The Clinical Laboratory Fee Schedule Yesterday, Today, Tomorrow

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ABBREVIATIONS: ASCLS = American Society for Clinical Laboratory Science; BBA = Balanced Budget Act; CLFS = clinical laboratory fee schedule; CMS = Centers for Medicare & Medicaid Services; CPI = consumer price index; CPT = current procedural terminology; FY = fiscal year; HCFA = Health Care Financing Administration; HHS = Department of Health & Human Services; HR = House of Representatives; IOM = Institute of Medicine; MSA = metropolitan statistical area; MMA = Medicare Prescription Drug, Improvement, and Modernization Act; NLA = national limitation amount; PL = public law

INDEX TERMS: Medicare payment for laboratory services; clinical laboratory fee schedule; Medicare laboratory fee schedule; Medicare clinical laboratory services; Medicare part B outpatient clinical laboratory reimbursement levels.

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LEARNING OBJECTIVES:

1. Describe at least three changes in Medicare payment methodology for laboratory services following the implementation of the clinical laboratory fee schedule (CLFS) in 1984.
2. List the key provisions of the Balanced Budget Act of 1997 affecting payment for Medicare laboratory services.
3. Compare the initial mechanism for annual inflation adjustments to the CLFS with the actual updates between 1991 and 2007.
4. Discuss two reasons for the actual decreases in reimbursement for laboratories since the CLFS was implemented.
5. Explain the difference between the "cross-walking" and "gap-filling" processes used to set CLFS payment amounts for new tests.
6. List five recommendations in the IOM Report "Medicare Laboratory Payment Policy: Now and in the Future".
7. Describe the key elements of the design for the Competitive Bidding for Medicare Clinical Laboratory Services demonstration project.
8. List the specific purposes for an alternative payment system outlined in the Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008.

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Introduction

For well over two decades, the laboratory community has been confronted with a myriad of legislative and regulatory changes in payment policies and reimbursement levels for services provided to Medicare beneficiaries for outpatient clinical laboratory services. When Medicare was first implemented, clinical laboratories were reimbursed according to usual, customary and reasonable charges and beneficiaries were responsible for a copayment. Following the enactment of the Deficit Reduction Act in 1984[1], payment to laboratories providing Part B services to Medicare changed to a national clinical laboratory fee schedule (CLFS) system. Although the fee schedule established in 1984 bears little resemblance to the actual cost of laboratory testing in 2009, it remains the mechanism by which laboratories are reimbursed. An Institute of Medicine study in 2000 made several recommendations for reimbursement that have yet to be implemented. This article will review the many problems and challenges to the CLFS that have occurred since its inception in 1984.

The Beginning

Initially under Medicare, clinical laboratories were paid for outpatient Part B services based on customary and reasonable charges. Each state had fiscal intermediaries (which reimbursed hospital laboratories) and carriers (which reimbursed independent and physician office laboratories) and each had different ranges of customary and reasonable charges. Clinical laboratories found collecting the then-required beneficiary co-payments of 20% to be exceedingly difficult, as most did not have a billing relationship with patients. In addition, the costs of billing and collecting such small amounts were financially and administratively burdensome. Thus, the laboratory industry supported the fee schedule system implemented in 1984 that eliminated the co-payment requirement. Though the reimbursement levels under the CLFS were reduced somewhat, laboratories anticipated a decrease in the amount of bad debt compared with that incurred when attempting to collect co-payments. The fee schedule was based on 60–62 % of prevailing charges at the time[1,2]. The National Limitation Amount (NLA)[2,3], established by Congress in 1986, was to serve as a ceiling on payment for each laboratory test. NLAs are based on the median of all local carrier fees for each test and were originally set at 115% of the median charges. The actual payment to a laboratory is the lowest of the provider's charge, the contractor's fee schedule amount, or the NLA[2,4]; most laboratories are paid at or near the NLA. The fee schedule was to be maintained with an annual update, based on the Consumer Price Index (CPI) increase.

