

A brief history of medical diagnosis and the birth of the clinical laboratory

Part 4—Fraud and abuse, managed care and lab consolidation

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A look at the administrative functions of the laboratory over the last 30 years supports the theory that the business of healthcare in the United States is no different from any other business. It will probably always be relatively easy to find reputable labs that want nothing more than an honest week's pay for an honest week's work; but there will always be those that want an honest week's pay for an honest day's work, too.

Medicare law is like the federal tax code in that lab operators will continue to look for loopholes that allow them to profit in some way that may or may not always be ethical or legal. As a result, government investigation and prosecution of Medicare and Medicaid fraud and abuse now seem almost commonplace. Managed care also made its mark on the lab, causing reference and hospital labs to lay off workers and trim costs wherever possible in an effort to maximize profit in a new, corporate style of healthcare.

This article (the last in our four-part lab history series) attempts to describe the effects of fraud and abuse, the resulting government crackdowns that came in response, and the effects of managed care on the U.S. laboratory.

Fraud and abuse

Conspicuously high costs lead to more regs. When Nixon assumed office in 1970, his administration confronted rapidly escalating Medicare and Medicaid costs. In a July 1969 press conference, he declared a massive healthcare emergency and predicted a breakdown in the medical system if the "\$60 billion crisis" was not addressed. Several factors contributed to

Driven by pressures from government regulations and managed care to cut costs, today's labs are run more like businesses than traditional hospitals or charitable institutions of yesteryear.

the crisis. First, private insurers and government programs effectively insulated patients and providers from the true cost of healthcare and therefore reduced the incentive to weigh costs against benefits. Second, hospitals were encouraged to solve financial problems by maximizing reimbursements. In the end, the solution for hospitals became a problem for society. Medicare also paid physicians according to "customary fees" assumed to be "prevailing" fees for an area. This encouraged young physicians with no record of fees to bill at unprece-

dent levels, as well as encouraged doctors to practice in high-priced areas.

At first, Medicare allowed a charge of 1% of lab fees for unidentified costs, but in 1968, it was reduced to zero, eliminating Medicare contributions to hospital profit, bad debt or charity allowances. Hospitals responded with cost-shifting, and independent labs responded with price increases.

The U.S. government then countered with more than 100 amendments to the Social Security Act in 1972. These new laws included fee schedules for routine laboratory work on the basis of the lowest charge paid within a region, significant limitations on other reimbursements for hospitals and extensive limits on prevailing charges for physicians.

Kickback scams and overcharging. In 1976, several reports began to surface of independent laboratories paying kickbacks to doctors in return for their Medicaid business. Cash, salary subsidies for lab employees, obscene sums of money for small or nonexistent office space, medical supplies and personal perks, such as cars for physicians, were some of the kickbacks reported. Multiple tests were billed to Medicaid by independent labs on behalf of physicians when in reality, only a frac-

