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CMS Proposes More Cuts to Lab Payments; Pathology Services Could See 26% Hit

The proposed physician fee schedule for 2014 will be published in the July 19 Federal Register. *Comments will be due 60 days after publication.*

If the ongoing Medicare payment cuts for clinical laboratory services weren't enough, the Centers for Medicare and Medicaid Services (CMS) is now proposing to reduce payment under the clinical laboratory fee schedule to reflect technological changes.

In addition, CMS is also proposing to cut Medicare payment for pathology codes by 26 percent overall when services are provided by independent laboratories. These cuts are generally related to CMS's proposal to cap the payments for certain nonfacility services at the facility rate plus the lower of the outpatient payment or ambulatory surgical center rate and its proposal to revise the Medicare Economic Index and adjust relative value units.

While the actual impact of these proposed cuts will depend on a lab's test mix, the technical component of some tests may be cut by 50 percent to 70 percent, say sources.

CMS proposed the changes as part of its 2014 physician fee schedule proposed rule, announced July 8.

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Court Dismisses Labs' Lawsuit Against Aetna Alleging Improper Exclusion From Network

A federal trial court has dismissed a lawsuit filed by several independent clinical laboratories in California accusing Quest Diagnostics of conspiring with large health insurers to exclude competing labs from in-network designation (*Rheumatology Diagnostics Laboratory Inc. v. Aetna Inc.*, N.D. Cal., No. 3:12-cv-5847, 6/25/13).

The U.S. District Court for the Northern District of California said claims filed by Rheumatology Diagnostics Laboratory Inc. and other excluded laboratories, which alleged the conspiracy was designed to drive competing labs out of business, failed to plausibly allege that the defendants conspired to restrain trade or that Quest monopolized the relevant markets in violation of the Sherman Act or California's Cartwright Act.

The court specifically found allegations of a conspiracy among the defendants were inadequate and that claims that defendants engaged in an unreasonable restraint of trade or were monopolizing or attempting to monopolize the laboratory services market were not adequately supported.

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CMS Proposes More Cuts to Lab Payments, *from p. 1*

Adjustments for Technology

Under the clinical laboratory fee schedule (CLFS), once payment is established there is only one opportunity for CMS to reconsider the basis or amount of payment (within one year of when payment is set). Once the reconsideration process is complete, payment is not further adjusted except by a change in the consumer price index for urban areas (CPI-U), the productivity adjustment, and any other adjustments required by state.

In 2013, lab fees were cut by 4.95 percent due to a combination of reductions in the CPI-U, the productivity adjustment, the Patient Protection and Affordable Care Act, a 2 percent cut to help pay for this year's Medicare physician fee fix, and the 2 percent across-the-board sequester. This year marked the third time in four years that the lab fee update has fallen into negative territory.

"This lack of an established mechanism to adjust payment amount is unique among the Medicare payment schedules and systems," says CMS, noting that generally fee schedules are evaluated and adjusted each year to reflect the changing mix of services.

According to CMS, there has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS, which has resulted in the increased use of point-of-care testing, brand new tests being developed, and the proliferation of laboratory-developed tests. These advances, says CMS, have made testing more efficient and automated.

"There are also brand new technologies that did not exist when the CLFS was established, most notably genetic and genomic tests," writes CMS. "The cost of sequencing a genome has dropped dramatically since the early inception of this

CMS Wants to Bundle Payment For Lab Tests Under Outpatient Payment

In a separate rule announced July 8, CMS is proposing to package payment for certain clinical diagnostic laboratory tests into the base payment for the ambulatory payment classification under the outpatient prospective payment system (OPPS).

Since the beginning of the OPPS, clinical laboratory tests provided in hospital outpatient settings have been separately paid to hospitals at clinical laboratory fee schedule rates and have been excluded from the OPPS.

"It is our intent to make the OPPS a more complete prospective payment system and less of a fee schedule-type payment system that makes separate payment for each separately coded item," writes CMS in its OPPS proposed rule for 2014. "We have examined the services performed in the hospital outpatient setting to determine those services that we believe should be packaged in order to make the OPPS a more complete and robust prospective payment system. . . . Based on this approach, we believe that laboratory tests . . . that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient settings are services that should be packaged."

Molecular pathology tests (CPT 81200-81383, 81400-81408, and 81479) would be exempt from this proposed packaging policy since CMS believes these relatively new tests have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting.

technology in 2001 from more than $95 million per genome to approximately $5,700 in early 2013."