Table 1. Summary of major legislation affecting payment for medicare laboratory services

Omnibus Deficit Reduction Act of 1984
Eliminated reasonable charge as a basis for payment
Set fee schedule payments at 60–62% of prevailing charges
Required annual adjustment for fee schedules according to the CPI

Consolidated Omnibus Budget Reconciliation Act of 1985
Established payment caps (NLAs) at 115% of the median of all local fee schedules

Balanced Budget Act of 1997
Reduced payment caps for Medicare Part B laboratory services to the lowest of the actual charge, 74% of the NLA, or 100% for new test without NLA
Required use of negotiated rulemaking to establish national coverage and administrative policies for Part B laboratory services
Required DHHS to fund an IOM study on Medicare Part B payments for laboratory services
Eliminated payment rate increases from 1998 through 2003

Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003
Required competitive bidding demonstration projects for clinical laboratory services
Eliminated clinical laboratory fee schedule payment updates for 5 years (2004-2008)

Throughout the history of the CLFS there have been ongoing changes and both legislative and regulatory proposals made to lower the cost to the Medicare program (discussed later in this article). Key provisions of major legislation affecting payment for Medicare laboratory services will be highlighted and are summarized in Table 1.

Fee Schedule Cuts

Laboratories did not anticipate the expansion of Medicare expenditures and the many legislative and regulatory proposals to decrease the CLFS. Beginning in 1985, legislation mandated across-the-board budget costs including a 1% reduction in Medicare payments. The Omnibus Budget Reconciliation Act of 1987 reduced the CLFS limits to 100% of the national median (previously set at 115%), reduced payment for certain automated, high volume tests by over 8% and deleted the CPI update for 1988. In the budget bills for FY 1989 and FY 1990, the Congress further reduced the fee caps from 100% to 93% and 88%, respectively, of the national median. The Balanced Budget Act of 1997 mandated $2 billion in laboratory cuts over five years, capped the CLFS at 74% of the national median with no CPA updates for five years and authorized a study of laboratory reimbursement methodologies in the Institute of Medicine study[5]. During this period, the laboratory experienced actual decreases in reimbursement from 115% of median charges to 74% while other health care providers usually experienced only a decrease in the amount of reimbursement increases.

As overall Medicare expense continued to increase, the administration's FY2001 budget proposal presented a variety of options to reduce Medicare clinical laboratory service payments even further. With an estimated cost savings of

$3.24 billion over five years, the target areas for the laboratory cuts included:

- Reinstatement of 20% coinsurance,
- Reduction of the fee schedule CPI increase by 1% for fiscal years 2003–2005,
- Reduction in laboratory payments by 30% for four common, high volume laboratory tests: hemoglobin A1c, thyroid stimulating hormone, prostate-specific antigen, and urine culture.

In addition to actions taken by the Congress, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)—changed the reimbursement of tests termed "automated" so reimbursement was determined by the total number of automated tests on the bill, regardless of whether tests were billed by individual CPT codes or by new panel CPT codes, further decreasing reimbursement. That year also marked the initiation of a negotiated rulemaking process to design national uniform policies for coverage and payment of clinical laboratory services under Medicare Part B.

Fee Schedule Updates

The initial CLFS in 1984 included a mechanism for annual inflation adjustments based on the CPI. After a few years, the updates were reduced to a rate less than the CPI or eliminated altogether. For example, following an update in 1997, CLFS rates were frozen from 1998 to 2002 followed by a modest 1.1% inflation update in 2003. In 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) cancelled a scheduled 2.6% update and enacted another five-year freeze for 2004 through 2008 as an alternative to a 20% co-payment requirement for Medicare beneficiaries[6]. When the MMA freeze ends, laboratories are scheduled to receive a 4.5% update beginning January 2009.

