

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

Part 3—Medicare, government regulation and competency certification

By Darlene Berger, former MLO editor (1998-2000)

Part 3 in this four-part series was originally published in October 1999.

Timeline

- 1966** Medicare/Medicaid officially goes into effect.
- 1967** G.I. Abelev shows that alpha-fetoprotein is elevated in serum of patients with testicular teratocarcinoma; MetPath Laboratories is founded; U.S. enacts the Clinical Laboratory Improvement Act (CLIA '67).
- 1968** The first random-access analyzer is introduced by DuPont (the ACA); the 1% Medicare allowance for unidentified costs is reduced to zero; Canada enacts the Federal Medical Care Act, creating a single-payer national health program.
- 1969** High-performance liquid chromatography becomes widely applied in analytical chemistry; because of changes in reimbursement policy, hospital-based pathologists begin founding independent regional laboratories; Roche Biomedical Laboratories Inc. is founded; *Medical Laboratory Observer* is launched in July as a bimonthly magazine.
- 1970** Monarch Marking and Plessey Telecom introduce the bar code; U.S. Occupational Safety and Health Administration is founded.
- 1971** Savory develops the serum albumin assay on the Technicon



At first, Medicare was “found money” for healthcare providers in the U.S.; but the program’s vulnerability soon became apparent, spawning a decades-long government effort to regulate providers who participated in the program.

Much of the history of the clinical lab during the last 30 years can be described as a reaction to the development of Medicare and Medicaid, as well as to the regulatory bodies that were established to oversee the administration of these programs. As medicine became more sophisticated, more and more healthcare services were developed over the years. Predictably, demand for services rose as well, and with it came the American democratic view that physician services should be available to all. Medicare and Medicaid were a boon to healthcare providers. As the programs’ costs increased, loopholes for excessive reimbursement were closed, but resourceful providers continued to find new ones. What followed was a decades-long period of government regulation to control costs and ensure quality of healthcare services that continues today.

The Medicare/Medicaid bonanza
Legislators made several attempts at

establishing a national health insurance plan in the United States as early as 1914, but the political interests of trade unions, employers, and physicians defeated such legislation in the first half of the century. Like the many proposals for national health insurance that preceded them, Medicare and Medicaid were actually responses to public concern for greater access to medical services.

When the Medicare bill was first proposed, the American Medical Association (AMA) opposed a government insurance plan, calling it a threat to the doctor-patient relationship. Strategists for the bill proposed excluding physicians’ services, as well as coverage for all groups except the aged. The AMA then introduced its own “Eldercare” bill, which included physicians’ services and claimed to provide broader benefits. Polls also indicated that the majority of those questioned thought Medicare should cover doctors’ bills, as well. The programs that are now Medicare and Medicaid are the result of strategists putting back the provi-

sion for physicians' bills. Part A Medicare benefits cover hospital, nursing home, and other institutional healthcare expenses and are paid for by Social Security; part B consists of government-subsidized voluntary insurance to cover physicians' bills and other non-physician services, including laboratory tests; and Medicaid provides expanded assistance to the states for medical care for the poor. President Johnson signed the programs into law July 30, 1965. Some doctors protested, but they eventually figured out that Medicare was a bonanza.

Part of the reason Medicare gained the acceptance of doctors and hospitals was the establishment of a buffer zone between the providers and the federal bureaucracy. Under Part A of Medicare, the law allowed groups of hospitals, nursing homes and other facilities the option of nominating *fiscal intermediaries* instead of dealing directly with the Social Security Administration. These intermediaries provide reimbursements, consulting and auditing services. As expected, the majority of hospitals and other institutions nominated Blue Cross. Under Part B, the secretary of the Department of Health, Education and Welfare (HEW) was to choose private insurance agents called *carriers* to serve the same function in a geographical area. The majority of these carriers were Blue Shield plans. This meant that the administration of Medicare was conducted by private insurance systems originally established to suit provider interests, and the government handed over direct control of the program and its costs.

Finally, Medicare made its way into law because it paid hospitals according to their costs rather than a schedule of negotiated rates. The rules for calculating these costs were quite favorable to hospitals and included costs for depreciation on assets. This allowed the hospitals with the newest, most expensive facilities to garner the most capital through reimbursement. Some observers have said that Medicare offi-

cials understood these drawbacks but accepted them because they feared a hospital boycott. By the 1970s, huge increases in costs caused a reversal in prevailing assumptions about the need to expand medical care. The need became one of curbing medicine's apparently insatiable appetite for resources.