Omnibus Budget Reconciliation Acts, 1986 to 1996

- OBRA '86** In hospitals using labs outside the hospital performing tests on hospital outpatients, the hospital must bill the Medicare program directly for these services and the outside lab must look to the hospital for reimbursement. This meant hospitals would have to act as their own fiscal intermediaries in this situation.
- OBRA '87** This Act authorized the Secretary of Health and Human Services to impose sanctions against labs or physicians who knowingly decline assignment of Medicare benefits on fee schedule testing. It also eliminated a previously existing allowance for return on equity of capital for hospital outpatient departments, including laboratories, and reduced Medicare laboratory reimbursement from 155% to 100% of the national mean of carrier-wide fee schedules.
- OBRA '89** OBRA '89 reduced the lab fee schedule from 100% to 93% of the national median of carrier-wide fee schedules and required that all labs participating in the Medicare Program comply with the Clinical Laboratory Improvement Amendments of 1988. It also provided for Medicare coverage of a preventive lab service for the first time (screening Pap smears conducted every three years), and it included a provision barring "self-referral" to labs owned by physicians (the Stark self-referral ban). This was due to congressional concern that physician ownership of labs produces overutilization, a concern supported by a report of the General Accounting Office comparing utilization rates and charges for physician-owned and nonphysician-owned labs. Certain exceptions were spelled out (e.g., "Safe Harbor" provisions).
- OBRA '90** This Act reduced the lab fee schedule from 93% to 88% of the national median of carrier wide fee schedules. All labs, including physician office labs, became subject to mandatory Medicare assignment. The Act also changed the definition of a shell lab to one that does not perform (on site) 70% of the tests for which it receives requisitions. It also established the "72-hour rule" by which all Medicare services (including labs) provided to a Medicare beneficiary within three days of admission to hospital are included in the Prospective Payment System reimbursement to the hospital for that admission. OBRA '90 also required that all entities providing Medicare services disclose their ownership structure to HHS. This included depreciation, interest, taxes, insurance, and similar expenses both for plant and movable equipment.
- OBRA '93** OBRA '93 reduced the lab fee schedule from 88% to 76% of the national median of carrier-wide fee schedules over a three-year period according to the following schedule:
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|------|-----|
| 1994 | 84% |
| 1995 | 80% |
| 1996 | 76% |
- OBRA '93 also froze the annual consumer price index update for 1994 and 1995.

tion of the billed tests were actually ordered. Relatively few labs were involved in the bilking, but they gave all laboratories a bad reputation.

Independent labs were not the only opportunists. A 1976 General Accounting Office report found that some physicians who did their own billing were overcharging Medicare and Medicaid patients 100-400% on tests performed for them by commercial laboratories. One physician in Atlanta had paid out only \$15 for a test and received \$276. Other transgressions included charging for in-office tests that were performed by an independent lab. To combat overcharging, the Department of Health, Education and Welfare (HEW) proposed limiting reimbursement to the lowest charge in the range of "going rates" in an area. The College of American Pathologists (CAP) President Dennis Dorsey argued at the time that rates that seem out of line with national statistical norms may be legitimate to a local area and may not be abusive. Pathologists constrained by an income ceiling might be forced to concentrate

on providing services for which adequate compensation was available, Dorsey maintained. After the dust settled, the United States enacted legislation that banned 100% reimbursement by Medicare for lab services performed in an independent laboratory for hospital inpatients when the hospital pathologist did separate billing for these services.

The Medicare-Medicaid Fraud and Abuse Amendments of 1977 also offered a new means of enforcement. One section calls for disclosure of an ownership of 5% or more in a facility such as an independent laboratory in order to participate in Medicare and Medicaid. Another makes it illegal to either pay or receive any remuneration, including a kickback, bribe or rebate, for referring a patient or a specimen from Medicare or Medicaid patients. Previously misdemeanors, such kickbacks became felonies, and violators were punished with up to five years in prison, a \$25,000 fine or both.

In 1980 the secretary of Health and Human Services (HHS) again tried another strategy. A restatement in the

Federal Register of an old but unenforced rule was published: Medicare Part B covered services must be performed personally by the hospital-based physician. If not, they were to be reimbursed under Medicare Part A, which figured claims based on “reasonable costs” (as opposed to “reasonable charges” under Part B). The subsequent reduction in payment would threaten the very existence of many lab services, CAP claimed. CAP filed a lawsuit challenging the HCFA notice in an Arkansas U.S. District court and won.

HCFA

While Medicare was originally passed as an amendment to the Social Security Act, Medicaid was linked to federal welfare programs. In 1977, the outspoken Secretary of HEW, Joseph Califano, proposed establishing the Health Care Financing Administration as a way to manage Medicare and Medicaid—both healthcare-related programs—together, and HCFA was founded.

