



AdvaMedD_x

A Division of the Advanced Medical Technology Association

A Policy Primer on Diagnostics

June 2011

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Overview of Diagnostics

Diagnostic tests are an important part of medical care.¹ For purposes of this paper, we define “diagnostic tests” as those tests performed on samples taken on and from the body, and used in a broad range of applications. These tests are also referred to as “in vitro diagnostics” or “IVDs.” Test results can be used to aid the patient, physician, and caregiver in reaching decisions. Depending on the test and the methods used, testing can be performed at a centralized laboratory, the hospital bedside, the physician’s office, the clinic, the workplace, and even the home. Diagnostic tests are often the least expensive component of the health care pathway, yet they influence more than 70 percent of health care decisions.

Diagnostic tests provide objective information about a person’s health. This information can be used for many purposes. Some tests are used for risk assessment purposes—to determine the likelihood that a medical condition is, or will become, present. Other tests are used to monitor the course of a disease or to assess a patient’s response to treatments, or even to guide the selection of further tests and treatments.

Most often, test results provide information that along with the patient’s history and other medical information helps the physician work with the patient so they can decide what might be the appropriate actions for additional testing or treatment. On some occasions, the information from a single test is enough to convince physician specialists that a cascade of sophisticated medical interventions are in order; and sometimes it is all that is needed to end them. More often, diagnostic tests provide information that, along with other tests and observations, helps shed light on whether or not a disease is present, has progressed, or has changed its course so that a judgment can be made on what treatment regimen might be most appropriate for a particular patient at a given time.

¹ This paper relies heavily on the findings and analysis set forth in a number of reports, including: The Lewin Group, *Comparative Effectiveness Research and Personalized Medicine: From Contradiction to Synergy* (Washington, DC: Personalized Medicine Coalition, October 28, 2009); The Lewin Group, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement* (American Clinical Laboratory Association and Advanced Medical Technology Association, September, 2009); President’s Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* (Washington, DC: Office of Science and Technology Policy, Executive Office of the President, September, 2008); The Lewin Group, *Laboratory Medicine: A National Status Report* (Centers for Disease Control and Prevention, May, 2008); Institute of Medicine, *Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment* (Washington, DC: National Academy Press, 2007); The Lewin Group, *The Value of Diagnostics: Innovation, Adoption, and Diffusion into Health Care* (Washington, DC: Advanced Medical Technology Association, 2005); Institute of Medicine, *Medicare Laboratory Payment Policy: Now and in the Future* (Washington, DC: National Academy Press, 2000).

Diagnostics can help assess information that has an impact on the public health as well as individual patient health. Examples include tests that are used to identify emerging infections, antibiotic resistance, exposure to toxic substances, and detection of chemical and biological threats. Diagnostic tests can be used during public emergencies often at the point of care, to provide rapid information needed to triage patients and to confirm the presence of communicable disease. Diagnostic tests are also increasingly used to assess the quality of patient care that is provided for medical conditions like diabetes, heart failure, and colon cancer.

Over the years, technological advances and automation have made tests easier to use and more accurate, and have led to more precise and more timely results. These advances have led to point-of-care tests that facilitate more rapid decision-making by medical practitioners. Another advance, made possible by discoveries about the human genome, has opened the door to personalized medicine approaches that can tailor medical treatments to individual patient needs, transforming modern medicine.

There are more than 4,000 different diagnostic tests available today. Diagnostic tests are performed close to 7 billion times each year in the United States. They influence most of the dollars that are spent on health care delivery while accounting for only a small fraction of U.S. health care expenditures.

The current environment for diagnostic tests is dampening incentives for continued product innovation, and it is threatening patient access to tests that can improve patient outcomes. First, serious challenges exist with assessing new tests. The initial challenge is in gaining Food and Drug Administration (FDA) clearance or approval for diagnostics tests. The level of evidence required to demonstrate safety and effectiveness, as well as clinical utility continues to grow. Further challenges have led to difficulties in securing insurance coverage when insurers insist on direct evidence of clinical utility, the impact of a specific test on patient outcomes. A new paradigm is needed for assessing diagnostic tests. Second, the current process of securing billing codes is lengthy and complex and the codes themselves have not kept pace with the development of promising and innovative new diagnostic tests. Third, the Medicare fee schedule that assigns payment rates for these tests, and provides a foundation for the rates paid by both public and private payers, is in desperate need of modernization. The current rate-setting process is slow and inefficient, the rates paid for some tests likely do not cover the costs of providing the service, and the rate-setting structure for new tests does not provide the return on investment needed to generate the evidence that insurers prefer.

In-Vitro Diagnostic Tests

Diagnostic tests are performed on samples taken on or from the body. These tests are a key component of modern health care, and they are used for a wide range of patient conditions. The information these tests provide helps physicians and caregivers prevent, diagnose, treat, and manage disease.

As mentioned, these tests—often referred to as *in vitro*² diagnostic tests—are a key component of modern health care.³ These tests are performed on samples taken from the body, such as blood, urine, saliva, spinal fluid, and DNA, and they vary in their complexity.

Some are simple tests that can be performed reliably at the point of care in physician offices or even at home, while others require expensive equipment and supplies, sophisticated methods, highly-skilled technicians, and specialized personnel to interpret results and are performed in large laboratories. The most specialized of these tests are known as “esoteric” tests.⁴

Diagnostic tests involve the instruments, equipment, and/or other items used to analyze specimens (which range from hand-held devices to desk-top analyzers to items of capital equipment used in large clinical laboratories), as well as the reagents used in performing diagnostic tests. Reagents are essential to tests because these are the substances that cause a reaction with the sample (e.g., chemicals that mark cancer cells so that they can be distinguished from healthy cells under a microscope).⁵

Diagnostic tests are performed in a variety of settings: hospital laboratories, independent laboratories (including large reference laboratories), physicians’ offices, and, in the case of tests like pregnancy tests and blood glucose tests, the home. These tests are commonly relied on by physicians and caregivers to prevent, diagnose, treat, and manage disease. Each year these tests impact the lives of millions of Americans.

Table 1 provides a number of examples of the health conditions for which diagnostic tests are used, as well as their prevalence and impact (i.e., the number of Americans affected and the spending on the condition).

² *In vitro* tests are medical devices used to perform diagnoses on patient specimens in a controlled environment outside a living organism. “In vitro” means “in glass” in Latin. By contrast, *in vivo* tests are performed within a living organism.

³ IOM, *Medicare Laboratory Payment Policy*, p.1.

