Federal reimbursement to laboratories

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The change from a predominately fee-for-service payment environment to managed care has significantly reduced revenues for many clinical laboratories. Medicare is rapidly becoming the most favorable payer in areas with high managed-care penetration. This trend has not gone unnoticed by Congress, and congressional and regulatory initiatives are rapidly moving to reduce federal laboratory reimbursement. The efforts by both the private and public payors to further restrict payments could have a profound effect on the scope of testing offered by hospital-based laboratories. On-site nonemergency testing capability will be dependent on the cost to provide the service and the level of reimbursement. Laboratory providers have an opportunity to influence the extent of laboratory cost-reducing initiatives. To effect congressional or regulatory change requires an understanding of the federal Medicare payment system and a well-organized effort.

INDEXING TERMS: managed care • Medicare • Health Care Financing Administration • clinical laboratories

MEDICARE OVERVIEW
Congress in 1965 established the Medicare program to provide healthcare benefits to persons 65 years of age or older and certain disabled beneficiaries. In 1974 they expanded the program to include most persons with end-stage renal disease. In 1966 there were 19.1 million persons enrolled in the Medicare program; by 1994 this had grown to >36.9 million persons [1]. Because of this growth, the Medicare program has been subject to frequent legislative and administrative changes, many of which have significantly influenced the delivery and payment of healthcare services, especially clinical laboratory and other diagnostic services.

The Medicare Program consists of two distinct insurance programs. Part A, Hospital Insurance Benefits for the Aged and Disabled, covers services furnished by hospitals, home health agencies, hospices, and skilled nursing and end-stage renal disease facilities. Part B, Supplementary Medical Insurance for the Aged and Disabled, covers a wide range of medical services and supplies—including physician services, outpatient hospital services, and home health services not covered under Part A, as well as diagnostic laboratory tests, x-rays, and the purchase or rental of durable medical equipment. The Social Security Act mandates that only services determined to be reasonable and necessary are paid for under the Medicare program.

The Health Care Financing Administration (HCFA) is the federal agency primarily responsible for the administration of the Medicare program. HCFA responsibilities include (a) formulation of policy and guidelines, (b) contractor payment oversight and operation, and (c) maintenance and review of utilization records. HCFA contracts with private insurance companies to serve as fiscal agents between the providers and the federal government and locally administer Medicare Part A and Part B. Medicare “intermediaries” process Part A claims for inpatient hospital care, skilled nursing facilities, home health agencies, and hospice services. The intermediaries also process hospital outpatient Part B claims such as claims for clinical laboratory outpatient services. Medicare “carriers” process all other claims for Part B services. These include physician services, commercial laboratory services, durable medical equipment, and other nonphysician supplies and services as described above. The responsibilities of the intermediaries and carriers are similar in that both are charged with assuring that claims are only paid for medically necessary services and guarding against fraud and abuse. The intermediaries also have the responsibility of determining cost and reimbursement amounts for hospitals, whereas the carriers have the additional responsibility of determining charges allowed by Medicare and assisting in fraud and abuse investigations [1].

CLINICAL LABORATORY FEE SCHEDULE
The payment for clinical laboratory service as we know it today has its roots in major pieces of legislation enacted from 1984 through 1988. Before 1983, hospital Part A payments were made on the basis of “reasonable cost.” This changed when Congress enacted the Social Security amendments (Public Law 98–21).