Five-Year Review

CMS is proposing a process under which it will systematically re-examine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount.

"We believe such adjustments could be made both to increase fee schedule amounts (for example, in situations where new high-cost technologies are employed), and to provide for reductions in existing amounts (for example in situations where technology reduces costs through increased efficiencies)," writes CMS. "We expect that most payment amounts will decrease 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."

CMS proposes to begin reviewing codes that have been on the CLFS the longest and then work its way forward, over multiple years, until it has reviewed all of the codes. The agency says it will begin the review in 2015 and estimates it will take at least five years to review all of the existing codes.

The American Clinical Laboratory Association says it is deeply concerned with the proposals to cut lab and pathology payments, particularly since they come on the heels of a series of devastating cuts already experienced by clinical laboratories this year.

Despite clinical labs accounting for just 1.6 percent of annual Medicare spending, payments for lab services have been cut by more than 11 percent since 2010 and face double that amount over the next nine years.

Lab Groups Seek Wide-Ranging Changes In Molecular Pricing Initiative

While a variety of trade associations representing the laboratory sector have submitted their comments to the Centers for Medicare and Medicaid Services (CMS) regarding price-setting for molecular tests, their voices are unified on the issue: the process is flawed, and changes should be made immediately.

In their remarks, leaders from the American Clinical Laboratory Association (ACLA), the Association for Molecular Pathology (AMP), and the California Clinical Laboratory Association (CCLA) have criticized CMS in how it has handled the shift from the code-stacking to the gap-fill methodology to determine molecular test pricing. Two of the associations suggested the use of the crosswalking process instead.

CMS announced interim pricing on 114 Tier 1 and Tier 2 tests in May (*NIR, May 9, 2013, p. 1*). The interim pricing is based on rates determined by Medicare administrative contractors (MACs) using the gap-fill methodology. CMS is expected to release final pricing by Sept. 30 and will use that data to set national pricing for next year.

However, many labs say that as a result of the delays in setting concrete prices, they have not even been paid by MACs for the molecular testing they have performed

this year. The pricing released by the MACs has also varied widely. Many labs say the prices in some instances will not even cover their costs for performing the tests.

"Had the stacking codes still been in place or CMS required that the MACs determine pricing by Jan. 1, these laboratories would not face this challenging situation of providing much-needed patient care without compensation for the services already rendered," AMP President Jennifer L. Hunt, M.D., said in her comments to the CMS.

"We repeatedly have voiced our concerns with the lack of transparency in the instructions that CMS has given to contractors who priced the molecular pathology tests and in the methods the contractors have used to arrive at their prices," wrote ACLA President Alan Mertz. "Prices for several of the tests are set too low, and the proposed prices will not even cover the costs of furnishing some tests by some laboratories. We also are concerned that certain contractors used the gap-filling exercise inappropriately to create new non-coverage policies."

"CMS did not provide adequate directions to the MACs on what data to collect; contractors did not understand nor did they have the resources to assemble appropriate costing data; the contractors did not have the resources to evaluate the costing data appropriately; and, finally, laboratories have difficulty accurately identifying all the cost information without specific direction."

— Jennifer Hunt, M.D., AMP President

According to a letter penned by Michael Arnold, president of CCLA, one of the most active state-level trade groups, the recent recoding of molecular tests by the American Medical Association led to a "re-pricing initiative" by CMS that translated to reimbursement cuts ranging from 20 percent to 80 percent.

Mertz and Hunt were also critical of the lack of transparency among the MACs and noted that few have been willing to engage in dialogues with the laboratories regarding price-setting. And in some instances, Mertz said, contractors appeared to simply copy the Tier 1 prices set by Palmetto GBA, which employed its MolDX program in part to arrive at its pricing.

"CMS did not provide adequate directions to the MACs on what data to collect; contractors did not understand nor did they have the resources to assemble appropriate costing data; the contractors did not have the resources to evaluate the costing data appropriately; and, finally, laboratories have difficulty accurately identifying all the cost information without specific direction," Hunt wrote. "The premise that this process can lead to accurate and fair pricing policy cannot be supported."

Arnold was highly critical of the gap-filling methodology itself. "This has historically proven to be a very flawed process at best in the very few single, isolated cases where it has been attempted in the past decade," he wrote.

Both Arnold and Mertz suggested that the crosswalking process is a better methodology to use to set prices. Arnold wanted it applied retroactively to last Jan. 1.

