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Medicare Reimbursement: CMS Provides Needed PAMA Relief—But Newly Covered Hospital Labs Must Report in 2019

The battle between CMS and the lab industry over Medicare Part B pricing for lab tests **could be on the road to resolution** notwithstanding the ACLA's recent court loss. **But even as the legal battle continues, the** final 2019 Clinical Laboratory Fee Schedule (CLFS) (Final Rule) **offers significant relief that may**

CMS Definition of Applicable Laboratory

An entity that's a laboratory (as defined in CLIA) that bills Medicare Part B under its own NPI and/or that gets more than 50% of its Medicare revenues during a data collection period from the CLFS and/or Physician Fee Schedule (PFS). Applicable labs must also meet a "low expenditure threshold," i.e., get at least $12.5K of Medicare CLFS revenues for clinical diagnostic lab tests that are not advanced diagnostic lab tests (ADLTs).

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Kickbacks: OIG Okays Incentivizing MDs to Order More Early Screening Tests

Proactive rather than reactive has become a mantra of the modern health care model. Early and periodic testing of patients is a critical element in this strategy. The problem is that not a lot of physicians have gotten the "memo." Consequently, payors may have to prod physicians out of their old school ordering patterns by offering incentives to increase early and periodic screenings, diagnostic and treatment (EPSDT) services. The problem, of course, is that paying physicians incentives to order tests is a blatant kickback violation. So it might surprise you to know that a

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result in higher Medicare reimbursement rates for all labs. At the same time, it may also imperil the hospital labs that are now subject to pricing data reporting requirements but may not realize it.

One major part of the problem is the current definition's reliance on NPI number which precludes hospital outreach labs that bill under the hospital NPI from counting as "applicable laboratories." In the Final Rule, the CMS acknowledges the problem and characterizes the arguments made by industry during the comment period to include more hospital outreach labs as "particularly compelling."

> Simply stated, CMS wants more hospital representation but not too much more.

At the same time, the comments also reveal the agency's hand and the essence of its philosophical difference with industry. Simply stated, CMS does want more hospital representation but not too much more. Reasoning: By basing the definition on CLFS/PFS rather than inpatient and OPPS revenues, the intent of the PAMA legislation is to exclude hospital labs and "limit reporting primarily to independent laboratories and physician offices."

A Significant Concession

Notwithstanding its reservations, CMS included a significant change in the Final Rule by adopting an American Clinical Laboratory Association recommendation to treat hospital outreach labs that use the Form CMS-1450 14x TOB to bill for non-patient lab services as "applicable laboratories."

Result: Many hospital outreach labs that had been **prohibited** from providing commercial payor information to CMS are now *required* to provide this data. Robust reporting from hospital labs could positively impact future Medicare reimbursement rates for all labs.

No Time to Waste

This is a potential game changer that positively impacts Medicare reimbursements for all labs. The tricky aspect of the change is that it takes effect **in the next data collection and reporting periods** (Jan. 1, 2019 thru June 30, 2019, and Jan. 1, 2020 thru March 30, 2020, respectively).

The risk is that hospital outreach labs may not realize that they're now considered "applicable laboratories" who are required to report their pricing data. Applicable laboratories that fail to report could be subject to civil monetary penalties of up to $10,000 per day for each day they fail to report.

A Less Significant Concession

In addition to addressing the hospital labs situation, the Final Rule provides

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for more PAMA relief by excluding Part C Medicare Advantage payments from the denominator by which the CLFS/PFS numerator is divided. The Final Rule, in other words, makes it easier for labs with significant MA plan revenues to qualify as "applicable labs" under the majority of Medicare revenues threshold (see the shaded box above for the technical definition of "applicable laboratory).

While a step in the right direction, these changes aren't nearly as significant as the hospital outreach lab concessions, especially since they wouldn't kick in for another two years. "These modifications are insufficient because the changes outlined in the final PFS rule will not take effect until 2021. Regional and community clinical laboratories face an unsustainable 10% cut in less than two months, on January 1, 2019," according to an NILA and AAB statement.