1 Nonstandard abbreviations: HCFA, Health Care Financing Administration; PPS, prospective payment system; DRG, diagnosis-related group; DEFRA, Deficit Reduction Act of 1984; CPI, consumer price index; NLA, national limitation amounts; CPT, common procedural terminology; AMA, American Medical Association; ICD-9-CM, international classification of diseases, 9th revision, clinical modification; GGT, γ-glutamyltransferase; and CPK, creatine phosphokinase.
which replaced the reasonable-cost methodology with the prospective payment system (PPS) for hospital services. Under PPS, a hospital is paid a predetermined amount on the basis of the patient's diagnosis within a "diagnosis-related group" (DRG). All medical care, including laboratory services, required during a person's inpatient hospital stay is bundled under a fixed payment amount /2/. The DRG amount received by the hospital may be less than the hospital's actual cost or it may be more. PPS is the healthcare system's first real experience with capitation and risk sharing. If hospitals are efficient and make a concerted effort to contain costs, they can make a profit under PPS, but if they have not contained costs the hospital must absorb the loss. Congress, through PPS, effectively transferred the risk for the cost of care for inpatients to the provider hospitals.

Up to 1984, independent and physician office laboratory services were reimbursed under Medicare Part B at 80% of reasonable charges. The Deficit Reduction Act of 1984 (DEFRA) instituted major changes in the payment of clinical laboratory services. It required (a) establishing area-wide fee schedules, (b) direct billing by the entity performing the laboratory service, (c) waiving the Part B deductible and coinsurance for laboratory services billed on an assigned basis, and (d) payments for independent laboratory claims based on assignment. DEFRA also authorized the $3.00 specimen collection fee.

DEFRA legislated the fee-schedule rates to be computed by using 1983 "reasonable charge" data maintained by Medicare carriers. The 75th percentile of area prevailing rates was the basis for calculation of the first-year fee-schedule rates. DEFRA also specified that the fee schedule was to be adjusted annually on the basis of the consumer price index (CPI). Since the methodology of establishing the fee-schedule amount is defined in statute, HCFA does not have the ability to change fee-schedule amounts for tests that have 1983 charge data even when this data appears to be in error. DEFRA also required two clinical laboratory fee schedules be established, one fee schedule for hospital outpatients and the other for independent and physician office laboratories. The rate for hospital laboratories was set at 62% of the area prevailing charges and at 60% for independent and physician office laboratories. The 2% differential for hospitals was to compensate for higher overhead cost. This 2% provision was later repealed in 1988 except for sole community provider hospitals.

All outpatient laboratory services are subject to the fee schedule except for services required to be performed by a physician. These services have since been included in the physician fee schedule, on the basis of the relative value scale. Laboratory procedures and services associated with blood and blood products are not considered clinical diagnostic tests. Therefore, they are not subject to the fee schedule and are cost-based reimbursed.

The payment levels for the majority of tests listed on the fee schedule, as stated above, are based on 1983 charge data. Increases in the individual payment amounts can only be made on the basis of the CPI. For the past several years Congress has frozen the CPI increase for clinical laboratory service, and it appears the fiscal 1996 congressional budget will mandate continuing the freeze for the next 7 years.

NATIONAL LIMITATION AMOUNTS
The payment allowance for laboratory services was further restricted when Congress legislated the establishment of national limitation amounts (NLAs). The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) required NLAs to be applied to the payments for outpatient clinical laboratory tests. For services rendered on or after July 1, 1986, the NLA was set at 115% of the median of all the fee-schedule amounts established for each covered test. The NLA has continued to be lowered each year and in 1996 will be at 76%, a 4% decrease from 1995. It also is anticipated that starting in 1997 the NLA will be further reduced to 65% of the median.

NLAs for new test procedures are set through a process called gap fill. Once the Food and Drug Administration approves a new test procedure, the American Medical Association (AMA) Common Procedural Terminology (CPT) Editorial Panel may establish a new code for the procedure if a current code does not exist. The allowance for the first year of the new code will be the local area's prevailing charge for that service. For example, in 1994 the CPT added a code (83527) for "Insulin, free" /3/. Each of the 55 carrier areas determined a payment level for this test on the basis of their individual charge data. The local payment amounts were in effect for the first year of the code only. During the first year the carriers reported their prevailing allowances to HCFA. An average rate was determined and then multiplied by 80%, the mandated level of the NLA for 1995. Because of this process the 1995 NLA for "Insulin, free" was $18.48. States where the prevailing amount for the test is <$18.48 will continue to be paid at the prevailing rate. States where the prevailing allowance is higher than the NLA are reduced to the NLA.

