Bloomberg BNA

Medical Devices Law & Industry Report™

Medicare Reimbursement for Clinical Laboratory Tests Enters New Waters

BY PETER M. KAZON AND JOYCE E. GRESKO

A new policy released by the Centers for Medicare and Medicaid Services (CMS) in the CY 2014 Medicare Physician Fee Schedule final rule could change the way Medicare prices are determined for clinical laboratory tests.[1] With some minor changes, CMS finalized a proposal from earlier in the year to adjust payments for clinical laboratory tests paid for under the Clinical Laboratory Fee Schedule (CLFS) based on ''technological changes'' in the way tests are delivered, compared to when they were first priced by the Medicare program. This review of Medicare payment rates for lab tests, which is scheduled to begin in 2014, could affect high-volume tests, tests that have experienced high spending growth, and expensive laboratory tests in particular. This follows several other cuts in Medicare reimbursement for laboratory reimbursement in the last several years. The laboratory industry should pay close attention to how CMS decides to proceed with this payment adjustment exercise, which could have an impact beyond the Medicare program.

Adjusting Fee Schedule Amounts Based on ''Technological Changes''

Under the Secretary of Health and Human Services' authority to make adjustments to the CLFS ''as the Secretary determines are justified by technological changes,''[2] CMS plans to review certain codes on the CLFS to determine whether and how much they should be adjusted. CMS defines ''technological changes'' as ''changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.''[3] Each year, beginning with the CY 2015 Physician Fee Schedule proposed rule, the agency will identify a set of codes, describe how each of them have been impacted by technological changes, and propose an associated adjustment amount for each.

Originally, CMS said that it would review codes that have been on the CLFS the longest and work its way forward until it had reviewed all codes, taking about five years to get through the 1,200 or so codes that are on the fee schedule, and it would not review a test for technological changes or propose a new fee schedule adjustment until a code had been on the CLFS for at least five years. CMS ultimately decided that, rather than reviewing the codes roughly chronologically, as proposed, it will examine not only the codes that have been on the CLFS the longest, but also high-volume test codes, those with generous reimbursement, and those that have experienced high spending growth, ''among other considerations.'' Additionally, if CMS identifies codes that are clinically or technologically similar to the ones identified for payment review, it would consider them for review at the same time. The agency did away with the requirement that a code must be on the CLFS at least five years before a pricing review, stating that it is possible that ''new technologies could be developed that make it more or less costly to perform a test'' within a shorter timeframe. In each annual rulemaking cycle, the agency also plans to list the codes for which it thinks there is insufficient information to support or

[1] 78 Fed. Reg. 74230, 74440 (Dec. 10, 2013).

Peter M. Kazon and Joyce E. Gresko are attorneys with Alston & Bird LLP in Washington. Kazon is a member of the advisory board for Bloomberg BNA's Medical Devices Law & Industry Report.

[2] 42 U.S.C. § 1395l(h)(2)(A)(i).
[3] 42 C.F.R. § 414.511.

 ISSN 1935-7230

establish an adjustment to technological changes, and it will solicit comments on those codes.

The public also will be invited to nominate test codes for review, provide information on how the technology for performing the tests has changed over time, and suggest data to support revised payment amounts for the test codes. CMS will retain the discretion to determine which of these publicly-nominated codes will move through the payment revision process. When a member of the public proposes a code in comments on a Physician Fee Schedule proposed rule, CMS will not in the final rule state whether or not it intends to let the code move through the process; rather, when it agrees with the public nomination, it will identify those test codes in the following year's proposed rule, discuss how they have been impacted by technological changes, and propose an associated adjustment. In each year's proposed rule, CMS also plans to list those publicly-nominated codes it determined should not be reviewed for adjustment.

Under this plan, finalized payment revisions would take effect on January 1 each year. This means that the first set of codes that CMS proposes for payment adjustment in the CY 2015 proposed rule, most likely released in early July 2014, would become effective on January 1, 2015. CMS plans to apply the CPI-U and multifactor productivity adjustment after it establishes a new payment amount.

Background on the Clinical Laboratory Fee Schedule

The Clinical Laboratory Fee Schedule was established in the Deficit Reduction Act of 1984 and currently has about 1,200 distinct codes.[4] Initially, for independent laboratories, the fee schedule rates were set at 60 percent of the prevailing charges, 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 mandated a lower update factor or no update at all.[5] 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 (NLA) 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).[6]

In more recent years, Congress has cut CLFS rates even further in its efforts to offset other healthcare-related expenditures. A provision in the Affordable Care Act applied a 1.75 percent downward adjustment to reimbursement for clinical laboratory tests on the CLFS for each of the years 2011 through 2015.[7] A 2012 law reduced the payment amounts on the CLFS in 2013 by 2 percent and established those reduced amounts as the base rates for 2014 and subsequent years. [8] On top of those cuts, the across-the-board budget cuts known as sequestration reduced all Medicare payments, including those for clinical laboratory tests, by an additional 2 percent. All told, many common laboratory tests are paid today at lower rates in actual dollars than they were in the early years of the fee schedule. For example, when adjusted for inflation, the 2013 NLA for a lipid profile is 57 percent less than it was in 1994. A glycosolated hemoglobin test is reimbursed at an inflation-adjusted rate that is 40 percent lower than 1994. A common thyroid function test has seen about a 41 percent decrease in inflation-adjusted reimbursement since then.

