Medicare Clinical Laboratory Fee Schedule: Time for a Change

BY MICHAEL H. PARK AND JOYCE E. GRESKO

On April 1, 2014, President Obama signed the “Protecting Access to Medicare Act of 2014,” which, among other things, will revamp the way that clinical laboratory tests are priced on the Medicare Clinical Laboratory Fee Schedule (CLFS), the first major overhaul of the fee schedule in its three decades in existence. Laboratories had been preparing for the Centers for Medicare and Medicaid Services (CMS) to adjust prices on the fee schedule based on “technological changes,” a process that the agency set in motion in 2013 and was getting ready to implement later this year. As of the date of enactment of the recently-passed legislation, Congress removed CMS’s authority to make adjustments based on technological changes and instead directed CMS to implement a market-based pricing system for clinical laboratory tests furnished on or after January 1, 2017. These changes usher in an era for the clinical laboratory industry in which Medicare prices reflect private market dynamics, a significant departure from the existing reimbursement system and Medicare policy as a whole. CMS first must develop the parameters and processes for data collection, pricing, and other aspects of the new law, and clinical laboratories and other stakeholders will have several opportunities to shape the process as it unfolds in the coming years.

The Clinical Laboratory Fee Schedule until Now

The CLFS was established in the Deficit Reduction Act of 1984 and currently has about 1,200 distinct codes.1 Initially, for independent laboratories, the fee schedule rates were set at 60 percent of the prevailing charge, which was the 75th percentile of “customary charges” from 1983. The law also provides for an annual update to the rates, based on the Consumer Price Index for all Urban Consumers (CPI-U), although in most years Congress opted for a lower update factor or no update at all.2 Effective July 1, 1984, laboratories were reimbursed the lower of submitted charges or the relevant fee schedule rate. In 1985, Congress mandated the establishment of a National Limitation Amount for clinical laboratory fees, which initially was 115 percent of the median of all local fee schedule amounts for each test but which gradually has decreased to 74 percent of the median (100 percent of the median for new tests performed on or after January 1, 2001).3

In 2013, CMS used the Medicare Physician Fee Schedule (PFS) rulemaking cycle to propose adjustments to prices on the CLFS based on technological changes that have occurred since each test first appeared on the fee schedule, statutory authority that the agency has not exercised in the past.4 CMS proposed adjusting prices based on this authority because “payment amounts are essentially locked in place and do not

---

1 In reality, there is not one national fee schedule; rather, there are 56 state- and territory-based fee schedules. The differences in prices on each of the fee schedules often are negligible. Further, all of the fee schedules are capped by the National Limitation Amounts, and the CLFS works as a de facto national fee schedule.
3 Centers for Medicare and Medicaid Services, Clinical Laboratory Fee Schedule Fact Sheet (April 2013).
change when the cost of the test changes," and it had no other way to adjust fee schedule prices.\(^5\) The agency surmised that the cost of performing many tests has decreased due to efficiencies stemming from more advanced materials, processes, and machinery in clinical laboratories. Each year, beginning with the CY 2015 PFS proposed rule, the agency would identify a set of tests, describe how each of the tests had been impacted by technological changes since they first appeared on the CLFS, and propose associated adjustment amounts. It would begin by reviewing the codes that had been on the CLFS the longest, those with high volumes, those with generous reimbursement, and those that had experienced the highest spending growth throughout the years. Under this plan, new prices would have been announced in the PFS final rule in early November of each year and take effect roughly two months later, on January 1. The new payment amounts would be subject to adjustment based on the CPI-U and the multifactor productivity adjustment included in the Affordable Care Act.\(^6\)

Organizations representing clinical laboratories were wary of CMS’s plans to adjust the CLFS based on technological changes. One unanswered question was where CMS would get information about the technological changes that have had an impact on the cost of performing laboratory tests, how accurate that information would be, and how much of the information the agency would share with the public when proposing new prices. It was not at all clear that CMS had a deep well of laboratory expertise internally, and it rejected the idea of assembling a panel of laboratory experts to help it develop new prices. Laboratories were concerned about the real possibility of large and immediate cuts to reimbursement for certain tests, because CMS’s process did not include any mechanism for implementing cuts over time, or for limiting the amount of reimbursement reductions in any given year. Yet another concern voiced by the laboratory industry was CMS’s failure to acknowledge that, while certain changes in laboratory processes may have decreased the cost of performing some tests, many other changes have increased costs, such as compliance with the Clinical Laboratory Improvement Amendments (CLIA) and implementing regulations. Even after the final rule was issued, the laboratory industry engaged in an ongoing dialogue with CMS and continued to voice its concerns and propose solutions.