Certain new codes will have an NLA established the first year. This occurs when HCFA determines that the new code is sufficiently similar to a current code. In these cases the payment data is simply crosswalked to the new code. Many codes were crosswalked in 1993 simply because of renumbering. However, HCFA may set an NLA for a new code that does not have payment data that can be crosswalked. This occurred with the new molecular diagnostic codes in 1993. HCFA set the payment levels for the four new codes based on one-fifth of the 1992 payment level for the Southern transfer test. To assure that inappropriate payment amounts are not set for the first year of a new code requires close monitoring and input from laboratory providers.

CODING SYSTEMS
Common Procedural Terminology (CPT). The Medicare program adopted the AMA's CPT coding system to report professional services provided to Medicare beneficiaries. The AMA in 1966 developed the CPT coding system to describe the professional medical, surgical, radiology, laboratory, and anesthesiology physician services. A different code is assigned to every service and procedure a physician performs. In this way, each procedure or
service can be identified by a number instead of a lengthy written description [4].

The AMA revises the CPT annually to include new procedures, delete obsolete procedures, and modify existing procedures to reflect changes in medical practice. The changes are prepared by a CPT Editorial Panel with the assistance of a CPT Advisory Committee made up of physicians representing all specialties of medicine. The CPT Pathology and Laboratory section (80,000 series) underwent extensive revision in 1993. The section now more adequately reflects today's laboratory technology, making the correct coding of test procedures much less complicated. Laboratory technology, however, continues to outpace coding updates, making billing of new technology difficult. The AMA CPT editorial process requires 2 years from time of petition for a new code to its assignment.

HCFA Common Procedural Coding System. The AMA's CPT descriptions are limited to physician procedures and services. It does not include codes for nonphysician services or medical and surgical supplies that also are covered by Medicare. To resolve this, HCFA developed its own terminology and codes for services not contained in the CPT. The AMA's CPT codes and the codes developed by HCFA are collectively known as HCFA Common Procedural Coding System (HCPCS), which describes a group of codes. There are three levels of codes: level I, which are CPT codes; level II, which are national codes; and level III, which are local codes. National codes are alphanumeric codes A-R and V. The national codes frequently used by the laboratory are the G code for billing specimen collection and the P codes for billing the travel allowance for specimen collection of a homebound or nursing home patient. Q codes are national codes that may be assigned by HCFA on a temporary basis. Laboratory tests may have a Q code assigned until a CPT code becomes available. In 1994 a Q code (Q0126) was issued by HCFA for billing bacterial antigen tests. They discontinued the use of this code when a CPT code (86313) became available in 1995.

If a CPT definition is in conflict with HCFA's regulatory policy, HCFA may designate a national code for billing the service to Medicare. For example, Medicare does not pay for finger or heel sticks. When the CPT changed the description for the venipuncture code in 1993 to include finger or heel sticks, HCFA no longer covered CPT code 36415 and issued a national code, G0001, in its place. Laboratories billing Medicare for the collection fee must use G0001 to be paid the $3.00.

The third level of codes, local codes, are developed and made available through the local Medicare carrier with approval of the HCFA regional office. They are also alphanumeric W-Z codes. The local codes may vary from state to state. Local codes are made available on an "as needed" basis for a new procedure not in the CPT or on the national list.

International Classification of Diseases, 9th revision, Clinical Modification. The International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) is used for coding diseases and other data contained in the patient's medical record. Medicare adopted the ICD-9-CM coding system in 1989 because it provided a standard way of recognizing and tracking services by diagnosis. For Medicare to cover a test it must directly relate to the patient's illness or injury (or symptom or complaint). The ICD-9-CM coding system provides the mechanism to communicate to Medicare the specific disease, injury, impairment, etc. that caused the patient encounter. ICD-9-CM coding is required on Medicare claims submitted by physicians and hospitals for inpatient and outpatient services.