The cumulative CLFS updates during the period 1991–2007 totaled 12.3%, while the actual CPI increases during those years totaled 46.5%. A comparison of the CPI updates with the CLFS updates, by year, is presented in Table 2.

Specimen Collection Fee

Reimbursement for specimen collection by venipuncture was set at $3.00 in 1984 and has never changed. The $3.00 fee may never have completely covered the cost of a venipuncture, but that amount is clearly inadequate today given the rising costs of gloves, safety devices, and personnel. The Medicare Laboratory Services Act of 2001 (HR 3388) would have raised the specimen collection fee to $5.25, the level it would have reached had CPI adjustments been applied during the ensuing 17 years[7]. Despite strong support of this bill, and subsequent versions, by ASCLS and the other Clinical Laboratory Coalition organizations, reimbursement remains at $3.00.

Pricing of New Tests and Technology

Each year, new laboratory test codes are added to the CLFS and corresponding fees are developed. For newly developed tests considered to be similar to existing tests, CMS assigns a CLFS payment rated based on reimbursement of the existing tests, a process referred to as "cross-walking"[8]. If a newly developed test is considered truly novel or breakthrough technology for which there is no existing similar test, CMS asks contractors to independently set rates for the first year, using data from manufacturers, other contractors, or other information—a process known as "gap-filling"[8]. CMS subsequently sets the NLA for new technologies at 74% of the median rate of all carriers.

These processes of "cross-walking" and "gap-filling" remain archaic and inappropriate for establishing payment levels for new laboratory tests[9]. The inadequate reimbursement for the rapidly growing molecular diagnostic and genetic tests points out the flaws of these payment processes and the need for change.

Table 2. Medicare Clinical Laboratory Fee Schedule Updates, Compared with the CPI 1991–2007

	1991	92-93	94	95	96	97	98-2002	03	04-08	Cumulative	Average
CPI Increase %	4.2	3.0	2.6	2.8	3.0	2.7	1.5-3.7	2.1	2.5-3.2	46.5	2.74
CLFS Updates %	2.0	2.0	0.0	0.0	2.9	2.3	0.0	1.1	0.0	12.3	0.72

The Medicare Clinical Laboratory Fee Schedule Improvement Act of 2006 (HR 5369) was introduced in May 2006 to primarily address issues with the pricing of molecular diagnostic and other newer testing[10]. The legislation called for correction of erroneous determinations and other changes in the fee schedule, issuance of regulations on gap-filling methodology, increased transparency of the process for determining CLFS amounts for new tests, and mandatory advance notice of test amounts being considered for adjustment under inherent reasonableness authority. The bill also directed the HHS Secretary to establish a demonstration project to evaluate new approaches to coding and payment under the Medicare program specifically for new or existing molecular diagnostic tests. Neither HR 5369, nor its successor introduced during the 110th Congress, has been acted upon.

Laboratory Co-Payments

In 1984 Congress eliminated Medicare beneficiary co-payments for laboratory services[1]. With a co-payment system, a laboratory would bill Medicare for 80% of the fee schedule amount and bill the beneficiary for the remaining 20%. However, several federal budget proposals have called for re-imposing the beneficiary co-payment as one means to control the utilization of services and reduce the costs to the program. Co-payment is not likely to affect utilization of laboratory tests because physicians, not patients, initiate tests. Not only would the imposition of co-payments shift the costs of the Medicare program to the beneficiaries, the cost to the laboratory for billing and collecting the co-payment could often exceed the amount billed.

Table 3 illustrates the approximate co-payment amount for a few commonly ordered tests, based on the 2008 Fee Schedule NLA for each[11]. In all cases, the costs associated with billing are likely to exceed the co-payment amount.

Institute of Medicine Study

In response to ongoing and strong opposition from the laboratory community to proposals to lower Medicare costs for laboratory services, the U. S. Congress mandated, in the 1997 Balanced Budget Act (BBA), that a study be conducted to assess alternative Medicare payment methodologies for laboratory services. The Institute of Medicine (IOM) conducted the study during 1999–2000.