Another adjustment to payment rates for clinical laboratory tests is the multifactor productivity adjustment included in the Affordable Care Act.[9] It is to be applied to items and services furnished by Medicare Part B suppliers in 2011 and subsequent years. The U.S. Bureau of Labor Statistics says that multifactor productivity factors such as this reflect ''the joint effect of many factors, including research and development, new technologies, economies of scale, managerial skill, and changes in the organization of production.''[10] In 2014, the productivity adjustment cut 0.8 percent from the CLFS; in 2013, it cut rates by 0.9 percent; and in 2012, it adjusted rates downward by 1.2 percent.

It is against this backdrop that CMS proposed to adjust CLFS rates based on technological changes, stating, curiously, that ''[s]ince there is currently no process to make such adjustments for the CLFS, payment amounts are essentially locked in place and do not change when the cost of the test changes.''[11] Laboratories, whose reimbursements have been affected adversely by Affordable Care Act-mandated cuts, rebasing, sequestration, and multifactor productivity adjustments, probably would disagree.

Widespread Concerns in the Laboratory Industry

CMS has said that a key goal in establishing the technological changes review process is to ensure payment accuracy. Despite this laudable goal, laboratories have not found much to like in CMS's plans to adjust CLFS prices based on technological changes. Chief among laboratories' concerns is that CMS's payment adjustments all will be in one direction – downward. In the proposed rule, CMS said as much: while some prices on the CLFS may increase, it expects that most rates will go down due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend of costs once technology has had an opportunity to diffuse.[12] Many laboratories became uneasy that CMS looked to the recent pricing exercise known as ''gap-filling'' that was used to establish new prices for molecular pathology tests as evidence that the cost of performing many tests has decreased since Medicare Administrative Contractors initially established payment amounts for the

[4] 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 are negligible.

[5] 42 U.S.C. § 1395l(h)(2)(A)(i).

[6] Centers for Medicare and Medicaid Services, Clinical Laboratory Fee Schedule Fact Sheet (April 2013).

[7] Pub. L. 111-148, Sec. 3401(l).

[8] Pub. L. 112-96, Sec. 3202.

[9] Pub. L. 111-148, Sec. 3401(l).

[10] U.S. Bureau of Labor Statistics, Multifactor Productivity FAQs, *available at*: http://www.bls.gov/mfp/mprfaq.htm.

[11] 78 Fed. Reg. 43282, 43350 (Jul. 19, 2013).

[12] 78 Fed. Reg. 44442.

  MELR ISSN 1935-7230

tests.[13] The gapfilling process has reduced Medicare reimbursement for almost all molecular pathology tests, relative to the reimbursement that laboratories were receiving under the previous process-correlated stacking codes.

Many laboratories believe that the yearly multifactor productivity adjustment mandated by the Affordable Care Act already takes into account the effects of any technological changes on costs. CMS plans to adjust prices based on ''changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used,'' while the annual productivity adjustment accounts for ''research and development, new technologies, economies of scale, managerial skill, and changes in the organization of production.'' The overlap in these concepts may end up decreasing payments to laboratories twice for the very same technological changes.

While CMS has identified changes in the laboratory industry that it says have decreased costs, the agency does not seem to have acknowledged other changes in the laboratory industry that have increased the costs of performing laboratory tests since the CLFS was established. For example, the CLFS predates the Clinical Laboratory Improvement Amendments (CLIA), which was passed by Congress in 1988 and which added immeasurably to the complexity of operating a laboratory and performing many tests. Also, computer software and hardware, including the laboratory information systems that now are nearly universal among laboratories, were barely in existence when the first tests were placed on the CLFS and priced. These and other changes have offset at least a portion of any cost reductions wrought by technological changes.

Many questions remain about the transparency of CMS's pricing review process and the relatively short period of time allowed for public comment on codes proposed for pricing review. It still is not clear how many test codes CMS plans to review each year. (Initially, it proposed to review the prices for all 1,200 codes in about five years, meaning that each year, it would have to review upwards of 200 codes.) Even if CMS proposes to review the prices for half as many test codes each year, still, it would be a large number of tests for which it would need to determine the impact of technological changes on costs, perform a data analysis, and propose an associated adjustment amount for each test. This is especially true since there is no ready source of information for how technology has changed for individual laboratory tests over the previous decades and what impact these changes may have had on the cost to perform the tests, and CMS itself does not have a deep well of expertise in this subject area. Some stakeholders suggested that CMS should assemble a panel of laboratory experts to assist it in analyzing technological changes and associated price adjustments, much in the same way that the American Medical Association's Relative Value Scale Update Committee assists CMS in determining appropriate changes to the Physician Fee Schedule. CMS rejected this suggestion, saying that developing a formal advisory committee would be a time-consuming and resource-intensive process.