**Protecting Access to Medicare Act of 2014**

The main purpose of the Protecting Access to Medicare Act was averting the estimated 24 percent cut to Medicare reimbursement for physicians as a result of the Sustainable Growth Rate (SGR) formula, scheduled to occur on April 1, 2014, if Congress did not act. One of the provisions included in the legislation to offset the cost of avoiding the physician reimbursement cut was a section entitled “Improving Medicare Policies for Clinical Diagnostic Laboratory Tests.”\(^7\) It adds a new section 1834A to the Social Security Act that provides the outline of a process CMS will use to collect data from laboratories on private payor rates paid to them for individual laboratory tests and to develop new market-based prices. It specifies that until December 31, 2016, CMS will use methodologies that currently are in place for pricing, coding, and coverage of laboratory tests. Beginning January 1, 2016, and every three years thereafter, most laboratories that receive a majority of their Medicare revenue under the CLFS or PFS will be required to report to CMS the rates paid to them by each private payor during a particular reporting period for laboratory tests, along with the volume of such tests for each payor for the reporting period.\(^8\) If a lab has different payment rates for the same payor or different rates paid by different payors for the same test, it will be required to report all rates. The information is not to include payments made on a capitated basis, but the rates are to include discounts, rebates, coupons, and other price concessions. An officer of the laboratory company must certify to the accuracy and completeness of the information reported, and Civil Monetary Penalties could be imposed for failure to report, misrepresentations, or omissions. Information reported by a laboratory is not to be disclosed in a way that identifies a payor or laboratory, except in a few limited circumstances.\(^9\)

**Clinical Diagnostic Laboratory Tests**

Medicare reimbursement for most clinical diagnostic laboratory tests furnished on or after January 1, 2017, will be equal to the weighted median of private payor rates for the most recent data collection period, and those prices will stay in effect until the year after the next data collection. (This applies to lab tests furnished by hospital labs, also, when the tests are not bundled with other services.) The weighted median will be calculated by “arraying the distribution of all payment rates reported for the period for each test, weighted by the volume for each payor and each laboratory.” For the calendar years 2017 through 2019, a Medicare payment amount for a lab test cannot be reduced more than 10 percent of the payment amount for the previous year, and for 2020 through 2022, the reduction is limited to 15 percent of the previous year’s rate. (The law does not have any language about reduction limits beyond 2022. Presumably, any remaining reductions would be implemented thereafter, and for tests for which the initial data collection occurs after 2022, there may be no limit on year-to-year reductions.) Payment amounts will not be subject to geographic adjustments, budget neutrality adjustments, annual updates, or “other adjustments.” However, a provision that could

---

6 Pub. L. 113-114, Sec. 3401(b).
8 The term “private payor” includes health insurance issuers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations.
9 The circumstances under which such information could be disclosed are “as the Secretary determines to be necessary” to carry out the new pricing system, or to permit the Comptroller General of the United States, the Director of the CBO, or the Medicare Payment Advisory Commission (MedPAC) to review the information.
be important to laboratories servicing skilled nursing facilities and home health agencies is a $2.00 increase in the sample collection fee that otherwise would apply.  

New Advanced Diagnostic Laboratory Tests

Congress established a separate pricing mechanism for what it termed "new advanced diagnostic laboratory tests." An "advanced diagnostic laboratory test" is one that is offered and furnished only by the developing lab and that meets one of the following criteria: (1) the test is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the Food and Drug Administration (FDA); or (3) the test "meets other similar criteria established by the Secretary." (It is not entirely clear from this definition whether this would apply to new laboratory developed tests (LDTs) that are molecular diagnostic tests or if Congress had another class of tests in mind.) For a new advanced diagnostic laboratory test that has not been paid under the CLFS, the payment amount at first will be "based on the actual list charge"—the publicly available rate on the first day on which the test is available for purchase by a private payor. A lab offering an advanced diagnostic laboratory test will have to report private payor rates to CMS within approximately six months of when the test is offered initially, and CMS will use that data to develop a Medicare rate in the same way it does for other tests, as outlined above. There is one catch: if the "list charge" the lab reported to CMS initially is greater than 130 percent of the market-based rate that the agency eventually calculates, CMS is required to recoup the difference between the two amounts (the legislation does not specify how this recoupment is to take place). CMS also is required to establish temporary codes under the Healthcare Common Procedure Coding System (HCPCS) for new advanced diagnostic laboratory tests and to establish HCPCS codes for such existing tests.