⁴ Lewin, *The Value of Diagnostics*, pp. 16-17. “Esoteric” tests are relatively uncommon tests. As these tests are performed more commonly, they may no longer be considered to be “esoteric.” An example of this is polymerase chain reaction (PCR) testing. See also: IOM, *Medicare Laboratory Payment Policy*, p. 65.

⁵ Lewin, *The Value of Diagnostics*, pp. 49-50.

Table 1. Sample of Priority Health Conditions, Associated Tests, and Impact

Health Condition	Test Examples	Number of Americans Affected	Spending on Condition
Heart Disease	<ul style="list-style-type: none"> ✓ Lipid panel (cholesterol, Triglycerides) ✓ Troponin 	79.4 million (2004)	\$403 billion (2006)
Respiratory Disease	<ul style="list-style-type: none"> ✓ Blood gas test ✓ Bacterial culture ✓ Viral culture 	15.7 million (asthma); 1.3 million (pneumonia)	\$144.2 billion (2006)
Cervical Cancer	<ul style="list-style-type: none"> ✓ Pap smear ✓ Human papillomavirus DNA testing 	11,150 cervical cancer diagnoses (2007)	\$1.7 billion (2004)
Colorectal Cancer	<ul style="list-style-type: none"> ✓ Fecal occult blood test 	112,340 colon cancer diagnoses (2007)	\$8.4 billion (2004)
Diabetes	<ul style="list-style-type: none"> ✓ Glucose ✓ HbA1c 	20.8 million (2005)	\$132 billion (2002)
End Stage Renal Disease	<ul style="list-style-type: none"> ✓ Creatinine ✓ BUN 	472,000 (2004)	\$32.5 billion (2004)
HIV/AIDS	<ul style="list-style-type: none"> ✓ Antibody testing ✓ CD4 testing ✓ RNA 	1.2 million (2006)	\$21.1 billion (2006)
Influenza	<ul style="list-style-type: none"> ✓ Viral culture ✓ Serology ✓ Rapid antigen testing 	5-20% of the U.S. population is infected with the influenza virus each year	\$200 on treatment per infected person (2003)
Health Care Associated Infections	<ul style="list-style-type: none"> ✓ Viral culture ✓ Molecular typing of microbial pathogens 	1.7 million (2006)	\$10,500-\$111,000 per case (2004)

SOURCE: Adapted from The Lewin Group, *Laboratory Medicine: A National Status Report* (Centers for Disease Control and Prevention, May, 2008), p. 23.

Wide Range of Tests and Uses

There are thousands of diagnostic tests, and they can be classified many ways. Professionals often group them according to the way they gather information or the type of technology they employ. These tests can also be classified according to how they are used and the purpose they serve in the health care delivery system.

Though the precise figure is not known, in 2008 the Centers for Disease Control and Prevention (CDC) estimated that approximately 6.8 billion diagnostics tests were performed annually in the United States. This figure is growing given the aging and the growth of the population,

continued research and development of new tests, increased use of diagnostic tests as quality indicators, and increased consumer awareness of, and demand for, tests.⁶

Clinicians and laboratory professionals tend to classify diagnostic tests according to the way they gather information or the type of technology they employ. For example, some tests are general chemistry tests that provide measures of base compounds in the body, like cholesterol tests and urinalysis tests. Others are microbiology tests that are used to detect disease-causing agents, like viruses. Another grouping is molecular tests which are studies of a person’s DNA or RNA. Molecular tests may indicate the presence of disease or one’s susceptibility to disease.

Table 2 provides a number of these test categories, along with test examples for each category.

Table 2. Categories of Diagnostic Tests

Test Category	Test Purpose	Examples
General Chemistry	Measurements of base compounds in the body	<ul style="list-style-type: none"> ✓ Urinalysis test strips ✓ Calcium level test ✓ HbA1c tests ✓ Fecal occult blood tests (FOBT)
Immunochemistry	Match antibody-antigen response to indicate the presence or level of a protein	<ul style="list-style-type: none"> ✓ Immunoassay test for troponin ✓ Antibiotic susceptibility tests ✓ Alpha-fetoprotein (AFP) tests ✓ HIV antibody tests ✓ Substance abuse tests ✓ Tumor marker tests
Hematology / Cytology	Study of the blood, blood-producing organs, and cells of the body	<ul style="list-style-type: none"> ✓ Complete blood count ✓ Coagulation tests (e.g., INR) ✓ Papanicolaou (PAP) smear
Microbiology / Infectious Disease	Detection of disease-causing agents	<ul style="list-style-type: none"> ✓ Streptococcal testing ✓ Bacterial urine testing / urine culture ✓ West Nile virus blood screening
Molecular	Study of DNA and RNA to detect genetic sequences that may indicate presence or susceptibility to disease	<ul style="list-style-type: none"> ✓ HER2/neu over-expression testing to identify patients who are more likely to respond to the breast cancer drug Herceptin ✓ BRCA-1 and BRCA-2 testing to indicate an individual's risk of developing breast or ovarian cancer ✓ Nucleic acid hybridization tests and nucleic acid amplification tests ✓ Pharmacogenomic profiling ✓ HIV viral load testing and other HIV assays

SOURCE: Adapted from The Lewin Group, *The Value of Diagnostics: Innovation, Adoption, and Diffusion into Health Care* (Washington, DC: Advanced Medical Technology Association, 2005), pp. 23-24.

⁶ Lewin, *Laboratory Medicine: A National Status Report*, pp. 67-69.

The information provided by diagnostic tests informs decisions that are made throughout the health care continuum. Tests can be used to screen for a disease or to provide early disease identification; to diagnose a disease; to provide prognostic information by assessing the degree of disease progression or severity; to assist in selecting drugs or targeting medical treatment; and to monitor the course of a disease or condition.

Table 3 identifies the various uses these tests can perform in the health care continuum, and it provides test examples for each of these uses. Some tests can be employed for more than one type of use. For example, a blood glucose test can be used to screen for and to diagnose diabetes. It can also be used to monitor a diabetic patient’s condition and evaluate the results of treatment.