Mertz also asked for assurance that when national lab prices are released, the "median price will be the median of all the contractor prices, not the median of the individual state prices set by the contractors."

Court Dismisses Labs' Lawsuit Against Aetna, *from p. 1*
Judge Jon S. Tigar granted the defendants' motions and dismissed the plaintiffs' complaint with leave to replead.

Challenged Conduct

Rheumatology Diagnostics Laboratory Inc., Pacific Breast Pathology Medical Corp., Hunter Laboratories LLC, and Surgical Pathology Associates sued Blue Shield of California Life & Health Insurance Co. (BSC), Blue Cross and Blue Shield Association (BCBSA), Aetna Inc., and Quest Diagnostics Inc., alleging that they had conspired to allow Quest to monopolize markets for specialized testing. According to the plaintiffs, Quest has 70 percent of the market in Northern California for outpatient laboratory testing.

BCBSA in 2012 revised its licensing agreement for BCBS plans or "Blues plans" to require labs to submit claims to a patient's home Blues plan. This requires labs to develop claims submissions processes for each Blues plan area nationwide and cross-reference each patient to the appropriate plan coverage area, regardless of where the patient's sample was drawn or where the lab is located.

According to the plaintiffs, this made it impossible for independent labs to obtain in-network status for each BCBS plan where a patient may need to submit a claim. The plaintiffs alleged that this makes them lose business to the only two in-network labs for all Blues plans, the largest of which is Quest Diagnostics.

The result of these two changes to the licensing agreement, the plaintiffs contended, is to drive the Blues plans in every state into nearly exclusive arrangements with Quest, which has a national presence, because specialty labs located in other states are unable to negotiate in-network status with all 38 Blues plans.

The new licensing agreement also changed how claims are paid to out-of-network labs. Instead of paying a lab directly, even when the lab has a valid assignment of benefits from the patient, BCBSA's agreement mandates only payment directly to the patient. This, the independent lab plaintiffs alleged, forces them to absorb extra costs chasing down those payments and engaging in collections against patients.

Exclusion From Market

The result of these two changes to the licensing agreement, the plaintiffs contended, is to drive the Blues plans in every state into nearly exclusive arrangements with Quest, which has a national presence, because specialty labs located in other states are unable to negotiate in-network status with all 38 Blues plans. In fact, the plaintiffs alleged, many Blues plans simply refuse to add other labs to their network, and a few have open, exclusive contracts with Quest. The plaintiffs alleged that it is no accident that Quest gets all BCBS business under the contract changes and that BCBSA and Quest initiated this policy change together.

The plaintiffs also complained that Aetna, at Quest's behest, dropped 400 regional labs from in-network status. While Aetna denied Quest's request for an exclusive contract in return for steep discounts, the plaintiffs alleged, it did agree to kick out Quest's main competitors (including Hunter Labs) and to give Quest a right of first refusal that permits Quest to control what labs are allowed in-network status. The plaintiffs also alleged that Aetna discourages doctors from using independent labs even when their patients' policies allow for it.

For its part, the plaintiffs alleged that BSC accepted a 10 percent discount on Quest's services to exclude two of its competitors from the Blue Shield network.

The plaintiffs contended that the combined effect of these contractual practices is to drive them from the market because they cannot compete with Quest's reimbursement rates as out-of-network labs. They alleged that Quest conspired with both insurers to restrain trade in an attempt to monopolize specialty lab testing and that they are directly harmed—along with competition among all labs for business through the insurers—as a result.

The plaintiff labs alleged that the insurers and Quest violated the Sherman Act, California's Cartwright Act, and California's unfair competition law and committed intentional and negligent interference with the plaintiffs' prospective business. The plaintiffs also alleged that Quest violated California's Unfair Practices Act by engaging in predatory pricing and agreements with doctors that violate the anti-kickback statutes.

The defendants on Feb. 7, 2013, moved to dismiss the complaint for failure to state a claim.

Conspiracy Claims Fall Short

In dismissing case, the judge concluded that the plaintiffs failed to sufficiently argue that the insurers conspired with each other to enter into agreements with Quest; that the 10 percent discount Quest provided BSC for kicking two competitors out of its network harmed any labs other than the two excluded competitors; that Aetna's policies are damaging enough to competitors to be illegal, given that Aetna only insures 9 percent of people in America; that Quest has a monopoly or monopoly power in the markets identified; and that BCBS conspired with Quest in formulating its policy to exclude out-of-state labs from its network.

The plaintiffs have 45 days from the date of dismissal to file an amended complaint.