HCFA was also conceived as a mechanism for rooting out fraud and abuse, and the Office of Inspector General (OIG) was created as an arm of HCFA for that purpose. In 1978, final rules implementing the 1972 Medicare Amendments were enacted. These included a list of 12 lab tests for which the reimbursement was set at “lowest charge” defined as the 25th percentile of all charges in a locality, and it was up to HCFA and the OIG to enforce those rules.

By 1979, HCFA was also administering interstate licenses required under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) for labs conducting interstate business. The Administration also began performing lab inspections, which were previously handled by the CDC.

Later, the OIG began to look at pricing in various markets. Over the years, HCFA's own efforts to hold down the cost of lab tests have taken various forms, including proposed national fee schedules, pilot projects of competitive bidding for contracts to supply lab services to Medicare/Medicaid programs and proposed prospective payment systems that fixed lab reimbursement rates based on a patient's diagnosis.

HCFA also began enforcing CLIA regulations by imposing settlement agreements on labs that were found to be out of compliance by the OIG. Settlement agreements allowed the labs in question to avoid having to publicly admit to any wrongdoing, but forfeit for a length of time certain rights to a defense if charged with the same violations again. Other provisions in settlement agreements called for suspension of a lab's license with an obligation for the lab to pay its employees during the suspension period and bans for defined periods on efforts to recruit new clients.

HCFA also played a role in implementing and enforcing congressional legislation pertaining to healthcare providers who received Medicare/Medicaid funds. For example, the Deficit Reduction Act of 1983 mandated the use of the prospective payment system for Medicare beneficiaries; and as part of that system, HCFA imposed the use of a new billing protocol that required physicians to code tests based on a list

of numbered, allowable diagnoses known as Diagnosis Related Groups (DRGs). DRGs were first developed at Yale University in 1981 as a research tool. Designed according to patterns of care received, length of stay and overall use of services, the codes were used to classify hospital admissions for statistical purposes and planning. Each diagnosis and procedure was coded according to the International Classification of Diseases—Ninth Revision—Clinical Modification (ICD-9) for purposes of DRG assignment.

A year after DRGs came on the scene, the U.S. government upped the ante again with the Deficit Reduction Act of 1984. That legislation mandated a Prospective Payment System (PPS) to set predetermined prices for hospital admissions of Medicare patients. The DRG system would consist of 23 major diagnostic categories organized by organ system and disease etiology, and reimbursement would be provided for each of 467 DRGs. Lengths of stay within a single DRG were not to be statistically different. Hospitals reacted by reducing length of stay per admission; labs instituted hospital lab outreach programs to supplement their declining Medicare/Medicaid revenues; and utilization of tests increased for independent labs.

After DRGs came the 1985 Balanced Budget and Emergency Deficit Control Act (Gramm-Rudman-Hollings bill), which authorized the President to impose automatic spending cuts on the congressional budget when deficit reduction targets were not met.

Lab fees were easy targets because of earlier reports of fraud and abuse. Consequently, the final budget reconciliations between the President and Congress from the late 1980s and through the 1990s were filled with deeper and deeper cuts to federal reimbursement for lab services (*see box, “Omnibus Budget Reconciliation Acts, 1986 to 1996”*). These Omnibus Budget Reconciliation Acts often included other stipulations for lab reimbursement, as well.

It seems unlikely that Federal scrutiny of labs will ever decrease in intensity as HCFA continues to seek new ways to tighten Medicare/Medicaid reimbursement policies. Now “compliance plans” are a routine part of any upstanding laboratory's central operations.

Managed care

Managed care has been in the making since the enactment of the Medicare and Medicaid programs. By making healthcare lucrative for providers, government financing made it irresistible to investors, who then began to form large corporate enterprises. Many nursing homes and hospitals had been proprietary facilities, but they were usually small and individually owned and operated. The corporate transformation of healthcare began with the purchase of these facilities, which became the building blocks for corporate healthcare chains.