Table 3. Uses of Diagnostic Tests

Test Use	Purpose	Example
Screening, Early Disease Detection	To detect asymptomatic disease or a predisposition to disease in order to take action to prevent it by modifying a risk factor or to treat it earlier	<ul style="list-style-type: none"> ✓ Blood cholesterol tests / heart disease ✓ Fecal occult blood tests / colorectal cancer ✓ Pap tests / cervical cancer ✓ Genetic tests ✓ Blood glucose tests / diabetes
Diagnosis	To make a diagnosis when symptoms, abnormalities on physical examination, or other evidence suggests, but does not prove, that a disease may be present	<ul style="list-style-type: none"> ✓ Blood glucose tests / diabetes ✓ Streptococcus / bacterial infection ✓ Brain natriuretic peptide (BNP) / heart failure
Disease Staging, Prognosis	To determine the extent of disease progression or severity and the likelihood of recovery or risk of future adverse health outcomes (e.g., cancer relapse)	<ul style="list-style-type: none"> ✓ Testing for co-morbidities (e.g., hypertension, cardiovascular disease, acute respiratory infection) ✓ Blood clotting tests for pre-surgical risk assessment ✓ Cardiac marker testing (e.g., troponin, myoglobin) / rapid assessment of heart injury, heart attack
Drug Selection, Treatment Monitoring	To allow accurate and targeted treatment selection tailored to individual needs	<ul style="list-style-type: none"> ✓ HER2/neu over-expression testing to identify patients who are more likely to respond to the breast cancer drug Herceptin ✓ Oncotype DX, a gene expression profile test, to quantify the likelihood of breast cancer recurrence and potential benefit from chemotherapy in women with newly diagnosed, early stage breast cancer

Test Use	Purpose	Example
Disease or Condition Monitoring and Management	To understand the course of the disease or the effect of a therapy in order to evaluate the success of treatment and the need for additional testing or treatment	<ul style="list-style-type: none"> ✓ Blood glucose tests and HbA1c tests for diabetes monitoring ✓ Viral load, CD4 count, complete blood count, blood chemistry tests to assess treatment response in HIV patients ✓ Cholesterol tests to monitor effectiveness of lipid-lowering drug therapy ✓ Alpha-fetoprotein tests to monitor effectiveness of therapy for patients with cancers of the liver, testes, or ovaries

SOURCE: Based on: The Lewin Group, *Laboratory Medicine: A National Status Report* (Centers for Disease Control and Prevention, May, 2008), pp. 25-31; The Lewin Group, *The Value of Diagnostics: Innovation, Adoption, and Diffusion into Health Care* (Washington, DC: Advanced Medical Technology Association, 2005), pp. 30-40; 152-167.

Federal Regulatory Oversight

Diagnostic tests vary in their uses and their complexity. They also vary in the way they are regulated. In the U.S., FDA has regulatory oversight of all diagnostic tests that are considered to be medical devices. This includes all diagnostic tests that are manufactured and sold as kits to laboratories, physician offices and patients. Most tests that are developed and offered within a particular laboratory—laboratory-developed tests (or LDTs)—have traditionally not been regulated by the FDA. These tests (sometimes called “home-brew” tests) are not distributed or sold to other labs. These tests must go through analytical validation procedures and must meet certain criteria related to quality standards for all laboratories that perform tests. Until recently, FDA has not exercised its enforcement discretion over most LDTs; however, FDA has announced plans to implement a risk-based approach toward the oversight of LDTs.

Many common lab tests are commercial tests sold to laboratories, and they cannot be marketed in the U.S. without FDA clearance or approval. These tests are regulated by the FDA as devices according to the risk that they pose. Risk is determined by a product’s intended use.⁷

Class I devices have the lowest risk, and Class II and Class III devices have progressively higher risks. This classification scheme determines the FDA review process manufacturers must complete in order to obtain authorization for marketing in the U.S. [i.e., the section 510(k) premarket notification process, or the premarket approval (PMA) process]. Most Class II and some Class I medical devices are subject to section 510(k) premarket notification requirements.

⁷ For an overview of how FDA regulates *in vitro* diagnostic tests, see the FDA web site at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm>.

The PMA review process is required for Class III medical devices, those that pose the greatest risk.

The section 510(k) process requires manufacturers to notify the FDA at least 90 days in advance of their intent to market a product in the U.S. FDA then determines if the product is substantially equivalent to the safety and effectiveness of a legally marketed predicate device that is not subject to premarket approval, or if the device requires premarket approval (PMA). For devices undergoing 510(k) review, FDA requires performance information and other information appropriate for the risk level of the device. If a new device is found not to be substantially equivalent to a Class I or Class II device on the market, an applicant may resubmit another 510(k) with new information, request a Class I or II designation through the de novo process, or submit a premarket approval application.⁸ A new device that is found to be substantially equivalent is classified in the same regulatory class (either Class I or Class II) as the device to which it is found equivalent.

As part of the medical device framework, manufacturers of Class I tests have to register their tests with the FDA and follow general controls, such as adhering to good manufacturing practices, reporting device failures, and developing and using a system to remedy these failures. Class II tests pose greater risks than Class I tests, and they are subject to general controls as well as special controls. Special controls may include performance standards or special labeling requirements. Manufacturers of the highest risk products must submit a PMA to the FDA. A PMA approval is based on a determination by FDA that the PMA contains sufficient scientific evidence to assure that the device is safe and effective for its intended use(s). The test cannot be marketed until the FDA reviews and approves this application.⁹

Table 4. FDA In Vitro Diagnostic Test Regulation

Regulatory Pathway	Device Classification	Example
Section 510(k) Premarket Notification	Class I	✓ Sterile specimen containers ✓ Medicine droppers
	Class II	✓ Pregnancy test kits
Premarket Review (PMA)	Class III	✓ HIV test kits ✓ Immunohistochemistry kits

SOURCE: Adapted from The Lewin Group, *The Value of Diagnostics: Innovation, Adoption, and Diffusion into Health Care* (Washington, DC: Advanced Medical Technology Association, 2005), pp. 60-61.

Since FDA began regulating medical devices in the late 1970s, FDA has generally exercised “enforcement discretion,” and has not enforced applicable regulations with respect to LDTs, which they consider a class of in vitro diagnostic medical devices. At the time FDA began regulating medical devices, LDTs were generally relatively simple low-risk tests, or used for rare

⁸ The *FDA Modernization Act of 1997* provides that a manufacturer of a device for which there are no predicates (i.e., the device is found to be not substantially equivalent) can request that a risk-based classification determination be made for the device. This process is known as the De Novo Classification Process.

