

INSTITUTE OF MEDICINE

Shaping the Future for Health

MEDICARE LABORATORY PAYMENT POLICY

NOW AND IN THE FUTURE

Clinical laboratory tests are a key component of modern health care. Through the examination of body fluids and tissues, laboratory tests reveal important chemical and biological information about the body. Laboratory tests represent a small share of health spending, but play a complementary and an integral role in good medical care by helping physicians to diagnose and treat patients. Technological changes in laboratory testing, both those currently in the pipeline and those anticipated in the near future, offer the prospect of new opportunities for diagnostic, monitoring, and screening improvements.

Medicare, the federal program providing health care coverage for the elderly and disabled, is the largest payer of clinical laboratory services. It covers clinical laboratory tests used to diagnose disease, monitor a patient's condition, and, in some cases, screen patients to identify abnormalities. Medicare pays 29 percent of the nation's laboratory bill for inpatient and outpatient services. The Medicare Part B fee schedule for outpatient laboratory services, the subject of this study, accounts for approximately one-third of what Medicare spent for laboratory services, or 1.6 percent of its total annual budget, in 1998. While this is a small proportion of overall Medicare spending, maintaining beneficiary access to laboratory services is essential. In addition, there is evidence that Medicare policy influences other payers' policies.

At the request of the Congress, the Department of Health and Human Services (DHHS) arranged for the Institute of Medicine (IOM) of the National Academies to establish a committee to examine the laboratory industry; assess current Medicare payment policy; evaluate payment policy alternatives; and make recommendations to improve the system.

Assessment of the Current Medicare Payment System

Medicare currently pays for outpatient clinical laboratory tests using a prospective payment system (PPS) established in 1984. Payments for 1,100 tests are set separately in fee schedules for each of 56 geographic jurisdictions, limited by national fee caps called National Limitation Amounts (NLAs). Payments are based on what laboratories charged in 1983, updated periodically for inflation. Laboratories accept Medicare fees as full payment—there is no beneficiary cost sharing.

The committee conducted an extensive examination of the Medicare payment system for outpatient laboratory services and assessed the current methodology in light of goals the committee identified as significant.

- **Beneficiary access:** The committee found no evidence that beneficiaries have difficulty obtaining outpatient clinical laboratory services. The current geographic locations, number of sites, and capacity of the laboratories generally provide ade-



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quate access for beneficiaries. The Medicare program imposes no financial barriers to outpatient clinical laboratory services for beneficiaries. Finally, the committee found no evidence that Medicare beneficiaries are being denied STAT (literally, at once) tests when medically indicated.

- **Flexibility:** The committee concluded that existing mechanisms for keeping payments up to date are inadequate. The inflation factor and the NLA level raise or lower fees across the board for all tests, but do not provide adjustments to accommodate changes needed in payment levels for specific tests. The process for integrating new technologies into the payment system, including determinations of coverage, assignment of billing codes, and development of appropriate prices, is slow, administratively inefficient, and closed to stakeholder participation. These problems are likely to become increasingly important with the anticipated changes in laboratory technology and medical practice.

- **Transparency:** The committee concluded that the current payment system lacks “openness” and adequate procedures for stakeholder involvement. Clear and consistent information on how the system works and opportunities for the public and stakeholders to have input into decision processes are limited.

- **Value:** The committee found it had little data with which to judge whether Medicare spending in the aggregate is too high or low, whether Medicare is paying reasonable amounts for individual tests and services, or whether physicians are ordering tests appropriately. The committee concluded that Medicare purchases tests that meet Medicare standards for its beneficiaries with minimal or no beneficiary access problems. Medicare payment rates appear to be within the range of private payments.

- **Administrative simplicity and efficiency:** The committee concluded that administration of the Medicare outpatient laboratory payment system, with its 56 separate fee schedules and 56 separate processes for coverage determination, is unnecessarily complex and inefficient, particularly in the way the system incorporates new technologies and determines whether or not a laboratory’s claim should be paid. Since most of the fees on the 56 separate fee schedules are close to the NLA, this complexity is unnecessary.