In its first year, Medicare cost \$4.7 billion for 19 million people and represented less than 3% of the federal budget. By 1985 Medicare costs had risen an average of 17% per year—much faster than the average yearly increase in national healthcare costs.

The need for regulation

Soon after Medicare and Medicaid went into effect, the U.S. government became aware of the programs' vulnerability to fraud and abuse. It behooved the government to see that money was not being siphoned off through overcharging for services and that the quality of services financed with tax dollars was up to snuff.

The United States had established minimum quality requirements for clinical laboratories engaged in interstate commerce to participate in Medicare; but these requirements—collectively known as the Clinical Laboratory Improvement Act of 1967 (CLIA '67)—covered only those labs doing business across state lines—only a fraction of all U.S. clinical labs. The need to regulate all labs performing tests on human specimens became apparent to lawmakers; and throughout the 1970s, amendments to CLIA '67 were proposed to stiffen personnel requirements, as well as mandate inspections to certify that lab facilities met some minimum standards for accuracy and quality control.

CLIA took longer to revise, but by 1972, 100 new amendments to the Social Security Act were made, which included changes to Medicare law. These new Amendments established professional standards review organizations (PRSOs). These were groups assembled by HEW that reviewed

Auto-Analyzer; alpha fetoprotein (AFP) assay is commercialized by Abbott Laboratories Inc.; American Association of Clinical Laboratory Supervisors and Administrators, precursor to the Clinical Laboratory Management Association, is founded; Nichols Institute Inc., is founded.

- 1972 American Association of Pathology Assistants is founded.
- 1973 J. Westgard introduces Westgard control rules into clinical laboratory quality control; U.S. Centers for Disease Control is founded; National Accrediting Agency for the Clinical Laboratory Sciences is formed.
- 1975 The laser cell sorter is developed; Roche Diagnostics first commercializes the carcinoembryonic antigen assay; Association of Cytogenetic Technologists is founded; a "malpractice crisis" exists in the U.S. as physicians are sued in record numbers.
- 1976 The first automated radioimmunoassay is introduced by Micromedic Corp.; at least one gene is assigned to each of the 24 human chromosomes by this date.
- 1977 The Health Care Financing Administration is founded; the U.S. enacts the Medicare-Medicaid Fraud and Abuse Amendments; discounts for lab work are not prohibited if properly disclosed.
- 1978 Final rules implementing the 1972 Medicare Amendments are enacted; FBI's operation Labscam identifies doctors, hospitals, and clinics soliciting kickbacks as a precondition to doing business with labs.
- 1979 M.C. Yank introduces prostate specific antigen (PSA) as a serum tumor marker; R. Naito develops an artificial blood substitute; F. Mikkerson, F. Evereaerts, and T. Verheggen develop capillary zone electrophoresis (CZE); the Clinical Laboratory Management Association is founded.
- 1980 D. Colcher introduces the CA-72 serum tumor marker, primarily for colorectal cancer.
- 1981 H. Koprowski introduces CA-19-9 as a serum tumor marker primarily for pancreatic cancer; R.C. Bast introduces CA-125 as a serum tumor marker primarily for ovarian cancer.
- 1982 Corning Inc. acquires MetPath Inc.

- 1983** HCFA implements its Prospective Payment System using diagnosis-related groups (DRGs) as a basis for hospital reimbursement; Hybritech Inc. commercializes the PSA assay; Centocor Inc. commercializes CA-19-9 assay; Cambridge Life Sciences Inc. introduces biosensors; L. Lindholm introduces CA-50 as a serum tumor marker primarily for colorectal cancer; the American Association of Preferred Provider Organizations is founded; the U.S. enacts the Social Security Amendments of 1983.
- 1984** CA-50 assay is commercialized by Stena Diagnostics of Sweden; Genentech Inc. produces genetically engineered clotting factor VIII; DNA fingerprinting is developed; the U.S. enacts the Deficit Reduction Act of 1984.
- 1985** R. Tobias introduces CA-15-3 as a serum tumor marker primarily for breast cancer; R. K. Mullis et al. invent the technique of polymerase chain reaction, the first gene amplification technology; CA-125 is commercialized by Centocor Inc.; Beecham Pharmaceuticals, PLC, acquires SmithKline Laboratories to form SmithKline Beecham Clinical Laboratories, PLC; SmithKline Clinical Laboratories Inc. acquires American Biosciences Laboratories; the U.S. enacts the Balanced Budget and Emergency Deficit Control Act (Gramm-Rudman-Hollings bill).
- 1986** CA-72 is commercialized by Centocor Inc.; expands its accreditation activities beyond acute care hospitals and changes its name to the Joint Commission for the Accreditation of Healthcare Organizations.
- 1987** K.R. Bray introduces CA-549 as a serum tumor marker primarily for breast cancer; S. Fukuta introduces CA-195 as a serum tumor marker primarily for colorectal cancer; by this date at least 1,215 expressed genes are assigned to specific chromosomes.
- 1988** Hybritech commercializes CA-195; the U.S. enacts the Clinical Laboratory Improvement Amendments of 1988.
- 1989** Beckman Instruments and Applied Biosciences Inc.