Paradoxically, the U.S. government's efforts to regulate hospitals and contain healthcare costs set off a wave of acquisitions and mergers, and diversification in the nonprofit and for-profit medical care industry. In the early 1970s, for-profit

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hospitals and nursing home chains were on the rise, but still marginal players in healthcare as a whole. In about 10 years' time, however, large health-care corporations—as opposed to small, independent practitioners, hospitals and laboratories—have become a central part of the medical-industrial complex.

Five major changes in healthcare signify a movement toward integrated control:

- Change in ownership and control from nonprofit and government organizations to for-profit healthcare corporations
- Horizontal integration of free-standing institutions into multi-institutional healthcare systems, as well as the shift of control of these facilities from community boards to regional and national healthcare corporations
- Diversification and corporate restructuring that aggregated organizations operating in one market into even larger conglomerate enterprises, often organized under holding companies, and sometimes including both nonprofit and for-profit subsidiaries in a variety of healthcare markets
- Vertical integration, or the combination of different types of healthcare facilities (e.g., HMOs that include hospitals, kidney dialysis centers, and nursing homes)
- Industry concentration of ownership and control in regional markets and the nation as a whole

Managed care has affected nearly every aspect of laboratory operation, from physician office labs (POLs), to hospital labs, to reference labs. A central tenet of managed care is that fee-for-service healthcare encourages overutilization, and just as all of medicine has adopted a business orientation, so has the clinical lab.

Large managed care organizations (MCOs) and big hospital chains have learned to make money with smaller profit margins by increasing enrollment in health plans and through mergers and acquisitions that create larger organizations where fewer employees and managers do a larger volume of work. According to a 1995 *MLO* managed care survey, 35% of respondents noted changes in practice guidelines as a result of doing business with managed care companies. Panels and profiles were changed, and stricter test ordering protocols were imposed on physicians and nurses. Managed care also meant consolidation and downsizing for most labs, including layoffs of front-line bench technologists, as well as cross-training, reducing volume or discontinuing certain tests.

POLs

Managed care is credited with the demise of many POLs because many MCOs require physicians to send all their tests to large reference labs with which the MCOs have volume discounts. Physicians are then faced with two choices: either perform the test and get no reimbursement for it, or

send it out to the reference lab and delay diagnosis and treatment. Another managed care tactic has been to set fees for POL tests far below the level necessary to perform them in a POL.

A decrease in the market share of laboratory business held by POLs between 1986 and 1996 from 28% to 15% was at least partially caused by the rise in managed care in the United States; but managed care was not the only factor contributing to the ruin of so many of the physician-owned labs. CLIA '88 regula-

tions also played a role. Compliance with CLIA regulations increased the cost of running a POL by requiring lab inspections, QA/QC documentation and imposing licensing fees. Over the past five or six years, however, the complexity of office lab testing has decreased due to technological improvements in office lab equipment, and the number of CLIA-waived tests has increased. A subsequent rise in the number of CLIA licenses for POLs—from approximately 87,000 in 1997 to 92,000 by the end of 1998, according to HCFA data—indicates that the rise in the number of waived tests may have contributed to a comeback in the number of POLs.

Hospital labs

MCOs have been influential in reducing the number of days patients stay in the hospital and have discouraged consultations with specialists. The net result has been that hospital labs have done fewer lab tests on their inpatients. Many hospital labs also had to send some tests out to payer-specified reference labs, which caused an average loss of 12% of test volume, according to a 1995 *MLO* survey. To survive, the hospital lab has essentially entered the reference laboratory market by expanding its test volume to include non-patients, thereby reducing its cost per test.

Some hospital labs have formed alliances with other hospital labs in which each lab specializes in certain tests.

Other hospital labs have formed alliances with reference labs whereby the hospital labs agree to do certain tests for the reference lab, provided the hospital lab is willing to accept the payments negotiated by the MCO and the reference labs.

