers make mistakes with the explanation of benefits. Improper reimbursements should be challenged. It is important, in the first place, to submit correct matches of ICD-9 and CPT-4 codes to insurance carriers, as well as to Medicare, to minimize rejections. Insurance carriers may make key-stroke errors; therefore, it is important to check reimbursements carefully. It is also important to check the insurance carriers’ master pay list to determine that the fees listed are realistic.

An opportunity for the smaller reference laboratory lies in small contracts of ≤$500 per month. If the facility lies on one of the laboratory’s courier routes, there is little added expense in making a pick-up of specimens. Providing laboratory support for clinical trials is another potential source of revenue. The overriding issue in maintaining and growing a laboratory service is to examine both the rate of reimbursement for tests and the laboratory’s own cost of performing them and to refer those tests that cannot be performed at a profit to other laboratories.

**What are Managed Care Organizations Looking For from Laboratories?**

Bobbi Presser, Director of Network Management for CIGNA HealthCare of Arizona, gave the following insights into the perspective of managed care organizations (MCOs).

There are certain areas to note to set up a win-win relationship between a health plan and a clinical laboratory: (a) smart panels and reflex testing allow improved care and cut the costs in the system, (b) the cost of changing laboratories can be substantial, and (c) ongoing vendor relationships are important in increasing the chances of renewal of the contract.

MCOs wish to consolidate laboratory services with a single provider primarily to obtain consistency of test results and location of records in a single site for the entire operation. A partnership with a single laboratory facilitates total quality management as well as disease management. The single provider approach also enables better monitoring of physician utilization practices. The laboratory and MCO should have such a close relationship that they can jointly define disease management pathways and protocols and testing algorithms. In a capitated environment, such an approach creates the necessary win-win situation that benefits both the MCO and the laboratory.

From the MCO perspective, an essential requirement of
a laboratory partner is that it provides high quality, even if it is not the lowest cost laboratory. To minimize the trauma of switching laboratories, there should be a general consensus among the physician users that the laboratory is appropriate. The relationship between the MCO and laboratory should be such that they can work together to reduce the number of tests performed, even if the cost per test may increase as a result. A key factor in the success of a managed care partnership is the ability to provide data that enable test utilization to be studied. The specific data should be documented in the contract. The contract should also spell out expectations such as turnaround time standards for stat and routine tests. Rewards for desirable performance should be stated, as should the reports expected and their specific content. At a minimum, quarterly reports of activity will be expected. Information that a MCO can include in its National Committee for Quality Assurance reporting is especially useful. A partnership should include an oversight committee to resolve clinical, performance, and financial issues under the contract.

Panels in general lead to unnecessary tests, and there are real benefits in reducing the number of tests, because false positives can lead to considerable additional costs to work up the apparent abnormalities. A minimalist testing policy has benefits for both hospital inpatients and outpatients. Reflex testing can also reduce the time to work up patients. Such policies can be applied to all non-Medicare patients.

**Fraud and Abuse: The Enforcer’s Perspective**

Howard Young, from the Office of the Inspector General, US Department of Health and Human Services, discussed how the US government is dealing with healthcare fraud and abuse.

The Office of the Inspector General (OIG) of the HHS is charged with searching for fraud and abuse within HHS and its contractors, i.e., all healthcare providers. The OIG has many investigators in its Office of Investigations who investigate allegations of fraud and abuse. The Office of Audit Services looks at internal programs within OIG but also assists the Office of Investigations. Its staff has considerable expertise in the clinical laboratory area because of the Office’s participation in the US government’s Operation LABSCAM over the past few years. The Office of Evaluations and Inspections has a long-term charge to make Medicare and Medicaid better and to ferret out waste, fraud, and abuse. The Office of Counsel is charged with pursuing cases involving fraud and abuse and is also responsible for the development of model compliance plans.

The recent rise in healthcare fraud enforcement is largely attributable to a provision in the False Claims Act known as the qui tam, or whistle-blower provision. Not only are whistle-blowers protected from action by their employers, they may also share in the money recovered by the government.