medical necessity, appropriateness and quality of services paid for with Medicare and Medicaid funds. When final rules for implementing the Amendments were enacted in 1978, they included a list of 12 lab tests to be reimbursed at the lowest price at which similar tests were available in a geographic region. The price to be paid for the 12 tests, which represented 50–60% of all reimbursable lab services, was set at the 25th percentile for a given region. In other words, at least one in four labs would have to be charging at this definition of the “lowest price” or below it. Quality control, proficiency testing, as well as personnel competency rules, were also implemented. Medical technologists were required to have a bachelor’s degree or the equivalent, and if not, they would have to take a proficiency examination administered by HEW to qualify as “certified” to work in a lab that received Medicare reimbursement. The HEW exam was the closest the United States has come to uniform, national testing personnel standards. Even CLIA '88, which actually lowered education requirements for personnel performing high complexity tests, leaves considerable room for interpretation of standards for testing personnel.

The requirements for taking the HEW exam were a high-school diploma and four years of laboratory experience. At that time, HEW accepted no private certification in lieu of passing the HEW exam. The test included four sections on hematology, blood banking, clinical chemistry and microbiology, and the scores were not encouraging. The examination was given seven times between 1975 and 1987 to more than 65,000 individuals. This group represented 35–40% of all MTs (with and without the bachelor’s degree). Of that group, approximately 31,000—less than half—passed the test.

The beef over personnel competency

Personnel competency standards for lab professionals have been and contin-

ue to be controversial. Issues of control by pathologists, or by independent clinical laboratory scientists, as well as issues of race and socioeconomic status, have figured prominently in disputes over standards for laboratory personnel.

Groups that advocated for advancing the professional status of clinical laboratory scientists were in favor of a nationally administered test because it would validate their view that clinical laboratory science should be a profession independent of physician control; others were threatened by the possibility of being legislated out of a job. Labs that received Medicare funds were required to certify competency of all testing personnel to be eligible to participate in the program, so, technologists had an incentive to meet HEW’s requirements to make themselves attractive to current and potential employers.

One court case highlights a long-standing contention by some certifying organizations that education cannot be the only criterion for assessing competency and granting certification. In 1975, a U.S. District Court heard arguments that requirements that only college graduates could take civil service examinations for medical technologist certification were unfair. Margaret Townsend, a Nassau County, NY, blood bank medical technologist, decided to sue the county’s Civil Service Commission after being denied a chance to take the exam in 1973. Townsend, who had trained several younger MTs with bachelor’s degrees, successfully proved that the Commission’s requirements for medical technologists had a racially disproportionate impact and that college graduation did not have a meaningful relationship to the job in question. Moreover, acceptable college programs to train individuals for laboratory work did not yet exist. The case ultimately proved that the law would have to be changed to accommodate laboratorians like Townsend, who lacked the college degree but had needed experience.

commercialize the first CZE apparatuses; Allied Clinical Laboratories Inc. is founded.