Recommendations

After analysis of the current payment method and alternative approaches, the committee reached consensus on 12 recommendations for improving Medicare’s payment system for outpatient clinical laboratory services. The committee’s choices were guided by its previously stated goals. The committee recommends that the Medicare program implement a single, national, rational fee schedule that reflects the resources used to produce the services; simplify and open its administrative procedures; and collect data to monitor and assess the impact of the recommended changes.

Because changes in the current Medicare payment formula could require new legislation, implementation of many of the committee’s recommendations will entail congressional action. The committee recommends that HCFA, the administration, and the Congress work together to develop the necessary enabling authority and support.

Conclusion

Congress and HCFA have the opportunity to fix the current Medicare payment system for clinical laboratory services, averting the possibility of a crisis in the future. Payments for some individual tests likely do not reflect the cost of providing services, and anticipated advances in laboratory technology will exacerbate the flaws in the current system. Problems with the outdated payment system could threaten beneficiary ac-

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Congress and HCFA have the opportunity to fix the current Medicare payment system for clinical laboratory services, averting the possibility of a crisis in the future.

Recommendation 1: Medicare payments for outpatient clinical laboratory services should be based on a single, rational, national fee schedule.

Recommendation 2: On an interim basis, relative payments for Medicare outpatient clinical laboratory services should be based on the current National Limitation Amounts (NLAs).

Recommendation 3: A data-driven consensus process for refining the new Medicare national fee schedule for outpatient clinical laboratory services should be developed. HCFA should explore alternative methods for gathering data to be used in the process.

Recommendation 4: Medicare national fees for outpatient clinical laboratory services should be adjusted for geographic location. HCFA should also evaluate the need to adjust for certain other circumstances, particularly those likely to affect beneficiary access, and make recommendations to the Congress.

Recommendation 5: Processes should be put in place to refine and periodically update the fee schedule for Medicare outpatient clinical laboratory services.

Recommendation 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. The process and fees produced should not impede clinical decision making that is essential to providing appropriate care.

Recommendation 7: HCFA should review alternatives to the current system for coding outpatient clinical laboratory services for claims processing. More accurate, open, and timely coding processes for new technologies as well as tests and services should be sought.

Recommendation 8: The current policy of not requiring beneficiary cost sharing for Medicare outpatient clinical laboratory services should continue. Cost sharing is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program depending on its design.

Recommendation 9: HCFA should discontinue use of International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes as the basis for determining the medical necessity of clinical laboratory tests. HCFA should assess the need for any approach to evaluating the medical necessity of individual laboratory tests prior to payment of a claim. In addition, HCFA should evaluate alternative approaches for identifying and reducing unnecessary or inappropriate laboratory testing.

Recommendation 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.

Recommendation 11: HCFA should move promptly to consolidate the number of contractors processing all Medicare outpatient clinical laboratory claims, including claims from physician office laboratories (POLs) and hospital-based laboratories. The design of this consolidation should ensure that claims processing by regional laboratory carriers will not require major new billing procedures for POLs or hospital-based laboratories. Efforts should be made to strengthen local provider services and relations between carriers and laboratories.

Recommendation 12: HCFA should collect the data needed to effectively manage the performance of the Medicare outpatient clinical laboratory payment system.

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cess to care and the use of enhanced testing methodologies in the future, however, the committee found no evidence of this now. Although radical changes are not called for at this time, implementing the committee's recommendations should improve the efficiency of the system and ensure that Medicare beneficiaries continue to have access to high-quality laboratory services.

For More Information . . .

Copies of *Medicare Laboratory Payment Policy: Now and in the Future* are available for sale from the National Academy Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at www.nap.edu. The full text of the report is available on line at www.nap.edu.

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