Operation, or Project, Bad Bundle follows up on LABSCAM, which targeted independent clinical laboratories; however, Operation Bad Bundle is oriented to improper billing for hospital outpatient laboratory services. This is currently a major initiative of the OIG. To assist clinical laboratories, the OIG developed its model compliance plan for laboratories, which documents what it believes are the practices that should be embraced by clinical laboratories. It should be noted that the plan is voluntary; however, the plan does stem from some of the guidelines included in the Federal Sentencing Guidelines. The OIG anticipates developing model compliance plans for hospitals, home health agencies, and MCOs in the future.

Compliance plans for laboratories should be viewed as insurance for the future. They are likely to deter qui tam actions. The institution of compliance plans has spawned the development of a host of training programs. Education is the key to effective implementation of a compliance plan. It is probable that the model compliance plan will undergo considerable evolution with time.

For entities that have been involved previously in fraud or abuse, the government can require a corporate integrity agreement. Such an agreement may be binding for 3 or 5 years and require annual reports of any possible internal fraud or abuse or acceptance of overpayments. Annual reviews or audits by an independent auditing or law firm may be mandated. If the entity breaches or defaults on the agreement, the government will take punitive action.

The term “fraud” is used quite loosely by the government. Most cases of Medicare fraud have been prosecuted under the False Claims Act. This Act does not require criminal fraud or wrongdoing, nor does it require a specific intent to defraud. Reckless disregard as well as intentional wrongdoing is interpreted as fraud. Thus, not doing one’s homework can lead to fraud as interpreted by the False Claims Act. An effective compliance plan demonstrates that all areas with potential for possible fraud have been identified and addressed, thereby ensuring little likelihood of an entity running the risk of prosecution.

**Medicare Audits–Two Stories: An Inspector’s and the Inspected Laboratory’s**

**THE INSPECTOR**

John Beattie, of Parente, Randolph, Orlando, Carey, and Associates, discussed the process that US government enforcement agencies follow when performing Medicare audits.

Since 1993, the Department of Justice has made healthcare fraud its second highest priority after violent crime. In 1996, Medicare paid $168.6 billion to healthcare providers, and it is estimated by the Inspector General’s office that ~14% of this, or $23.2 billion, was improperly paid as a result of fraud, abuse, and errors. The Inspector General’s office estimates that fraud in the clinical laboratory
industry could account for as much as $28.6 billion or as little as $17.8 billion.

Medicare currently services 38 million people in the United States, and >800 million claims are processed each year, of which ~95% are filed electronically. Clinical laboratories are an ~$30–35 billion industry by best estimates. This industry is plagued in some sectors by overcapacity. The regulatory climate is now very strict, technology is changing, and profit margins are declining. Medicare reimbursement is declining, and the number of individuals receiving Medicare who are in managed care programs is consistently rising. Within the next few years, it is estimated that almost all of the Medicaid recipients within Pennsylvania will be in managed care. Medicare reimburses for laboratory fees by paying the lesser of actual charges or the national fee schedule. There has been a consistent reduction in the national fee limitation amounts since 1990. There will be no consumer price index increases from 1998 to 2002.

Investigations by the OIG take time. Many agencies are involved in the investigation of healthcare fraud and abuse, including the Federal Bureau of Investigation, the Inspector General of HHS, the Drug Enforcement Administration, the Postal Inspection Service, and the Defense Criminal Investigative Service. The mandate of the Federal Bureau of Investigation is broad. The focus of the Postal Inspection Service is on personal injury fraud. The Defense Criminal Investigative Service is responsible for investigating abuse in the Champus Program, a program that is oriented toward the military and their dependents. HHS investigates Medicare or Medicaid program problems.

The Office of Audit Services of the OIG is the auditing arm of HHS. The Office of Evaluation Inspections is a quick-response office for the Secretary of HHS. It relies heavily on testimonial evidence and surveys; however, in the auditor’s world, documentary evidence is premiere and testimonial evidence is at the bottom of the hierarchy. The Office of Investigation is involved in criminal, civil, and administrative investigations. It oversees the state Medicare fraud control units, which are mainly based in the state attorneys general offices, although some are in the state auditors’ offices. The Office of the Counsel for the Inspector General is involved in the development of model compliance programs.

The government’s main areas of focus are currently multichannel testing, hematology, urinalysis, microbiology, and cytology. The top 100 procedures account for close to 90% of all Medicare expenses, and the government focuses on these because that is where the money is.