New Tests That Are Not Advanced Diagnostic Laboratory Tests

New tests that are not advanced diagnostic laboratory tests will be paid at first using cross-walking (applying prices for tests that are similar or use similar resources) or gap-filling (Medicare contractors develop specific prices, and in the second year, the National Limitation Amount is the median of the contractor-developed prices). The legislation gives CMS even more leeway in the gap-filling process than it has now; in addition to the four current sources of information CMS can consult when gap-filling, as set forth in regulation, CMS also may consider "other criteria the Secretary determines appropriate."  

Clinical Laboratory Payment Advisory Panel

The legislation authorizes the creation of a clinical laboratory payment advisory panel. The purpose of the panel is to provide input on the establishment of payment rates for new tests, the factors for determining coverage and payment for new tests, and other matters related to the CLFS generally, both for new and old tests. CMS is to create the panel by July 1, 2015, and it is to be composed of those with laboratory expertise, including molecular pathologists, researchers, and health economists. The panel must be formed and conducted in compliance with the Federal Advisory Committee Act. The annual CLFS meeting will continue to be held so that CMS may hear from the public about a wide array of matters related to the CLFS.

Other Provisions

Possibly in response to the way that some coverage decisions for laboratory tests have been issued by Medicare administrative contractors recently, Congress included some parameters for issuance of coverage policies for clinical laboratory tests on or after January 1, 2015. After that date, Medicare administrative contractors may issue coverage decisions for clinical diagnostic laboratory tests only in accordance with the process for making Local Coverage Determinations (LCDs), including appeals and review processes. Henceforth, a coverage decision could not be made via a less formal process, such as through an article released by a Medicare contractor. Congress also gave CMS the authority to centralize coverage decisions and payment processing with one or more Medicare contractors (but not to exceed four).

Finally, the law calls for the Government Accountability Office (GAO) to perform, publish, and submit to the House and Senate committees of jurisdiction a study that analyzes the payment rates, the transition process, the impact on Medicare beneficiaries and laboratories that specialize in a small number of tests, the number of new HCPCS codes, spending trends for laboratory tests, and other issues. In addition, the Office of the Inspector General (OIG) is to publish annually an analysis of the top 25 laboratory tests and expenditures under Medicare and to conduct other analyses of the new payment system.

Rulemaking to Implement the Law

CMS is required to issue regulations by June 30, 2015, that set forth the parameters for laboratories to follow when reporting private payor rates. Although Congress sketched a broad outline for the process, there are many details of the overall process yet to be filled in, and Congress left many other matters for CMS to settle, as well. It is likely that the rulemaking that establishes the process for data collection also will include many other aspects of the CLFS reform law.

With respect to private payor rate reporting for tests currently on the CLFS, Congress left it up to CMS to determine the reporting period. The period could be the most recent quarter's payment rates, or it could be the rates paid in the last year. It also is possible that CMS could propose a longer reporting period and specify that the rate to be reported should be the lowest rate re-
ceived from a payor for a particular test or the average rate received (in the event that rates fluctuate). The format for reporting private payor rates also is left to the agency's discretion. CMS has the authority to establish a low-volume and/or low-expenditure threshold for reporting private payor rates, but the legislation does not require it to do so.

The law states that the payment rate information reported by a laboratory generally would not be disclosed in a way that identifies a payor or laboratory, except in the case of a provider that identifies a payor or laboratory. The Secretary determines to be necessary to carry out the requirements of the law or for review by a handful of other governmental bodies. In rulemaking, CMS could set forth the circumstances under which it could disclose payor or laboratory information. This potentially could help it avoid having to make a case-by-case determination about the necessity of disclosure, and it also could insulate the agency from criticism if it does disclose information in certain instances.

CMS may also determine how broad a spectrum of tests is covered by the term "advanced diagnostic laboratory tests" and how pricing is handled for new tests. Congress defined such tests as those that are offered or furnished only by the developing lab and that either are analyses of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result; cleared or approved by the FDA; or meeting "other similar criteria established by the Secretary." By establishing other criteria, CMS could expand this class of tests to encompass tests beyond lab-specific molecular diagnostics, and stakeholders commenting on a proposed rule may propose other classes of tests that could fit into this category.