⁹ Institute of Medicine, *Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary* (Washington, DC: The National Academies Press, 2010), pp. 25-27.

conditions for which adequate validation would not be feasible. However, the components of traditional LDTs were regulated individually by FDA as analyte specific reagents (ASRs) or other specific or general reagents.¹⁰

Each of the diagnostic laboratories that perform *in vitro* diagnostic tests in the U.S.—including the laboratories in which LDTs are developed and offered—are regulated under the Clinical Laboratory Improvement Amendments (CLIA).¹¹ Under CLIA, the Centers for Medicare and Medicaid Services (CMS) regulates all laboratories performing testing on humans that are intended to inform the prevention, diagnosis, or treatment of disease, and the FDA categorizes each test according to its complexity. CLIA requires every clinical laboratory that performs tests to apply for and obtain a certificate that corresponds to the complexity of tests that the lab performs. See Table 5 for a listing and explanation of these certificates.

Table 5. Types of CLIA Certificates

Type of Certificate	Explanation
Certificate of Waiver (COW)	Issued to a lab that performs only waived tests
Certificate for Provider Performed Microscopy (PPM) procedures	Issued to a lab in which a physician, midlevel practitioner or dentist performs specific microscopy procedures (a limited list of procedures of moderate complexity) during the course of a patient's visit
Certificate of Registration	Issued to allow a lab to conduct nonwaived (moderate and/or high complexity) testing until the lab is surveyed (inspected) to determine its compliance with CLIA regulations; only labs applying for a certificate of compliance or accreditation will receive a certificate of registration
Certificate of Compliance (COC)	Issued once the State Department of Health conducts a survey (inspection) and determines the lab is compliant with all applicable CLIA requirements; issued to a lab that performs nonwaived (moderate and/or high complexity) testing
Certificate of Accreditation (COA)	Issued by an accreditation organization approved by CMS to a lab that performs nonwaived (moderate and/or high complexity) testing

SOURCE: *Clinical Laboratory Improvement Amendments (CLIA): How to Obtain a CLIA Certificate*, CMS Brochure #5 (March, 2006). <http://www.cms.gov/CLIA/downloads/HowObtainCLIACertificate.pdf>.

The CLIA legislation was enacted in 1988, and the final regulations implementing it were published in the *Federal Register* on February 28, 1992. These regulations are based on the complexity of the test method, not the type of lab that performs it, so that the more complicated the test, the more stringent the requirements. These diagnostic tests can be “waived” if according to CLIA they are simple tests “that have an insignificant risk of an

¹⁰ Analyte specific reagents (ASRs) are biological or chemical reagents that are used to identify or quantify substances in biological specimens. They serve as the building blocks of diagnostic tests, and manufacturers must restrict their sale to labs designated as being of high complexity under CLIA. See Lewin, *The Value of Diagnostics*, p. 60.

¹¹ IOM, *Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary*, pp. 25-47.

erroneous result.” Tests may be “non-waived” if they are considered to be of moderate or high complexity. The FDA has authority over CLIA waiver determinations.

FDA is now reconsidering its policy of “enforcement discretion” toward the regulation of LDTs. It has indicated plans to apply a risk-based regulatory approach to LDTs, and the agency is currently developing a framework for implementation.

Laboratory Medicine

Most diagnostic tests are performed in hospital laboratories. Independent laboratories account for one-third of clinical laboratory testing. There are more physician office labs than any other type of laboratory, but they are responsible for performing less than 10 percent of lab tests, and about half of these tests are CLIA-waived.

More than 200,000 clinical laboratories provide testing services in the United States.¹² Recent analyses show that hospital laboratories, which comprise between 4 and 5 percent of U.S. laboratories, performed the majority of tests (55 percent). Independent laboratories, which account for close to 3 percent of laboratories, performed 32 percent of test volume.

Physician office labs, which comprised more than half of U.S. laboratories (53 percent), were responsible for just 8 percent of lab test volume. Physician office laboratories (POLs) tend to perform relatively simple or moderately complex tests to provide immediate, on-site tests results to clinicians.¹³ There are more POLs than any other type of laboratory, and about half the tests performed in them are CLIA-Waived.¹⁴

Other laboratories include local public health laboratories, and laboratories located in end stage renal disease dialysis facilities, ambulatory surgery centers, community clinics, home health agencies, nursing facilities, blood banks, hospices, and so forth. Though these various labs comprise close to 40 percent of the total number of clinical laboratories, they account for only about 5 percent of the tests that are performed. See Table 6 for information on the types of laboratories that perform diagnostic tests.

¹² Lewin, *Laboratory Medicine: A National Status Report*, p. 69.

¹³ IOM, *Medicare Laboratory Payment Policy*, p. 31.

¹⁴ In addition, it is estimated that 13 percent of testing is provider-performed microscopy (PPM), that 22 percent is moderate complexity, and that 4 percent is high complexity. Lewin, *Laboratory Medicine: A National Status Report*, p. 74.

Table 6. Types of Laboratories (2006)

Type of Laboratory	Number of Labs	Percent of Total Number of Labs	Percent of Lab Test Volume
Hospital Labs	8,680	4.4%	55%
Independent Labs	5,414	2.7%	32%
Physician Office Labs	106,190	53.6%	8%
Other Labs, including: ESRD Facilities; Clinics; Home Health Agencies; Nursing Facilities, etc.	50,000+ (est.)	39.4%	5%

SOURCE: Lewin Group, *Laboratory Medicine*, pp. 69-80. IOM, *Medicare Laboratory Payment Policy*, Appendix D, pp. 215-223.

Small Expense, Big Return

Spending in the U.S. for diagnostic tests is quite small when compared to the impact this spending has on health care. The information these tests provide influences the majority of health care decisions. Though the appropriate use of lab tests is integral to high-quality health care, tests that serve as quality measures are underused in practice.

Spending on laboratory services accounts for only 2.3 percent of U.S. health care expenditures and 2 percent of Medicare expenditures.¹⁵ At the same time, diagnostic tests are an essential part of modern medicine, and the information they provide influences most health care decision making.¹⁶ Advances in technology are likely to increase the role these tests play in detecting, treating, and monitoring disease.¹⁷

When diagnostic tests are appropriately used, they can lead to earlier, more targeted health care interventions, averting adverse health outcomes and unnecessary costs. That is why direct measures of test use—such as cervical cancer screening, LDL cholesterol screening following a heart attack, and Chlamydia screening—are often used to measure quality of care.

For example, HEDIS¹⁸ measures, used by 90 percent of managed care organizations and thousands of individual provider sites to measure quality of care, include 26 effectiveness of care quality measures, of which 16 (62 percent) are informed by diagnostic tests—including 6 (23 percent) that are direct measures of diagnostic test use (such as cervical cancer screening, LDL cholesterol screening following heart attack, and chlamydia screening).¹⁹ In addition, an expanding number of evidence-based clinical practice guidelines recommend use of specific diagnostic tests as part of the standard of care because of the tests' role in informing health care decision making.