The audit process that the OIG uses is based on five criteria: condition, criteria, cause, effect, and recommendation. “Condition” is what exists; “criteria” is what should be; “cause” is why the condition happened; “effect” is the difference and magnitude between the criteria and the condition (primarily monetary); and “recommendation” is what corrective actions should be. The criteria come from numerous sources: federal laws; regulations; Medicare manuals; intermediary and carrier bulletins; contracts, contracts between a provider and a managed care firm, in the case of a Medicaid MCO and the Medicaid contractor; legislative intent; and case law. An auditor is very concerned with what the intermediaries are communicating to the hospitals. The approaches of the intermediaries are not always consistent, particularly with respect to multichannel testing.

Condition is the exception to criteria. One cause of many problems that occur within the laboratory industry arises from problems with electronic data processing coding. It is necessary to have a multidisciplinary approach to coding, involving people with clinical, billing, and electronic data processing backgrounds. Effect includes the quantification errors. The recommendation in the report should always be practical. The government typically asks for a penalty twice the amount of the overpayment to deter this type of behavior.

The OIG’s audit process essentially consists of six phases: a preliminary planning phase, a pre-survey phase, a survey phase, a data collection and analysis phase, a reporting phase, and a postaudit evaluation. In the preliminary planning phase, the issue is identified, either through congressional inquiries, the HCFA, or individual research on audit process leads. The audit process itself will sometimes generate audit leads. In the preliminary planning stage, appropriate responsibilities are distributed among the OIG staff. In the pre-survey phase, criteria are reviewed to make certain that sufficient information has been gathered. The survey phase is the third phase before the audit actually begins. Within the OIG, this is the time when the go or no-go decision is made. If there is a go decision, the audit work will continue, an audit program will be developed, and simple sampling plans will be developed.

In the data collection phase, the laboratory receives the notice of audit. This is followed by an entrance conference. When the auditors go in, one of the things they want to look at is the laboratory’s fixed assets schedules because they want to make certain that the laboratory has the equipment necessary to perform the type of tests that are being billed. The Charge Description Master is a prime focus of an audit.

In addition to gathering documentary evidence and doing analytical analysis of the evidence that they gather, including volume analysis based on the laboratory’s revenue and use reports, the auditors will probably interview some of the laboratory staff. If the investigation is a criminal one, the Federal Bureau of Investigation, if it is involved, may simultaneously interview several different people within the institution, including laboratory staff, finance personnel, registration staff, and patients.

After an audit is conducted, an exit conference will be held before the formal issuance of a report. A draft is completed first. This will be reviewed by audit management including the regional inspector general. An independent review of the report will be done by someone
unassociated with the audit. The draft report will be sent to the laboratory director for his or her comments, and those comments will be incorporated into the report together with the OIG’s comments on the laboratory director’s comments. Ultimately, a final report is issued. The key laboratory findings generally involve unbundling, duplication, up-coding, tests not performed, tests not ordered, and medically unnecessary tests.

The primary defensive measures that a laboratory should have include having a government-mandated compliance plan as well as a voluntary compliance plan. Audited monitoring, hot lines, education, and training are all components of a voluntary compliance plan. The government’s compliance plan is only a guide. When a laboratory is developing its compliance plan, it is worth looking at the OIG’s work plan and emphasizing its targeted areas. A laboratory should also develop a policy on how to respond to issues of fraud. The policy should not be developed in a crisis mode. When the laboratory develops its compliance plan it is essential to give adequate attention to the confidential nature of investigations that may have to be conducted.

If a laboratory is served with a search warrant, no one should interfere with the search. It is desirable to identify the investigators and their associated agencies and to obtain a copy of the warrant and, if possible, the affidavit. The locations of the areas searched and the documents or other items seized should be recorded. Copies of all documents and electronic files seized should be requested.

**Medicare Audits—Two Stories: An Inspector’s and the Inspected Laboratory’s**

**THE LABORATORY**

Larry L. Small, Director of Compliance Services for Chi Laboratory Systems, gave the following advice to healthcare organizations undergoing Medicare audits.

A Medicare audit should be approached from a positive standpoint. Medicare is not the enemy, and the audit should be considered a learning experience for the billing and laboratory managers. An audit may identify lost billings and lead to quality improvement. Having an effective model compliance plan should be considered part of total quality management.