ICD-9 diagnosis codes have not been routinely required on claims submitted by independent laboratories. However, to prevent Medicare from paying for screening tests, carriers across the country are developing limited coverage policies for a number of high-volume tests. These policies specify the specific diagnoses or conditions for which a test will be considered a covered service. The tests most commonly limited are cancer tumor markers, cholesterol, HDL, lipids, y-glutamyltransferase (GGT), triglycerides, prostate-specific antigen, thyroid studies, occult blood, complete blood count, glucose, and ferritin[J]. Many physicians fail to provide the diagnosis code when ordering a test, and often, obtaining the information is difficult for the laboratory. The limited coverage policies appear to impose an unfair financial burden on the testing laboratory.

BILLING GROUND RULES

Medicare places the responsibility on the provider of laboratory services to select the code that most closely matches the tests ordered by the physician and provided by the laboratory. If a code for a specific analyte is listed in the CPT it must be used when submitting a claim for the tests. For example, it is incorrect to bill using the code for a glycated protein when performing a glycohemoglobin. It also is incorrect to bill a methodology code if a code for the specific analyte is available.

The provider also is held responsible for correctly applying Medicare's billing policies. Since the Medicare program gives considerable latitude to contractors to interpret payment policies, they tend to vary from carrier area to carrier area. For example, some carriers bundle the automated tests at two, whereas others require the use of an automated code for only one automated test. The local carrier or intermediary bulletins detail billing policies. Any new or revised policy will be published as a proposed policy with a comment period before becoming final. The local laboratory providers should actively monitor and respond to proposed policies affecting coverage of laboratory services. Providers may communicate their concerns either directly to the payor or to a member of the Carrier Advisory Committee. The Committee consists of representatives of the medical specialties, the hospital association, peer review organization, and beneficiary community. The local laboratories should know who is representing laboratory issues on the Committee and use the Carrier Advisory Committee to communicate with the payor regarding local payment policy.

The Medicare carriers and intermediaries normally monitor billing by postpayment audits. The payment of a claim does not mean the payor approved of the billing. The number of postpayment laboratory audits has increased dramatically over the past several years. HCFA has instructed local carriers to closely monitor the billing of laboratory services to identify
reimbursement and utilization patterns that deviate from the norm. Laboratories usually selected for audit are those that exceed the norm for billing certain codes. If overpayments are determined through audit, the law requires the contractor to request a refund, and normally this refund request will include some type of monetary penalty.

**Coding and Billing Challenges**

**Automated tests.** The CPT includes a list of 19 tests that can be and are frequently performed as "profiles" on automated equipment. These are commonly referred to as "automatable" tests. The majority of carriers have added tests to their automated test list. The tests most commonly added are GGT, creatine phosphokinase (CPK), triglycerides, iron, magnesium, and lactate dehydrogenase isoenzymes. There is little consistency among the carriers as to the tests added. In response to petitions from the laboratory community, HCFA proposed creating a single national list of tests subject to the payment limitations for the automated test. A HCFA draft detailing the proposal revisions to the carrier manual was first circulated November 1994 to the AMA and the American Clinical Laboratory Association for review and comment. After receiving comments, HCFA revised and recently issued a second draft of proposed revisions to the carrier manual. HCFA indicated that policy revisions are necessary because (a) the 19 tests included in the CPT are not all inclusive for tests performed on automated equipment, and (b) of the need to have a national standardized list, as the carriers vary with respect to the specific tests included on the list and on how the additional tests are paid. Some have added tests without making increases in the allowance and others have provisions for additional payment. HCFA representative Barbara Wynn, deputy director of the Bureau of Policy Development, stated at the Washington G-2 "Lab Institute '95" in September that the manual revisions will standardize the list of automated tests paid for by all carriers, and the revision would be effective January 1996. Tests to be added to the current CPT list of automatable tests are triglycerides, GGT, and CPK. Ms. Wynn further stated that they would issue a separate instruction that will provide for an additional 50e for each additional test over 19. The proposed national standardized automated list with the specific payment amount for >19 automated tests is generally well accepted by laboratory providers.