Congress gave CMS an opening to reshape the role of Medicare administrative contractors with respect to Medicare coverage and payment for clinical diagnostic laboratory tests. The agency now has the authority to move away from the current system, under which all Medicare Part B contractors make coverage decisions and process claims, to one in which a smaller number of contractors or just one contractor processes all claims. This may result in a Medicare coverage and payment contracting system for laboratory tests that is similar in some ways to that for durable medical equipment, with a limited number of specialized contractors responsible for coverage, claims processing, and payments for the entire industry sector. In a way, CMS has laid the groundwork for using specialized contractors with the MolDX Program that Palmetto GBA administers, assigning one Medicare contractor to establish coverage policies and payment levels for molecular diagnostics if CMS does propose to exercise its option to consolidate coverage and payment decisions with a small number of contractors, the laboratory industry is certain to scrutinize the agency's plans closely. Some laboratories feel that the MolDX Program has operated with less predictability, transparency, and structure than they would like, and they may not be inclined to support a contracting structure that resembles the MolDX program too closely.

The clinical laboratory advisory panel that Congress requires CMS to create may be without precedent or analogy in the Medicare space: an industry-specific, consultative body to provide advice and guidance on coverage and payment and the factors that should be determinative of each. It is similar in concept to MedPAC, which advises Congress on payment and coverage issues for all health care sectors that receive Medicare payments. Congress suggested the types of individuals who should be included on such a panel, but ultimately CMS will determine who serves on the panel and how transparent it will be about how it uses, or does not use, the panel's recommendations. The Federal Advisory Committee Act does not require an agency to accept public nominations for an advisory panel, nor does it prohibit an agency from doing so. Other HHS agencies regularly solicit public nominations for advisory committees, and CMS may follow suit for this panel.

In sum, Congress left a great deal to CMS to sort out in a short period of time before the private payor rate information collection is to begin, less than two years from now. This is not the CLFS reform that CMS expected to be implementing in the coming year, and it may take some time for the agency to switch gears and assemble the right resources to start the implementation process.

What to Watch for in the Months Ahead

The next two years are bound to be extremely busy ones for CMS, as it proposes and finalizes rules to implement the Protecting Access to Medicare Act, and for clinical laboratories that must adjust to an entirely new Medicare pricing system and prepare to report private payor prices to the agency. To be sure, the dust has not settled around the current reform legislation, and how the reforms play out will depend in large part on how CMS develops the implementing regulations and on the choices it makes in developing the process.

On balance, adjustments to the CLFS based on the Protecting Access to Medicare Act may be more favorable than the technological change-based adjustments that CMS was preparing to implement. Many in the laboratory industry have acknowledged that the time was ripe for some sort of changes to the CLFS, whose pricing system has been largely unchanged since its inception. CMS's plan to make adjustments based on technological changes would have been extremely challenging for the laboratory industry as a whole and for certain subsectors of the industry in particular. The expectation is that almost all prices would be reduced and that the process would be less transparent than many stakeholders would prefer. Perhaps most troubling was the fact that there would have been no limits on the amount that the price of a test could be cut in a given year. Some laboratories were concerned about their ability to absorb the expected price reductions.

The scope of the reporting requirements envisioned by the new law is incredibly broad, and a similar experience in California may shed light on the challenges of complying with such requirements. In 2012, the California legislature enacted similar reporting requirements to establish new payment levels for clinical laboratory tests paid for by the California Medicaid program (Medi-Cal). The law requires laboratories to report their pricing information for more than 400 separate codes to the California Department of Health Care Services (DHCS). Affected laboratories are required to submit rates for at least their top five payors for California, not including Medicare and Medi-Cal (but including other state Medicaid programs). If the top five payors do not account for at least 80 percent of the laboratory's private business, additional information must be included. Many laboratories that participate in Medi-Cal had dif-
ficulty assembling the required information by the first deadline on May 31, 2013, and DHCS was forced to extend the deadline for information submission by three months in order to allow laboratories to complete the process. The level of complexity of CMS’s data collection methodology could have an impact on whether clinical laboratories that participate in Medicare will have similar challenges complying with the federal law.

In the coming months, those in the laboratory industry and other interested stakeholders would benefit from learning more about the CLFS reform provisions Congress included in its law and what Congress left up to CMS to decide. Those who are able to should take the opportunity to share insights, expertise, and suggestions with CMS on the various provisions included in the CLFS reform legislation prior to the issuance of any proposed rules. Stakeholders also should monitor the Federal Register for notices and proposed rules from CMS to implement the reforms and submit comments on those aspects or the rules that affect their businesses. And, if CMS solicits public nominations for the clinical laboratory advisory panel, interested stakeholders should consider nominating those with laboratory payment expertise to serve on it.

After CMS issues the final rule by mid-2015, setting forth the process and parameters for private payor rate information collection, laboratories should pay close attention to reporting requirements, formats, and deadlines, and consult with legal counsel for compliance advice. Labs also should consider the resources they will need for data collection and reporting and begin to assemble the right team of individuals and relevant private payor rate information so that they are ready to comply with CMS’s reporting requirements.