What should be done to prepare for a Medicare audit? First, anticipate those areas likely to be audited and then make sure that the proper practices and procedures are in place and are being followed. Where they are defective, the procedures should be corrected. The compliance evaluation plan must be comprehensive and must encompass all departments. The audit must be unbiased and nonpolitical. If a material wrongdoing is identified during the self-audit, attorney-client privilege should be invoked.

There are seven steps to sound regulatory compliance: (a) the auditor needs to understand the relevant laws and civil or criminal penalties for breaking them; (b) the regulatory requirements and issues must be understood; (c) there must be appropriate policies and procedures in place; (d) standards of conduct must be established; (e) a proper training and implementation program must be in place, dealing with specific issues related to billing or the laboratory; (f) a monitoring system must be in place to verify that practices are being followed; and (g) records must be properly maintained to prove that services were requested. The statute of limitations for federal law is 6 years, and records must be kept for this time. Failure to do so exposes a facility to a $10 000 fine for each occurrence.

Typically, the most vulnerable area for an organization includes the data processing systems. These should be able to unbundle profiles, identify duplicates, rebundle tests into proper CPT code configuration, and eliminate tests that were not reported or performed. Many turnkey systems lack the capability to do this.

Repeated tests often present a billing problem. When a test is not performed, this may also present a difficulty because many computer systems are designed to bill on the receipt of a specimen. The 3-day window requires a computerized solution because manual systems often fail to link test values within this time and a patient’s admission. The “3-day rule” is very confusing because it is actually almost 4 days, or almost 96 h. For example, if a patient has outpatient testing on the first of a month and is admitted to the hospital at any time on the fourth, the outpatient testing falls within the 3-day rule.

Medical necessity diagnosis coding requires very sound practices, policies, procedures, and standards of conduct. One area of exposure is the requisition. This must include a place for the ICD-9 code, and it should state specifically the need for a code, not a narrative diagnosis. If a narrative diagnosis is provided, it should be converted into an ICD-9 code only by a person who has been properly trained in that function. Coding is best done by coders in the medical records department, which routinely has certified coders. If no diagnosis is provided on a requisition, it is necessary to call the ordering physician to obtain this information. It is important to document that a call was made, the time and date of the call, the name of the caller, to whom the caller spoke, and the information that was provided.

Advance beneficiary notices are difficult to implement, and it is difficult to bill a patient for tests that have been denied by Medicare. To bill for a test, a billing department needs to know that an Advance Beneficiary Notice has been signed. However, most laboratory information systems and hospital information systems are not able to transfer this information to the billing department. It is important with Advance Beneficiary Notices to ensure that appropriate specific wording is included.

Standing orders should be validated on a periodic basis, such as 6 months or minimally after 1 year. The validation should be documented. When a physician uses a standing order, there typically is no record on a requisition that the physician ordered the test; therefore, if one of the laboratory staff enters a request into the computer
and the test is performed and billed, the law has been violated. There must be a written document, such as a fax, with an authorizing physician’s signature on it to demonstrate that a physician did request the test.

In requisitions, the physician must be given the choice of ordering individual tests as well as panels. Ideally, the only panels that should be orderable are the HCFA-approved panels. The composition of these should be stated clearly on the front or back of the requisition form. The requisition should reflect the Laboratory Procedure Manual, in which the CPT code of each test should be included in its description. It is desirable to limit the number of tests for which there are several test options; for example, a complete blood count could be with or without a differential, and the differential could be manual or automated. The laboratory is obliged to find out from the physician which of these tests is the one requested. “Urinalysis” presents the same problem—whether it is dipstick alone or with a microscopic examination.

A laboratory should examine its tests that are frequently billed to Medicare annually to verify that test bundling is properly occurring before bills are issued.

When a self-audit discloses problems, it is important to have both the hospital compliance officer and his or her staff and a laboratory compliance team involved. The latter should comprise the billing manager, the laboratory manager, the outpatient manager, if such a position exists, and the computer system director. The laboratory team should establish policies with the authorization of the hospital compliance team.

In the event that Medicare does audit a laboratory, the laboratory staff should not assume that all the accusations by the auditors are accurate, and the accusation should be challenged appropriately. The challenge should be done rapidly, completely, and constructively.

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