One proposed revision to the carrier manual could potentially change the way laboratories do business. HCFA is proposing to eliminate the policy that all tests in an automated profile are covered and paid for if any one of the tests in the profile is medically necessary. HCFA is taking the position that the policy had value when automated technology required all tests to be performed. However, technology now allows for individual testing and it is no longer necessary to pay for tests that do not meet medical coverage requirements. The revised medical necessity policy would allow carriers to assume that the automated tests are covered if they have been ordered on a test-by-test basis rather than by simply checking off a custom profile. The payment cannot exceed the amount that Medicare would pay if only the medically necessary tests were ordered. It also requires carriers periodically to undertake physician and supplier education and suggests that carriers take additional action when medical review shows a pattern of overutilization of automated profiles with large numbers of tests. The further action would require either a diagnosis code or narrative to substantiate medical necessity.

HCFA recognizes that requiring laboratories to provide a diagnosis code or a narrative is especially burdensome. The CPT is considering replacing the automated codes (80002-80019) with small clinically relevant groups of tests, possibly effective January 1997. HCFA feels strongly that this will provide more assurance that the automated tests ordered are clinically relevant and medically necessary.

**Medical Necessity**

Carriers are required to develop local medical review policies when they find aberrances or overutilization. HCFA maintains that this gives them the authority to require medical necessity documentation when they suspect tests are not clinically relevant and medically necessary. They generally identify overutilization by data analysis. However, the data that the carriers are using to determine overutilization may be in itself flawed. The number of tests per 1000 beneficiaries for individual carriers is the total number of tests paid by the carrier divided by the total number of Medicare beneficiaries within that carrier's jurisdiction. The calculations are complicated by the fact that large national laboratories are performing tests for beneficiaries residing in other states. The problem with the data has been called to HCFA's attention and it is analyzing the impact of national reference laboratory data in detecting aberrancies.

HCFA is also taking steps to encourage greater consistency among the carriers' local medical review policies. A committee of carriers' medical directors is developing model policies. These policies will not become national policies but are meant to serve as a template for the local carriers. The carriers will have the latitude of adopting the template or adapting it to local area practice of medicine. In addition, the Bureau of Data Management and Strategy will be taking over management of the Minnesota Policy Retrieval System. This is a data base that will contain all local medical review polices developed by the carriers. This data base will be on-line and available for any carrier to access.

**Legislative Initiatives**

Congress is looking to the Medicare program to cut $270 billion over the next 7 years. It has not spared the clinical laboratories in determining areas to reduce projected payments. The proposed actions will affect laboratory Part B allowances. The major laboratory provisions affecting fee-schedule allowances are the freezing of the CPI update for 7 years and reducing the NLA in 1997 to 65% of the median. The national direct bill issue, copay, and competitive bidding are still being considered and could be included in the final legislation.

**Laboratories' Response**

Laboratory providers have the opportunity to voice their concern and affect many of the policies and regulations that determine how Medicare pays us for laboratory services. At the national level the AACC is a member of the Laboratory Budget Coalition that is working to prevent further reductions in
payment amounts. Members of this group include laboratory professional organizations and some industry members. The Coalition takes the laboratory provider position directly to congressional representatives. At the state level the laboratory professional groups must focus on educating members to the payment systems and take the opportunity to work with the Carrier Advisory Committees. Each carrier has an advisory committee that includes a pathologist. However, HCFA has instructed the carrier to have another laboratory consultant if the pathologist is not clinically oriented. There are mechanisms at both the federal and state level for communication on laboratory issues. We must become involved to assure that the clinical laboratory can continue to provide high-quality health-care and that access to new technology is not limited by the payment systems.

References