The complete ruling from the judge is available at *http://scholar.google.com/scholar_case?case=15610249581814621311&q=rheumatology&hl=en&as_sdt=2,26&as_ylo=2013*.

States Weigh in on EHR Donations by Labs

Tennessee Attorney General Robert E. Cooper Jr. (D) issued an opinion (No. 13-51) July 2 affirming that state law prohibits clinical labs from donating electronic health record (EHR) technology to doctors with which they have referral relationships.

The Tennessee Medical Laboratory Act bans labs licensed in the state from soliciting business in any way that implies an offer of rebates, fee-splitting inducements, or other unearned remuneration, according to the AG's opinion. The donation of EHRs by a lab to a physician would fall under those conditions, under the AG's analysis.

The opinion noted that labs licensed in Tennessee could donate EHR technologies or make monetary donations for EHR purchases to physicians in other states. The opinion was requested by Tennessee state Sen. Reginald Tate (D).

Cooper's office issued a similar opinion in March. That opinion had been requested by Sen. Doug Overbey (R).

The Tennessee prohibition exists despite protections at the federal level for EHR donations under the anti-kickback statute and physician self-referral law. Under the existing anti-kickback statute safe harbor and physician self-referral law exception, such technology donations by clinical labs to doctors would be protected, but those provisions do not preempt state law.

Those protections expire at the end of the year, and the Centers for Medicare and Medicaid Services and the Department of Health and Human Services Office of Inspector General have proposed extensions. However, the agencies indicated in the proposed rules they could restrict protected donors, with a specific eye on clinical labs as high-risk donors that could be excluded from future protections.

In a separate state development, the Washington State Legislature passed a bill that aligns the state's anti-rebate statute with the federal anti-kickback statute, essentially granting greater protection for EHR donation programs.

The action came in response to a recent opinion by the Washington attorney general suggesting that a clinical laboratory's donation of EHR technology to a physician customer violated the anti-rebate statute. It was drafted by the Washington State Hospital Association and the Washington State Medical Association.

Physicians and clinical anatomic pathology laboratories have long been at odds over the EHR issue, with some labs and pathology groups complaining that they are essentially blackmailed into covering 85 percent of the cost of physician's EHR software or else risk losing them as referral sources.

July Update of CLIA-Waived Tests, Billing Codes

The July 1, 2013, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes six tests approved by the Food and Drug Administration.

When billing for the tests below, you must use the QW modifier. This enables your local Medicare contractor to recognize the code as waived.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
82274QW G0328QW	Jan. 3, 2013	OSOM iFOB Test OSOM iFOBT Contol Kit
87804QW	Feb. 13, 2013	B Henry Schein OneStep+ Influenza A&B Test
G0434QW	Feb. 27, 2013	American Screening Corporation Discover Drug Test Cards
G0434QW	Feb. 27, 2013	American Screening Corporation Discover Multi-panel Drug Test Cups
81003QW	March 15, 2013	Moore Medical, mooremedical Urine Analyzer U120
82055QW	March 25, 2013	Chematics Inc. Alco-Screen Saliva Alcohol Test

The July update, plus a complete list of CLIA-waived devices, can be found in Change Request 8301, at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2734CP.pdf*.

CMS Gets Pricing Advice for New 2014 CPT Lab Codes

Clinical laboratory representatives gathered at the headquarters of the Centers for Medicare and Medicaid Services (CMS) this week to give recommendations on pricing of new and reconsidered codes for the 2014 Medicare clinical laboratory fee schedule.

While CMS officials requested that meeting participants not give recommendations on pricing of new molecular pathology (MoPath) codes currently being priced through the gap-filling process, there are two new Tier 1 molecular pathology procedures that were open for comment: CPT 81161—DMD, used for diagnosis of Duchenne/Becker muscular dystrophy, and CPT 812XX—MGMT (O6-methylguanine DNA methyltransferase), used for diagnosis and treatment of brain cancer.

The American Clinical Laboratory Association (ACLA) in its comments said it considered recommending a crosswalk to one of the existing Tier 1 or Tier 2 MoPath codes, but with pricing still in flux and some carriers not pricing all the codes, there is no sufficient crosswalk at this time. ACLA recommends that CMS take the median of the code stacks that were used to bill this test prior to the adoption of the Tier 1 MoPath codes.

For more on recommendations presented at the July 10 lab meeting, see the next issues of *Laboratory Industry Report* and *National Intelligence Report*.

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