The IOM issued a comprehensive report "Medicare Laboratory Payment Policy Now and in the Future" in November 2000 that included among its 12 recommendations the following[12]:

1) Medicare payments for outpatient clinical laboratory services should be based on a single, rational, national fee schedule.
2) On an interim basis, relative payments for Medicare outpatient clinical laboratory services should be based on the current National Limitation Amounts.
5) Processes should be put in place to refine and periodically update the fee schedule for Medicare outpatient clinical laboratory services.
6) To incorporate new tests into the Medicare laboratory fee schedule, there should be an open, timely, and accessible process that is subject to challenge.
8) The current policy of not requiring beneficiary cost sharing for Medicare outpatient clinical laboratory services should continue.
10) In its policy formulation processes, HCFA should provide opportunities for stakeholder input and develop better communication with contractors and other stakeholders when policies are being developed and once they are adopted.

In its conclusions, the IOM report suggests opportunities to fix the Medicare payment system for clinical laboratory services to avert the possibility of a crisis in the future. Payments for some tests likely do not reflect the cost of providing services, and anticipated advances in laboratory technology will worsen the flaws in the current system. Problems with the outdated payment system could threaten beneficiary access to care and the use of enhanced testing methodologies in the future.

Competitive Bidding for Medicare Clinical Laboratory Services

In order to decrease reimbursement, the Medicare program has attempted to implement competitive bidding

Table 3. Co-Payment amounts for commonly ordered tests

Test (CPT Code)	NLA (2008)	Co-payment (20%)
CBC w/ Auto Diff (85025)	10.86	2.17
TSH (84443)	23.47	4.69
Comprehensive Metabolic Panel (80053)	14.77	2.95
Glycosylated Hemoglobin (83036)	13.56	2.71
Prothrombin Time (85610)	5.49	1.10
Basic Metabolic Panel (80048)	11.83	2.37
Urine Culture (87086)	11.28	2.26

demonstrations for payment of Part B clinical laboratory services. Competitive bidding is a cost containment mechanism whereby clinical laboratories would submit price bids to Medicare. Based on predetermined criteria and the proposed bids, Medicare would select a winner or group of winners that will provide the services at a set price for a set period of time. The goal is to secure prices that reflect the cost of efficient production. An assumption is that competitors will reveal the minimum price at which a sale is acceptable. Perhaps not unexpected, the approach of competitive bidding consistently provoked significant controversy among laboratory stakeholders.

Since 1986, CMS has proposed a demonstration to competitively bid laboratory services several times. Congress directed CMS to implement a demonstration project as part of the 1997 Balanced Budget Act and reiterated its intent for CMS to conduct the project in the MMA of 2004. The magnitude and complexity of clinical laboratory services delivery contributed greatly to delays in preparing for the MMA-mandated demonstrations to begin. Initial design called for demonstrations in two metropolitan statistical areas (MSAs) meeting criteria related to the size of the population and the number of Medicare beneficiaries[13,14]. Projected to last for three years, the project was to include all laboratories in the selected MSA that bill more than $100,000 in non-patient laboratory tests annually to Medicare. Not only would laboratories be required to bid or lose the opportunity to do laboratory work for Medicare beneficiaries, the bidders would also be required to bid on all tests on the demonstration list, even if they do not perform the tests in-house. In the design, winning bidders will be paid for any Medicare test while losing bidders will be paid for no Medicare testing included in the demonstration.

Over the years, the American Society for Clinical Laboratory Science (ASCLS) and other organizations of the Clinical Laboratory Coalition, as well as manufacturers and others in the industry, have staunchly opposed competitive bidding for many reasons that include:

- It is anti-competitive. Incentives exist for laboratories to bid less than cost to win, in order to maintain the market share when the demonstration ends and losing laboratories may no longer exist.
- It will impact patient care. Fewer laboratories will provide services and beneficiaries may not have convenient access.
- Instead of simplifying the reimbursement mechanism, a nationwide program with each MSA setting its own fee schedule would be administratively complex and ineffective.