¹⁵ Lewin, *Laboratory Medicine: A National Status Report*, p. 2.

¹⁶ Lewin, *The Value of Diagnostics*, pp. 2-3.

¹⁷ IOM, *Medicare Laboratory Payment Policy*, p. 18.

¹⁸ Health Plan Employer Data and Information Set.

¹⁹ Lewin, *The Value of Diagnostics*, p. 2.

Unfortunately, tests that are evidence-based standards of care are often underused.²⁰ A sentinel study by the RAND Corporation indicated that, based on an analysis of 102 diagnostics-based quality indicators in 30 preventive, acute, and chronic conditions, these diagnostic tests were underused 51 percent of the time. The National Committee for Quality Assurance (NCQA) found that low compliance with diagnostics-based quality measures for diabetes, cardiovascular disease, colorectal cancer, and breast cancer alone was linked to 56,200 avoidable adverse health events, up to 34,000 avoidable deaths, and \$899 million in avoidable health care costs in 2004.²¹

Trends in Test Innovation

There has been rapid innovation both in the range and complexity of diagnostic tests, and in laboratory test methods and techniques. Advances in diagnostic products make it possible to detect diseases early, when they often can be best treated. Advances in laboratory medicine have also made lab tests easier to use and less subject to user error, they have led to more precise and timelier results, and they have helped transform medical practice. Key trends in diagnostic test innovation include: detecting disease before symptoms appear; predicting beneficial and adverse treatment effects; enabling personalized treatment regimens; facilitating point-of-care testing; and enabling home testing.

Technological advances are changing not only the way diagnostic tests are performed, but also the practice of medicine itself. Improvements in diagnostic tests and the methods to perform them provide increasingly more precise and timely information to assist medical caregivers to prevent and diagnose disease, monitor its progression, and guide therapeutic options. Laboratory innovations have resulted in many new tests that are more efficient and automated, and less subject to user error. In addition, many tests have become less invasive or easier to administer, causing less discomfort to patients.

*Detecting Disease Before Symptoms Appear.*²² Advances resulting from the sequencing of the human genome have made it possible to detect disease at earlier stages. New gene-based and other molecular diagnostic tests can identify a person's susceptibility to disease before symptoms occur. These tests help better inform patient and physician decision-making, permit prevention and earlier treatment that can delay or reduce adverse health outcomes, and reduce health spending associated with later-stage disease.

²⁰ Lewin, *The Value of Diagnostics*, p. 149.

²¹ Lewin, *The Value of Diagnostics*, p. 2. The RAND study was authored by Elizabeth A. McGlynn, Steven M. Asch, *et al.* and published in the *New England Journal of Medicine*, Vol. 348, No. 26 (June 26, 2003), pp. 2635-2645.

²² This section is based on Lewin, *The Value of Diagnostics*, pp. 32-35; 152-159.

- Example: Genetic testing for BRCA1 and BRCA2 mutations can indicate individual risk for developing breast or ovarian cancer.

*Predicting Beneficial and Adverse Treatment Effects.*²³ New gene-based and other molecular diagnostic tests can also be used to determine the benefits and harms for an individual of taking certain medications. These tests are known as *companion diagnostics*. Information on an individual's drug metabolism, for example, can yield information on who might benefit most from a drug and those at risk for atypical adverse reactions (through genetic variations influencing the rate and efficacy of drug metabolism, or other genetic variations related to drug response). Tests can also inform the optimal dose or treatment frequency needed to achieve a desired therapeutic effect in an individual patient.

- Example: HER2/neu testing to guide the prescription of the cancer drug Herceptin for breast cancer.
- Example: UGT1A1 testing to guide the dosage of the chemotherapy drug irinotecan for metastatic colorectal cancer.

*Enabling Personalized Treatment Regimens.*²⁴ Diagnostic tests—especially those that provide rapid or real-time results—are an essential part of individualized treatment regimens for many chronic diseases and conditions, like heart disease, arthritis, abnormal renal function, and certain viral infections. These tests inform treatment decisions and patient education efforts to achieve lifestyle changes. These tests also allow clinicians to reduce the likelihood of unnecessary adverse events.

- Examples: HbA1c tests (glycated hemoglobin) for monitoring diabetes; therapeutic drug monitoring tests to select drugs for resistant HIV strains; cholesterol (and other lipid) testing to monitor the effectiveness of lipid-lowering therapy.

*Facilitating Point-of-Care Testing.*²⁵ Tests are no longer confined to the laboratory. Point-of-care tests can now provide needed information close to where health care is delivered, facilitating more rapid diagnoses and treatment decisions and improved patient compliance with physicians' recommendations.

Technological innovations have led to point-of-care tests that are available for use close to where diagnostic and treatment decisions are made—at the patient's bedside, in the emergency room or clinic, at the workplace, in an exam room of a physician's office, and even

²³ This section is based on Lewin, *The Value of Diagnostics*, pp. 35-37; 159-162.

²⁴ This section is based on Lewin, *The Value of Diagnostics*, pp. 37-38; 164-165.

²⁵ This section is based on Lewin, *The Value of Diagnostics*, pp. 38-39; 58; 69.

at home. Point-of-care tests eliminate the need for trips to and from the central laboratory (and specimen collection sites that are run by laboratories). These tests enable physicians to make more rapid diagnoses and treatment decisions, and they improve patient compliance with physicians' recommendations.

The demand for point-of-care tests has spurred the development of smaller, faster, and easier to use tests that are more sophisticated in design than tests traditionally found in laboratories. Having this information available near the patient permits the physician to begin necessary treatment more quickly.

- Example: Troponin test, used to diagnose heart attacks in the emergency room; it measures the level of troponin, a protein that distressed cardiac cells secrete into the patient's blood stream.

While less than 10 percent of lab tests are performed in a physician office lab, these tests can provide immediate feedback to the clinician, offering the opportunity to address health care problems while the patient is still in the office. Some of the tests performed in the office include streptococcus testing, HIV (AIDS) testing, INR (coagulation) testing for coumadin and pregnancy testing. The ability to immediately treat the patient, without having to send a sample to a central hospital laboratory, can be critical to the patient's well-being.