[13] 78 Fed. Reg. 43350. For a fuller description of billing for molecular pathology tests and gapfilling, see the authors' Dec. 12, 2012, article in Bloomberg BNA's Medical Devices Law & Industry Report (6 MELR 773, 12/12/12).

Many fear that CMS may not conduct any thorough analysis of technological changes to laboratory tests but instead simply may pronounce that technological changes have decreased the cost of performing tests and propose cuts. CMS has said that each year in the Physician Fee Schedule proposed rule, it will list the test codes whose payment amounts it plans to adjust, discuss how the associated tests have been impacted by technological changes, and propose payment adjustments. However, it does not appear that the agency intends to disclose how it derived each new price and the basis for each price adjustment. CMS has said it does not intend to have any public process other than the comment period after the proposed rule is released. This means that an interested stakeholder will have roughly 60 days after a set of codes is proposed to assess each of CMS's price adjustments, assemble data to support or refute CMS's conclusions, and submit comments on the proposed rule. Especially for laboratories that perform many high-volume or high-growth tests, it could prove to be difficult — and expensive — to perform this kind of analysis for many tests simultaneously year in and year out.

Another significant concern that laboratories have is the effect that Medicare's technological changes payment adjustments could have on reimbursement from state Medicaid programs and from private payors. Oftentimes, other payors peg their prices to Medicare prices, either adopting them outright or paying a percentage of those prices. Reductions in Medicare reimbursement for high-volume and high-growth tests in the Medicare program could result in associated reductions in reimbursement from other payors for the same tests.

What to Expect in the Months Ahead

While many in the laboratory industry expect that CMS will in some way take technological changes into account and adjust reimbursement for clinical laboratory tests accordingly, it is not a foregone conclusion that it will happen exactly in the way that CMS plans. The laboratory industry is likely to continue to seek opportunities to work with the agency to build in safeguards to its pricing review process, and many feel that such safeguards are important, especially in the wake of payment reductions made through the gapfilling exercise for molecular pathology tests. As finalized, the regulation at 42 C.F.R. § 414.511 includes only a high-level description of how CMS will proceed. This provides an opportunity for stakeholders to try to shape the details of the process without requiring another round of notice-and-comment rulemaking. Laboratory representatives may push for more information exchange between CMS and affected stakeholders, greater advance notice of tests that may come up for review, and limits on the amount of reductions made to tests in a single year. While CMS has not yet signaled its intention to provide the public with the data it uses to arrive at conclusions about price adjustments based on technological changes, it is likely that CMS will expect any stakeholders who voice dissatisfaction with its process or conclusions to provide the agency with evidence showing why proposed cuts would be untenable. It remains to be seen how flexible the agency will be as it develops its process in the first years.

Other changes could improve the process CMS has contemplated, as well. For example, process-wise, CMS could build a mechanism into its process to give stake-

holders advance notice of the tests that it may propose for adjustment, perhaps through a public meeting, even before the Physician Fee Schedule proposed rule is released each year. For such an advance notice period to be meaningful, it would have to allow enough time for CMS to take stakeholders' views into account and to fine-tune its proposed payment adjustments, if necessary. CMS also could in some way provide the public with access to the data it uses to arrive at pricing decisions, thereby increasing the transparency of the process and giving stakeholders meaningful information to work with. Additionally, if the agency consults with any outside advisors to collect information about technological changes in the past few decades, it could make public the research and conclusions of those subject matter experts. On the numbers side, CMS could offset any payment adjustments by the reductions already taken as a result of the multifactor productivity adjustment. It also could cap a price adjustment for a test to no more than a certain percent in any given year, and it could limit aggregate reductions in laboratory payments resulting from this policy to no more than a certain percentage each year.

Regardless of how CMS proceeds, all clinical laboratories that receive reimbursement from Medicare should consider how best to plan and prepare for the first round of price reviews, which will be announced in the CY 2015 Physician Fee Schedule proposed rule early in the summer of 2014. It may be helpful to gather internal laboratory information on how a particular test was performed when it first was introduced, how the technology has changed throughout the years, and how any changes have increased or decreased the cost of performing the test. If possible, laboratories also should gather information on general changes in laboratory operation and administration that have affected the costs of providing tests, especially those changes made in response to federal regulatory requirements. It is a question of how, and not if, changes are going to come to the laboratory industry as a result of Medicare price adjustments based on technological changes, and as CMS readies itself to implement the changes, laboratories would be well-advised to prepare themselves, as well.

   ISSN 1935-7230