Still other hospital labs have evolved into their own type of reference lab, often called a core lab, in which several hospitals pool their resources to fund one large, shared laboratory. This core lab performs all non-stat testing for the participating hospitals and may have a relationship with another reference lab to do non-stat esoteric tests for which the core lab does not have the volume to justify doing itself.

Reference labs

MCOs found the reference lab very attractive because it was able to provide large volumes of tests inexpensively. MCOs have successfully negotiated capitated contracts with reference labs that were willing to predict test volumes for certain

populations and accept payment accordingly. Reference labs have also expanded their areas of expertise over the last two decades to include data collection and analysis that shows, for example, the number of tests ordered per physician or the number of abnormal results per physician. That information is then used by the MCO to identify and communicate with physicians who may be overutilizing certain lab tests. Reference labs also have branched out into new areas, such as cytology, histology and pathology, and have also served as advisors for POLs and hospital labs.

All has not been rosy for reference labs in a managed care-driven market, however. A destructive trend in reference lab testing began to emerge in the late 1980s in which contracts for certain tests done for MCOs stipulated prices that were below the cost per test. This was especially true of the Pap test—reference labs would perform Pap smears below cost for an MCO's network of physicians in the hopes that these same physicians would begin ordering *all* their tests from the reference lab. As more and more MCOs negotiated reference lab contracts for their health plan's diagnostic needs, physicians became accustomed to sending specimens out to whatever lab the patient's carrier specified, and the "pull-through" business vanished. Finally, in 1999, there are reports of labs walking away from unprofitable contracts, and reimbursement for Pap tests is beginning to come closer to what it actually costs.

Where do we go from here?

The commercialization of laboratory medicine over the past three decades has been characterized in three phases. During the academic phase (1950–1970), laboratory science became accepted as its own discipline within medicine and medical education; a second phase (1970–1985) was marked by the establishment of professional groups, such as the Clinical Laboratory Management Association, as well as management-oriented sections of already established organizations, including the CAP, the American Society for Clinical Pathologists, and the American Association of Clinical Chemists. During the third "business" phase (1985–present), laboratory medicine is still an academic discipline, but it appears to be inseparably linked to financial concerns, at least as long as managing costs of healthcare remain national concerns for nearly every country on earth.

At the dawn of the 20th century, it was almost exclusively the hospital that delivered a relatively meager menu of anatomic and clinical pathology services. Technological advances in the 1950s paved the way for advances in automation, instrumentation, quality assurance, and quality control. Those advances led to ever more efficient analytical processes and great strides in the accuracy and precision of results. When computers and data processing came onto the laboratory scene in the 1960s, the lab became a repository of information and knowledge about disease. New concepts emerged—of sensitivity and specificity, predictive values of laboratory studies, and variations in test results caused by analytical, biologic and pharmacologic factors. The capital inten-

sive developments of the 1950s and 1960s led to a trend toward large-volume testing in remote reference labs. The 1970s and 1980s brought more sophisticated computer systems to the lab that supported bar coding, which provided instant patient and specimen identification and tracking.

Only a few years ago, laboratory visionaries predicted that developments in molecular biology had the potential to change laboratory medicine in the same way that computed tomography and magnetic resonance imaging altered the practice of radiology. Speculation that routine hospital admissions testing done in the 21st century could include a panel of DNA probes in place of a chemistry profile or complete blood cell count now look more plausible than ever.

Since its inception in the mid-19th century, the laboratory has provided physicians with valuable information that support the accurate diagnosis and treatment of patients. It is the lab that gives all of modern medicine the authority that can only come from objective, scientific measurement and observation. Continued pressures from MCOs and government to keep test costs low are likely to spur further development of faster, more accurate, more precise tests that allow every earlier diagnosis and therapeutic intervention.

On the verge of the 21st century, the lab is providing more information about the human condition faster and more accurately than ever. It is strategically positioned for success in the healthcare industry—in the business of supplying critical information in the information age. □

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