As an example, a positive test for strep can allow the clinician to immediately prescribe antibiotics, catching an infection before it becomes severe, with potential health consequences (or ruling out strep and avoiding unnecessary use of antibiotics). Garnering information with a point-of-care test often allows immediate treatment, which avoids requiring the patient to make multiple trips to the physician office and pharmacy, saving time for both the patient and the clinician. Accurate diagnostic information at the point-of-care saves critical medical resources and improves both patient and clinician satisfaction.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), tests can be waived and performed in physicians' offices and other locations.²⁶ In addition to the traditional FDA regulatory route to market, the sponsor company must perform additional testing, demonstrating not only that the test is substantially equivalent to a laboratory test, but that it is safe and effective when used by non-laboratory personnel. In recent time, the regulatory path and associated submission requirements for laboratory testing in physicians' offices and

²⁶ Under 42 U.S.C. Section 263a(d)(3), waived tests are simple tests that "have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or ... pose no unreasonable risk of harm to the patient if performed incorrectly."

other waived settings has become increasingly lengthy, difficult and costly. Such challenges are posing barriers to innovation in CLIA waived testing. In light of the role of waived testing in the healthcare delivery system and overall benefits of these technologies, availability of and timely access to these technologies will continue to be important to meet the needs of patients and clinicians for rapid and reliable testing.

*Enabling Home Testing.*²⁷ While most diagnostic tests are performed by clinicians and laboratory personnel, consumers can also purchase some tests for private use. The most frequently used home testing devices include blood glucose meters for diabetics, pregnancy tests, and cholesterol tests. Other tests approved by the FDA for home testing include blood clotting tests (for patients taking blood thinning drugs like Coumadin), fecal occult blood tests (for detecting colon cancer), tests for detecting the hepatitis C virus (HCV) and HIV, and drug abuse tests. While some tests permit consumers to collect and analyze a sample without interacting with a laboratory, others require the sample to be sent to an independent laboratory for analysis with results reported to the consumer.

- Examples: Blood glucose meters for diabetics, pregnancy tests, cholesterol tests.

Challenges Posed by Personalized Medicine

The purpose of personalized medicine is to ensure that health care delivers the right treatment to the right patient at the right time. Reimbursement challenges can dampen incentives to develop the new molecular diagnostic tests that can inform personalized medicine approaches.

Diagnostic tests that involve the molecular analysis of genes, proteins, and metabolites are considered by many to be the key to personalized medicine.²⁸ These tests can be used to assess the efficacy of specific therapeutic agents in particular patients, to identify patients who may suffer disproportionately severe adverse effects from a given treatment or dosage, to determine the optimal dosages for drugs whose therapeutic effect is known to vary widely, to assess the extent or progression of a disease, and to identify patients who can benefit from specific preventive measures.²⁹

In its report, issued in 2008, the President's Council of Advisors on Science and Technology (the "President's Council") cited a number of obstacles to realizing the benefits of personalized medicine. Among the obstacles identified by the President's Council are reimbursement

²⁷ This section is based on Lewin, *The Value of Diagnostics*, pp. 39-40; 58-59.

²⁸ See Margaret A. Hamburg and Francis S. Collins, "The Path to Personalized Medicine," *New England Journal of Medicine* (June 15, 2010).

²⁹ President's Council of Advisors on Science and Technology, *Priorities for Personalized Medicine*, pp. 11-12.

systems that have an impact on patient access to genetic tests. The President’s Council identified three specific challenges for genomics-based molecular tests:

- (1) Reimbursement of a test as a low-margin commodity reduces the likelihood that the economic return from development of an innovative test will justify the required investment;
- (2) The low margins characteristic of reimbursement for *in vitro* diagnostic tests makes it difficult or impossible to conduct the elaborate clinical trial programs taken for granted in the development of new pharmaceuticals, and, to the extent that funds are available, companies developing these tests may invest available resources less than optimally, designing studies exclusively around the demands of regulatory approval and neglecting the evidence required by payers; and
- (3) Procedural hurdles associated with coding systems and payment systems are not designed to adapt in a timely way to advances in diagnostic technology.³⁰

Reimbursement challenges can dampen the incentive for new test development. Increased insurer demands for direct evidence of test impact on patient outcomes, cumbersome coding regimes, and rate-setting approaches that disregard test value create difficult hurdles for new test developers and slow patient access to promising tests.

Table 7. Obstacles to Personalized Medicine

✓	Methodological and logistical challenges in validating apparent correlations between genetic markers and disease
✓	Regulatory and reimbursement systems that were not designed to accommodate complex genomics-based diagnostics
✓	Absence of the electronic medical record-linked decision support tools needed to integrate the results of genomics-based diagnostic tests into routine clinical practice
✓	Intellectual property laws and practices that may present barriers to investment in genomics-based diagnostics
✓	Privacy concerns that may limit patient acceptance of genomics-based diagnostics
✓	Education of patients and physicians on the proper use and limitations of new genomics-based diagnostics

SOURCE: President’s Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* (Washington, DC: Office of Science and Technology Policy, Executive Office of the President, September, 2008), p. 9.

³⁰ President’s Council of Advisors on Science and Technology, *Priorities for Personalized Medicine*, pp. 47-48.

Medicare Clinical Laboratory Fee Schedule

Diagnostic tests are reimbursed by Medicare Part B under the Clinical Laboratory Fee Schedule. There are no beneficiary co-payments or deductibles for these diagnostic tests. A lab submits claims for tests to its local Medicare contractor. Claims are paid based on the local fee schedule rate that was established for the test in the locality where the lab is located. These local rates have a payment ceiling (a National Limitation Amount, or “NLA”). Contractors pay labs the lower of the charge for the test or the local contractor rate, as capped by the NLA.

More than 4,000 diagnostic tests are available for clinical use. Over 1,100 distinct tests currently have payment rates set on the Medicare Clinical Laboratory Fee Schedule, and about 500 of them are performed regularly.³¹ This Medicare fee schedule became operational in 1984, replacing a previous system under which tests were paid for on a “reasonable charge” basis by local Medicare contractors.

The Clinical Laboratory Fee Schedule was established by reducing³² the “reasonable charge” payment rates for each test in each locality, by eliminating beneficiary co-payments, and by permitting direct billing by laboratories. The Clinical Laboratory Fee Schedule is comprised of the rates set by local Medicare contractors for the 56 geographic areas that existed at the time the fee schedule was put into place.³³

Beginning in 1986, the local fee schedule rates for tests were capped by a National Limitation Amount (NLA), which was set at 115 percent of the median contractor rate for each lab test. The NLA was successively reduced over the years to where it stands today—at 74 percent of the median contractor rate for each lab test (or at 100 percent of the median for new lab tests for which an NLA was not established before January 1, 2001). Under the fee schedule, contractors pay labs the lower of the charge for the test or the local contractor fee schedule rate, as capped by the NLA.

