LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

ACLA Files For Summary Judgment, But Judge's Decision Unlikely Until Spring

As scheduled, the American Clinical Laboratory Association (ACLA) filed a motion for summary judgment on February 14 in its lawsuit against the U.S. Department of Health and Human Services (HHS). The lawsuit argues that CMS wrongly excluded the vast majority of labs, including nearly all hospital labs, from reporting private-payer data used to calculate new Medicare clinical lab test rates.

A decision from Judge Emmet G. Sullivan is not likely at least until after HHS files its response (due by March 16), and probably won't come until after all counter-arguments have been filed in mid-April.

Karen Lovitch

Historically, the courts have shown a high level of deference to interpretations of statutes made by those government agencies charged with enforcing them. "There's a high bar to challenging an agency, but it's not out of the question," according to Karen Lovitch, Practice Leader of the Health Law Practice at Mintz Levin (Washington, DC).

In its motion for summary judgment, ACLA argued that HHS's exemption of hospital laboratories from the PAMA reporting requirements is inconsistent with the statute's design, structure, and purpose. "Collecting data from a small, cherry-picked sample of laboratories does not come close to completing the task that Congress assigned. The Secretary's refusal to comply with Congress's mandate should not be tolerated. Instead, the Court should strike down the Secretary's final rule."

Although it may be a long shot, if Judge Sullivan rules in favor of ACLA, then the reimbursement rates for the 2018 Medicare CLFS would revert back to the 2017 levels, HHS would need to rewrite the definition of "applicable laboratory" so as to include hospital labs, and the private-payer data collection process would start over from scratch.

Laboratory Economics' PAMA Teleconference Highlights

During *Laboratory Economics'* special teleconference on February 1, Lovitch noted that ACLA may be using the suit to gain the attention of Congress and to force HHS to the bargaining table. ACLA is likely to be seeking an amendment to PAMA that would require hospital outreach labs to report their private-payer lab test rates during the next data collection period (Jan. 1, 2019 to June 30, 2019). CMS will use this information to set CLFS rates for 2021-2023.


Tom Hirsch

In the meantime, the prudent thing to do is assume that this year's 10% rate cut for most routine lab test codes on the Medicare CLFS will be followed by additional 10% reductions in both 2019 and 2020 as scheduled, advised Tom Hirsch, President of Laboratory Billing Solutions (Portsmouth, NH). "These cuts will eliminate any margin for most labs, unless they take corrective action. The train has left the station and you better start dealing with it quick."


Lale White

The million dollar question now is "Can labs stop private insurance companies from reducing their rates based on the new lower Medicare CLFS rates?" Labs have their greatest negotiating leverage for new assays, according to Lale White, President of XIFIN Inc. (San Diego). And she notes that hospitals that negotiate their contracts as a percentage of billed charges have leverage. "But for routine commodity tests, it's really difficult and a lot of payers have a 'take it or leave it' attitude when it comes to contracts."

Below we summarize answers by Lovitch, Hirsch and White to some of the key questions raised during *LE's* special teleconference, *Medicare's Market-Based Payment Start-Up: Strategic Options & Compliance Red Flags for Laboratories*.

Are there any penalties for applicable labs that did not report their private-payer data to CMS as required by PAMA?

Yes. The statute authorized CMS to impose civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation or omission in reporting applicable information. "But as far as I know, CMS hasn't done anything to figure out if any labs that were supposed to report, did not," said Lovitch.

If hospital outreach labs are required to report their private-payer payment rates in the next reporting period (Jan. 1, 2019 to June 30, 2019), can they do it?

White noted that most hospital outreach labs bill through their hospital's main billing department where lab payments are posted in a bundled fashion for an entire claim instead of at the CPT code level. As a result, the level of detail needed to report PAMA data has historically not been retained. "I'm hoping that hospitals have started to retain their ERA data and source data from which they could actually extract private-payer payments details."

Are there any winners under the new market-based CLFS?

Single source labs and specialty genetic labs fared the best with PAMA because they control their market pricing, according to White. Myriad's myRisk Hereditary Cancer Test, Veracyte's Affirma Gene Expression Classifier, Genomic Health's Oncotype Dx Breast Cancer Test, and CareDx's
AlloMap all received rate increases of between 6% and 14%.

