Medicare is the largest single purchaser of clinical laboratory services. Clinical lab services are tests on specimens from the body (such as blood or urine) that are used to diagnose and treat patients. Under Part B, Medicare covers medically reasonable and necessary laboratory services that are ordered by a physician or a qualified nonphysician practitioner when they are provided in a lab that is certified by the Centers for Medicare & Medicaid Services (CMS). With a few exceptions, Medicare does not cover routine screening tests unless directed to by law. Covered screening tests (with some restrictions) include screening tests for cardiovascular disease and colorectal, prostate, and cervical cancer.

The majority of lab services do not involve the work of a physician; these services are paid under the Clinical Laboratory Fee Schedule (CLFS). Lab services that include physician work, such as surgical pathology, are paid under the fee schedule for physicians and other health professionals. This payment basics document describes the CLFS. A separate document, Medicare Payment Basics: Physician and Other Health Professional Payment System, describes the fee schedule for physicians and other health professionals.

Clinical lab services are furnished by labs located in hospitals and physician offices, as well as by independent labs. Services may also be furnished by labs located in dialysis facilities, nursing facilities, and other institutions, but frequently these tests are paid under other Medicare payment systems.

Medicare spending for lab services under the CLFS grew by an average of 3.4 percent per year between 2005 and 2013. This growth was primarily driven by rising volume as there were very few increases in payment rates during those years. Spending fell by 9.0 percent in 2014 because, beginning in 2014, most laboratory tests provided in hospital outpatient departments were no longer paid separately under the CLFS (see below). From 2014 to 2016, Medicare payments for clinical lab services grew by an average of 1 percent per year, with total spending of $8.5 billion in 2016.

To pay for lab services, Medicare uses 56 carrier-specific fee schedules established in 1984. Payment rates for each test were set separately in each carrier’s geographic region, based on what local labs charged at the time; since 1984, the rates have been updated periodically for inflation and other statutory adjustments. In addition, there are national payment limits that cap the fee schedule rates for each test.

**Defining the product Medicare buys**

Medicare sets payment rates for approximately 1,250 Healthcare Common Procedure Coding System (HCPCS) codes used in the CLFS. A single HCPCS code may identify more than one testing method for a given substance or more than one substance analyzed by a single method.

**Setting the payment rates**

Unlike most other Medicare services, there is no beneficiary cost sharing for clinical lab services. Because each carrier established its own fee schedule based on charges from the laboratories in its region, fee schedule amounts may differ by region. CMS has transitioned from 56 carrier localities to 12 Medicare administrative contractor (MAC) jurisdictions. MACs continue to maintain the 56 different fee schedules established by carriers.

Beginning in 1986, the Congress established national limits on laboratory payment rates, called national limitation amounts (NLAs). The NLAs are set at 74 percent of the median of all carrier fee schedule amounts for each service (or 100 percent of the median for tests performed on or after January 1, 2001). The payment for each service is the lesser of the...
provider’s charge, the carrier’s fee schedule amount, or the NLA (Figure 1). Because so many of the carrier payment rates are constrained by the NLAs, most lab services are paid the same national rate. Unlike most other Medicare services, payment rates for lab tests are not adjusted for geographic differences in input prices.

Initially, lab payments were adjusted for inflation annually using the consumer price index for all urban consumers (CPI–U), but since 1987 the Congress has specified lower updates. For 2011 and subsequent years, the statute requires that the CPI–U update be reduced by a multi-factor productivity adjustment (MFP). The net update for 2017 is 0.7 percent.

When labs begin using newly developed tests, CMS uses a “crosswalking” method to assign payment rates based on their similarity to existing tests (Figure 2). For break-through technologies for which there are no similar existing tests, CMS relies on a “gapfilling” method in which the MACs independently set rates for the first year of use. Each MAC sets its own payment amount based on charges for the test and discounts to charges; resources required to perform the test; data from other payers; and charges, rates, and resources used for comparable tests. After one year, CMS sets the national rate at the median of the MAC rates. CMS uses the crosswalking method more frequently than the gapfilling method to set rates for new lab tests. After one year, CMS may reconsider both the payment method (crosswalking or gapfilling) and national payment amount for a new test.

In response to evidence suggesting that Medicare’s CLFS payment rates were excessive, the Protecting Access to Medicare...
Act (PAMA) of 2014 required the CLFS to be based on private payer rates. Beginning in 2017, certain labs are required to report to CMS the rates paid by private payers for the tests they provide. Beginning in 2018, CMS will use these data to set CLFS payment rates at the weighted median private payer rate for each test.

Beginning in 2014, payment for most laboratory tests provided in hospital outpatient departments is packaged with their associated visits or procedures. In other words, these tests are no longer paid separately under the CLFS. Exceptions to this policy include molecular diagnostic tests and tests provided to patients who do not receive other outpatient services during the same encounter. In addition, Medicare pays for all tests provided by critical access hospitals on a reasonable cost basis, instead of under the CLFS.