When new lab tests are assigned new or substantially revised billing codes, CMS sets rates for the tests in one of two ways. It either *cross-walks* the new test code to a clinically or technologically similar test already on the fee schedule, or it uses a *gap-fill* process to set the

³¹ Lewin, *Laboratory Medicine*, p. 3.

³² “Prevailing charge limits” for each test in each of the 56 local contractor jurisdictions were reduced by 40 percent.

³³ For information on this fee schedule, see: Raab, G. G. and Logue, L. J., “Medicare Coverage of New Clinical Diagnostic Laboratory Tests: The Need for Coding and Payment Reforms,” *Clinical Leadership & Management Review*, Vol. 15, No. 6 (November/December, 2001), pp.376-387; Lewin, *The Value of Diagnostics*, pp. 106-118; Lewin, *Laboratory Medicine*, pp. 327-328.

payment rate for the new test code. Most new tests are cross-walked to tests already on the fee schedule.

Cross-walked tests are paid the same local contractor rate (capped by the NLA) as the test to which it is cross-walked. Gap-fill pricing involves local contractors setting rates for the new test in their localities for the first year (though no particular pricing methodology is prescribed by CMS). CMS then uses local carrier rates as a basis to establish an NLA (set at 100 percent of the median of contractor rates) for the second year.

Over the years, as updates have been made to the fee schedule to account for inflation and as the NLA was reduced for existing tests from 115 percent to 74 percent of the median, most test prices have been constrained by the price ceiling of the NLA. In a recent analysis, the Office of the Inspector General of the Department of Health and Human Services found that close to 20 percent of all local contractor lab test rates on the fee schedule are at varying percentages below the NLA, and that this does not appear to reflect geographic differences in costs. The HHS IG found that all local contractors had lab test rates that varied from the NLA.³⁴

When Medicare cross-walks new test codes to existing tests on the fee schedule, the new test receives the local payment rate of the existing test, even if this rate does not reflect the costs and value of the new test, or if the rate was set in error in 1984 when the fee schedule was established, or if the local contractor set a rate that did not reflect lab costs to perform the test. There is no administrative method for adjusting the longstanding payment levels for tests priced on the Medicare Clinical Laboratory Fee Schedule.

Reimbursement Challenges

The current reimbursement environment for diagnostic tests is dampening incentives for continued product innovation, and it is threatening patient access to tests that can improve patient outcomes.

- ***Serious challenges exist with assessing new diagnostic tests. This has sometimes led to difficulties in securing coverage for these tests.***
- ***Current billing codes have not kept pace with the development of promising new molecular tests.***

³⁴ Office of the Inspector General, Department of Health and Human Services, *Variation in the Clinical Laboratory Fee Schedule* (Washington, DC: July, 2009).

- ***The Medicare Clinical Laboratory Fee Schedule which assigns payment rates for diagnostic tests, and which provides a foundation for the rates paid by both public and private insurers, is in desperate need of modernization.***

Tests Pose Unique Assessment Challenges. As the emphasis on evidence-based medicine has grown in recent years, and as new (and, often, more-expensive) tests have become available, diagnostic tests have come under increased scrutiny by insurers making coverage and payment determinations. There is a greater demand for evidence of a test’s *clinical utility* (the impact of a test on clinical outcomes and usefulness to patient and physician decision-making) in addition to its *analytic validity* (test accuracy or precision) and *clinical validity* (the probability of having a disorder based on a test result).³⁵

Table 8. Assessment of Diagnostic Tests

Criterion	Definition	Measure
Analytic Validity	A diagnostic test’s ability to measure the analyte (or genotype, in the case of genetic testing) of interest accurately and reliably	<ul style="list-style-type: none"> ✓ Accuracy (analytic sensitivity, analytic specificity) ✓ Precision ✓ Robustness
Clinical Validity	A diagnostic test’s ability to detect and predict the disorder that is associated with an analyte measurement; a test’s value to clinical decision-making	<ul style="list-style-type: none"> ✓ Clinical Sensitivity ✓ Clinical Specificity ✓ Positive Predictive Value ✓ Negative Predictive Value
Clinical Utility	Clinical effectiveness; the balance of risks and benefits associated with use of a test in routine clinical practice; usefulness and value of information, positive or negative, to person being tested	<ul style="list-style-type: none"> ✓ Intermediate / Surrogate Outcomes ✓ Health Outcomes (mortality, morbidity, quality of life) ✓ Adverse Effects of Diagnostic Use ✓ Adverse Effects of Treatment

SOURCE: Adapted from The Lewin Group, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement* (American Clinical Laboratory Association and Advanced Medical Technology Association: September, 2009), p. 8.

Assessing these tests presents unique challenges given the preference of insurers for randomized controlled trials (RCTs) that provide direct evidence of the impact a test has on patient outcomes. Unlike the situation that exists for evaluating therapeutic treatments—where treatments tend to lead directly to results—the impact of a diagnostic test on patient outcomes is not direct. There are typically several steps between the performance of a given test and a clinical outcome, and the ability of the test to influence outcomes is subject to factors that are beyond (or independent of) the technical attributes of the test itself.³⁶

The information that tests provide typically has an impact on a decision-maker’s thinking and therapeutic choices which, in turn, influence patient outcomes. In addition, clinicians may

³⁵ Lewin, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement*, p. 32.

³⁶ Lewin, *Laboratory Medicine and Comparative Effectiveness Research*, p. 14.

interpret and act on lab test information differently, and this can confound the evaluation of how a test has an impact on patient outcomes. Because of this, most evaluative studies of diagnostic tests focus on intermediate outcomes, like diagnostic accuracy or impact on diagnostic thinking, not patient outcomes. This fact complicates test assessments, and it underscores the need for evaluations that are sensitive to the specific context in which a particular test is provided. In addition, diagnostic and management processes can present a range of options that are more varied and more difficult to standardize than many treatment plans.