In addition, White noted that hospital outreach labs that do business under the hospital's NPI with contracts that are "a percentage of billed" have the ability to establish their own market pricing with private payers. "If these labs manage their contracts well and begin to run their labs as a revenue center with financial controls, they will not only have better margins than commercial labs, but they will have an opportunity to gain market share in regional areas where smaller labs will be disadvantaged."

Has CMS issued further guidance on Advanced Diagnostic Laboratory Tests (ADLTs)?
No. CMS has stated that it will require laboratories to submit documentation to support their application for ADLT status, including evidence of their empirically derived algorithms and how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. However, CMS has yet to release the application to be used for this purpose or any other guidance on the process, according to Lovitch.

What's the process for labs to follow in applying for a proprietary laboratory analyses (PLA) code and how is Medicare paying for these tests?
The process, as well as the current list, are on the AMA website. CMS issued about 30 PLA codes last year, noted White.

CMS is obligated to accept claims for the new codes. However, Medicare coverage is not guaranteed. Commercial payers are also not obligated to provide coverage for these new codes. Most labs that applied for codes have policies in place with at least some payers and agreements that the PLA is the code to use.

The downside to getting a PLA are that they now become established on the CLFS and therefore become reportable under PAMA. If not covered, the tests are now easier to identify by payers and easier to edit for denial versus using a not otherwise classified (NOC) code that may result in attachments and/or subsequent appeals that require more thorough payer consideration for payment or denial.

White said that getting a PLA code is generally beneficial only after coverage and pricing from private payers has been established.

Why did CMS choose not to finalize the private-payer rates for the definitive drug testing "G" codes?
CMS made a revision to its final CLFS for 2018 which excluded the private-payer rates calculated for the definitive drug screen codes (CPT G0480-G0483) because their code descriptions and Medicare rates were changed in 2017, after the initial private-payer survey period had ended, explained White.

The new calculation for the 2018 Medicare rates for these codes was derived from the fee for CPT 82542, resulting in a less drastic 2.7% reduction (*see page 13*).

In the future, rates for the definitive drug screen codes will probably be based on a pure PAMA private-payer market analysis.

Is there a potential compliance problem for labs customizing chemistry test panels (n-1) to take advantage of Medicare's new Automated Test Panel (ATP) payment policy?
"This is a loophole that I think will be quickly addressed by CMS. And I wouldn't advise labs to try and resuscitate their business by, for example, offering a metabolic profile with three less tests so they can bill for the individual tests and get four times the money," said Hirsch.

Anytime a laboratory is offering a panel on its requisition that was created by the laboratory, it should implement compliance safeguards to encourage physicians to order only medically

necessary testing, advised Lovitch. She said that custom panels and medical necessity are a focus of Medicare contractors and enforcement agencies.

According to Lovitch, compliance safeguards for custom panels should include, at a minimum:

- Offering only those custom panels for which the laboratory can document clinical utility for each test included.
- Clearly disclosing the contents of each test panel on the requisition.
- Educating physicians regarding Medicare's medical necessity requirements (e.g., in the annual notice to physicians, on the lab's website, in marketing materials, etc.).
- Including a medical necessity certification on the requisition and requiring a physician signature.

What are some strategies that labs should consider to cope with the rate reductions?
The PAMA reporting exercise showed that the financial systems that are in place at many labs, especially at hospital labs, are simply not adequate to capture the level of data required to recognize revenue and make collections. Stronger more automated financial systems will help labs not only report PAMA pricing information, but could also help them collect an estimated 5-10% of revenue that's written off from their accounts receivable because it's too expensive to collect using manual labor, according to White.

In addition, Hirsch said that labs will need to look at their costs for collecting samples. "You see other industries under price pressure that have eliminated some service elements and made their customers provide it. Lower reimbursement is going to be a reality in the laboratory space. So if you have a phlebotomist in a doctor's office or visiting a nursing home that draws only seven patients per day, you may need to tell that office to draw those patients yourself, I can't afford to have an FTE there," noted Hirsh.

And finally Hirsch emphasized the need for all labs to move away from payer contracts that adjust based on the current Medicare CLFS. "If you have a payer contract that's set as a percentage of Medicare's CLFS, you need to have it fixed to the 2017 CLFS or earlier. If someone is negotiating with payers based on the current CLFS or one that can be adjusted every year, you're setting yourself up for death."