CMS announced that the first site would be the San Diego-Carlsbad-San Marco MSA in California with bids due in April 2008. Opposition continued with hearings by the Small Business Committee of the U.S. House of Representatives. As a result, legislation was introduced in both the House and Senate calling for the repeal of the Medicare laboratory competitive bidding demonstration project. The "Medicare Improvements for Patients and Providers Act of 2008" (HR 6331, introduced June 28, 2008) also included a provision to repeal authority for the demonstration[15]. President Bush vetoed the legislation on July 15, but both the House and Senate voted overwhelmingly to override the veto that same day. With the veto override, HR 6331 became law (PL 110-275) and the competitive bidding demonstration project was permanently repealed.

The Time for Change Is Overdue—Modernizing the Fee Schedule

Since the implementation of the CLFS over 24 years ago, laboratories have experienced real reductions in their Medicare part B reimbursement levels, not just reductions in the rate of increase. Further, the cost of doing business with Medicare has increased with requirements for medical necessity and other documentation. The use of *advanced beneficiary notices* for non-covered services has made it more difficult to obtain payment for services already provided. It is estimated that, today, clinical laboratories are paid at only 75 percent of the 1984 fee schedule level when adjusted for inflation. The current fee schedule does not reflect changes in cost, technology, and the complexity and delivery of clinical laboratory services. A growing consensus among laboratory providers is that many procedures will be under-reimbursed while others may be overpaid unless the reimbursement system is based on the actual costs of providing the services.

Since the IOM report was issued in late 2000, representatives of the clinical laboratory community, under the umbrella of the Clinical Laboratory Coalition, have worked together to persuade Congress and CMS to implement the study recommendations. In 2005, the Clinical Laboratory Management Association (CLMA) and the ASCLS formed a task force to examine alternative payment methods. During its deliberations, the task force identified goals for an alternative payment system that included:

- To rationalize the clinical laboratory fee schedule so that it reflects today's market forces,
- To provide a mechanism to update fees on a regular basis,
- To ensure access to quality laboratory services, including new technology, and

- To counter worse alternatives, e.g., competitive bidding, inherent reasonableness, and co-payment cuts in reimbursement.

HR 6761, "The Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008", was introduced in July 2008 to require the Secretary of Health and Human Services to enter into negotiated rulemaking to modernize the Medicare part B fee schedule for clinical diagnostic laboratory tests[16].

The specific purposes stated in this Act include:

(1) Ensure Medicare beneficiary access to the best laboratory services and most advanced testing available,
(2) Modernize the fee schedule for clinical diagnostic laboratory tests under part B of the Medicare program to reflect the increased cost and enhanced technology involved in laboratory testing and to reflect accurately and equitably the value of such testing to the health care system,
(3) Involve relevant stakeholders in the clinical laboratory industry in the process of such fee schedule modernization, and
(4) Create mechanisms for periodic revisions and inflationary updates to the fee schedule in order to reflect market conditions.

Though no action was taken on HR 6761 during the 110th Congress, the bill is expected to be introduced again when the new Congress convenes in January 2009.

What Next?

As we approach the end of the first decade of the 21st century, health care continues to account for a growing percentage of the US economy. Undoubtedly all payers will seek to control their costs by reducing payments to health care providers. It will be incumbent on the entire laboratory community to participate in future governmental legislative and regulatory processes to ensure that the critical role of laboratory information to the health care delivery system continues to be recognized and reimbursed appropriately. Such efforts will be necessary to ensure that access, informed medical decision-making, patient and provider satisfaction, health care outcomes, cost effectiveness in service delivery and the quality of laboratory services are not compromised.

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