Given the multiple intervening steps between accurate tests results and improved health outcomes, conducting RCTs on diagnostic tests in order to establish direct evidence of their impact on patient outcomes can be time-consuming, complex, costly, and, in certain instances, infeasible.³⁷ The need for an RCT is diminished when the therapeutic decision based on accurate test information is well established and when there is strong evidence pertaining to the impact of the available therapy on patient outcomes or on a validated surrogate outcome. Whether a test result has an impact on patient management and outcomes might also involve decision analysis based on available evidence pertaining to clinician decision-making and other evidence (especially from RCTs) of the impact of the relevant therapies on patient outcomes.³⁸

While RCTs remain the preferred study design for establishing the causal effects of medical interventions on patient outcomes, other study designs can sometimes substitute for them. Further, other well-designed, non-randomized observational studies (like patient cohort studies, case control studies, registries, and surveillance studies), though less rigorous than RCTs, may provide evidence that is sufficiently strong to inform payers making coverage and payment determinations.³⁹

Coding Has Not Kept Pace With New Tests. Healthcare Common Procedure Coding System (HCPCS) billing codes must be used for processing claims for Medicare and Medicaid patients. Private insurers also make use of this coding system for billing purposes. Level I of the HCPCS coding system is composed of CPT (Current Procedural Terminology) codes, five-digit numeric codes (each with a descriptor) which are maintained by the American Medical Association.⁴⁰

³⁷ Lewin, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement*, p. 24; Lewin, *Laboratory Medicine and Comparative Effectiveness Research*, p. 28.

³⁸ Lewin, *Laboratory Medicine and Comparative Effectiveness Research*, pp. 21; 28.

³⁹ Lewin, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement*, pp. 24-25.

⁴⁰ For more information on the CPT Coding Process, see: <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq/code-becomes-cpt.shtml>.

Level II of HCPCS is composed of five-digit alpha-numeric codes (with descriptors) assigned by CMS staff to identify items and services not identified by CPT codes.⁴¹

More than 1,000 of the 7,000+ codes in CPT have been assigned to identify diagnostic tests and test methods. These codes are updated on a yearly basis. However, currently the process for developing CPT codes does not keep pace with rapid developments in laboratory technology.⁴²

The code descriptor that most closely matches the test that is ordered by the physician and performed by the laboratory must be used when submitting a claim. If a code for a specific analyte exists, it must be used. It is not correct to use a more general code, or a code for the test method that is used in performing the test if a specific analyte code is available.⁴³ If a distinct HCPCS code does not exist that adequately identifies a new test, a test developer can apply for a new (or revised) code, use a miscellaneous code (often as an interim measure until a new code is assigned), or use an existing method code (or codes, if necessary) to describe the techniques used to perform the test.

Securing a new billing code is both a time-consuming and complex process, requiring significant time and resources on the part of the manufacturer or product developer. There are firm deadlines for submitting applications, and the process can take from 14-26 months. Test developers are also required to demonstrate in their application for a new CPT code that the clinical efficacy of a new test is well established and documented in U.S. peer reviewed literature. The process of securing new codes would benefit from increased transparency and stakeholder input.⁴⁴

When no specific existing code is available, an independent lab can seek (and is typically assigned) a “miscellaneous” code to identify a new laboratory-developed test for billing purposes. The lab can seek from its local Medical contractor a payment rate for the new test using that miscellaneous code because all claims for the test will be submitted to that contractor. This approach is not available for a manufacturer of a comparable test who plans to sell the test to multiple labs around the country.

Some tests (particularly complex molecular tests) can be billed using multiple existing CPT codes that identify the various distinct methods, or steps, taken in performing the test. These “stacked” codes—each with a separate payment rate—can sometimes combine to provide a fair payment to the lab performing the test. However, these generic method codes do not

⁴¹ For more information on HCPCS Codes and how the Centers for Medicare and Medicaid Services maintain this coding system, see: https://www.cms.gov/medhcpcsgeninfo/01_overview.asp.

⁴² Joan Logue, “Federal Reimbursement to Laboratories,” *Clinical Chemistry*, Vol. 42, No. 5 (1996), pp. 818-819.

⁴³ Logue, p. 819.

⁴⁴ Lewin, *The Value of Diagnostics*, pp. 95-99.

identify for the insurer what specific test was performed. In addition, this approach provides disincentives for a lab to develop or to make use of a test which has fewer steps, even if it is a better test.⁴⁵

With the development of new molecular—especially genetic—tests, the current coding system faces challenges in assigning codes that have the necessary specificity to identify new tests. Currently, the AMA CPT Editorial Panel is considering refinements to the way it codes molecular tests.

The Medicare Clinical Laboratory Fee Schedule Needs Modernization. The Medicare Clinical Laboratory Fee Schedule was designed in the early 1980s. In a Congressionally-mandated study examining this payment system that was completed in 2000, the Institute of Medicine concluded that this system was not only “outdated,” but also “irrational.”⁴⁶

Institute of Medicine found the Medicare payment system for diagnostic tests to be deficient in three important areas:

- *Flexibility.* 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.
- *Transparency.* The 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.
- *Administrative Simplicity and Efficiency.* The fee schedule’s administrative operations are 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.⁴⁷

Though some progress has been made in recent years by Medicare to seek stakeholder views during the process of setting rates for new tests,⁴⁸ the underlying problems with the Clinical Laboratory Fee Schedule (e.g., the sometimes wide geographic variation in payment rates for particular tests, the lack of a straightforward methodology to price new tests, the lack of a

⁴⁵ IOM, *Policy Issues in the Development of Personalized Medicine in Oncology: Workshop Summary*, pp. 52-54.

⁴⁶ IOM, *Medicare Laboratory Payment Policy*, pp. 2; 18.

⁴⁷ IOM, *Medicare Laboratory Payment Policy*, pp. 7-8.

⁴⁸ Section 531 of the *Benefits Improvement and Protection Act of 2000* required Medicare to conduct an open, public meeting to solicit stakeholder views on the pricing of new test codes.

mechanism to correct longstanding, historical anomalies in rate-setting or to make adjustments, the frequent lack of year-to-year payment rate updates), combined with deficiencies in coding and uncertainties with respect to coverage, have a direct impact on medical innovation and patient access to new diagnostic tests.

Medicare fee schedule payments do not recognize the value new tests provide. The current rate-setting approach for new tests does not support the return on investment that would support the generation of the evidence needed to fully evaluate clinical performance prior to marketing,⁴⁹ and, by focusing on matching new tests to existing tests (and their payment rates), it provides little reward for creating additional value.⁵⁰ Local variations in payment rates force laboratories to cross-subsidize tests for which payment rates are too low, and they distort laboratory incentives for efficiency, threatening patient access. Because private health insurers use Medicare payment rates as a reference point in setting their own payments, these deficiencies in the Clinical Laboratory Fee Schedule are further magnified.

⁴⁹ Janet Woodcock, “The Human Genome and Translational Research: How Much Evidence is Enough?” *Health Affairs*, Vol. 27, No. 6 (November/December, 2008), pp. 1616-1617.

⁵⁰ President’s Council of Advisors on Science and Technology, *Priorities for Personalized Medicine*, p. 47.