- 1991** By special act of Congress, the Veterans Administration is exempted from the provisions of CLIA '88.
- 1992** Final regulations implementing CLIA '88 take effect; National Health Laboratories Inc. agrees to refund \$110.4 million to the Civilian Health and Medical Program of the Veterans Administration (CHAMPUS), Medicare, and Medicaid as a settlement to the largest medical fraud case in U.S. history; the Stark physician self-referral ban goes into effect.
- 1993** E. Koh, R. Ito, and M. Bissell introduce the first commercial method using CZE—urine vitamin C.
- 1994** Regionalization of different types of lab services into cooperative networks of labs emerges as a trend in changing laboratory structure.
- 1995** National Labor Relations Board rules that medical technologists are professional employees; NHL merges with Roche Biomedical, creating LabCorp.
- 1996** HCFA introduces the Alternate Quality Assessment Survey that allows certain labs to fill out a form for certification; a trend emerges in the sale of hospital labs to large commercial labs.
- 1997** Consolidated laboratory networks emerge as a trend in cost-cutting in the U.S.; FBI accuses Columbia/HCA of engaging in a “systemic corporate scheme” to defraud Medicare; JCAHO recognizes COLA accreditation; HHS publishes its model compliance plan.
- 1998** FDA approves Dako’s immunohistochemical assay, Herceptest, for detection of HER2 protein, the target of trastuzumab (Herceptin), a genetically engineered treatment for metastatic breast cancer.
- 1999** Continued deciphering of the human genetic code promises to dramatically expand the menu of diagnostic and prognostic tests; Quest Diagnostics acquires Smithkline Beecham Clinical Labs.

Portions of this time line are reprinted with permission from CLMA.

Private quality initiatives

Around the same time CLIA '67 was enacted, a group of clinicians and laboratory scientists, calling themselves the National Committee for Clinical Laboratory Standards (NCCLS), was meeting to discuss ways of improving patient services. The group sought to develop a consensus process for standardizing laboratory test methods. The Committee’s first manual of operating procedures detailed a proposed mechanism for developing and reaching a consensus on standards. The consensus structure comprised committees for various lab disciplines and subcommittees in subdivisions of disciplines. The consensus process consisted of a system of development, evaluation, and scrutiny at multiple levels, as well as provisions to give consideration to dissenting opinions at all stages of review of proposed guidelines. The American National Standards Institute accredited NCCLS in 1977, and NCCLS subsequently became the home of the National Reference System for the Clinical Laboratory, a collection of broadly understood reference systems intended to improve comparability of test results. NCCLS standards are voluntary, but they are widely recognized as best laboratory practices.

No teeth in self-regulation

Self-regulation had been the method of choice for labs that wanted to prove their reliability by following NCCLS standards or by voluntarily submitting to private-sector quality assurance programs, such as the College of American Pathologist’s accreditation program; but legislators criticized the voluntary system as having no repercussions for labs grinding out low-quality or unreliable work.

CLIA '88

After years of attempts to update CLIA '67 to include all labs in the U.S., one bill finally made the quantum leap to legislation when President Ronald Reagan signed the Clinical Laboratory Improvement Amend-

ments of 1988 (CLIA '88) into law. The new regulations were to take effect January 1, 1991, but practical problems revealed by the lab industry in meeting the new regulations delayed their implementation until 1992. Under the Amendments, all labs are required to have a certificate issued by the Department of Health and Human Services (HHS). HHS certifies only those labs that have adequate quality assurance and quality control programs in place and that successfully pass proficiency tests. The Amendments also classified all tests into three levels: waived (tests of low complexity that required no oversight), moderate complexity and high complexity. Requirements for testing personnel for each level are also outlined. The physician lobby intercepted early attempts to pass revisions to CLIA '67 because of their stake in physician office labs (POLs). To get the law passed, it was revised to include less stringent requirements for POLs performing low-complexity tests. Such tests qualified for waiver of CLIA '88 requirements.

CLIA '88 expanded CLIA '67 from a few thousand interstate labs to virtually every clinical laboratory in the country, including POLs, and has had a profound effect on nearly every aspect of laboratory operation in the United States. □

Editor’s note:

In part 4 of the lab history series, we examine the government’s efforts to eradicate fraud and abuse, the advent of managed care, and the development of the consolidated, core lab.

References

1. CLMA. Ensuring universal access to quality laboratory services: CLMA White Paper. *Clinical Laboratory Management Review*. 1994;8(3):198–240.
2. Starr P. *The Social Transformation of American Medicine*. New York: Basic Books Inc.; 1982.
3. MLO. Margaret Townsend v. the system. *Medical Laboratory Observer*. Washington report. 1976;8(3):21–22.
4. MLO. HEW’s proficiency exams are just around the corner. *Medical Laboratory Observer*. Washington report. 1976; (6):23–24.
5. MLO. New Medicare regs zero in on labs. *Medical Laboratory Observer*. Washington report. 1978;10(7): 19–20.