Future Lab Reimbursement Issues Still on the Table

The Final Rule addresses but reserves for later determination issues affecting future Part B reimbursements for lab tests, including:

Weighted Median Pricing: Some industry groups have called for a "weighted median" formula for calculating Medicare reimbursements which would consider the percentage of hospital labs in relation to the total market. For example, if hospital labs make up 20% of the market, data from those facilities would be weighted to 20% of the final calculation.

Low Expenditure Threshold: Another big concern for the lab industry is CMS' proposal to reduce the "low expenditure threshold" for reporting private payor lab prices by 50%, from $12,500 to $6,250. Reducing the threshold wouldn't make a significant impact on PAMA pricing and could overburden small labs, industry experts argue.

LDTs: FDA Approves First NGS Residual Cancer Detection Test

The FDA broke new ground by allowing marketing of Adaptive Biotechnologies' ClonoSEQ assay, a next generation sequencing (NGS)-based test for minimal residual disease (MRD) in patients with acute lymphoblastic leukemia (ALL) or multiple myeloma.

The ClonoSEQ Assay

ClonoSEQ, which uses NGS technology to assess disease burden, is the first and only assay to be cleared by the FDA for MRD assessment in any lymphoid cancer and the first FDA-cleared diagnostic assay powered by immunosequencing.

"Determining whether a patient has residual cancer cells remaining after treatment provides information on how well a patient has responded to therapy and how long remission may last. Having a highly sensitive test available to measure minimal residual disease in ALL or multiple myeloma patients can help providers manage their patients' care," noted FDA Commissioner **Scott Gottlieb**, M.D.

PCR v. NGS

MRD is a general measure of the amount of cancer in the body (tumor burden), specifically the number of cancer cells that remain in a person's bone marrow, either during or after treatment. Measuring MRD provides a tool to detect very low levels of tumor burden. MRD is useful to evaluate in patients who have responded to therapy when their tumor burden is below what can be detected with standard methods. The detection of MRD is associated with recurrence of the disease in those patients. Currently, providers test for MRD using diagnostics called flow cytometry assays or polymerase chain reaction (PCR)-based assays. Those methods are usually capable of measuring MRD down to 1 in 10,000 or 1 in 100,000 cells.

By contrast, ClonoSEQ is an in vitro diagnostic that uses multiplex PCR and NGS to identify and quantify certain gene sequences in DNA extracted from bone marrow from patients with ALL or multiple myeloma. The ClonoSEQ assay measures the amount of MRD and is capable of detecting MRD at levels below 1 in 1 million cells.

"MRD testing provides patients with real-time insights about their response to therapy or the depth of their remission, therefore the MMRF is deeply committed to this important advancement in patient care," noted **Paul Giusti**, president and chief executive officer of the Multiple Myeloma Research Foundation. "The sensitivity of the test is extremely important, as the number of cells remaining after treatment has been linked to patient outcomes. This clearance provides patients and physicians with access to a highly sensitive, standardized MRD test that can be an important tool in guiding treatment decisions."

Medicare Appeals: CMS Tries to Speed the Process & Unjam the Backlog

On Oct. 2, CMS proposed revisions to rules for appealing adverse Medicare claim determinations (Proposed Rules). The goal is to speed the process that currently takes three to four years and loosen the backlog that has been damming the appeals flow for years.

Why Should You Care?

Having to wait several years is problematic for any business, notes **Stephen Azia**, a shareholder with Baker Donelson. And, while you can defer any required Medicare repayment during the first two levels of appeal, you must pay out the money before starting the third (although you may be to get an order staying repayment). "That can put you out of business," says Azia.

How Medicare Appeals Work

Labs and other providers denied a Medicare Parts A, B, or D, claim may appeal through four levels:

- The first two levels are with contractors;
- The third level is before an administrative law judge (ALJ); and
- The fourth level is to a federal district court provided that the amount in controversy meets the required minimum.

While the process is fair, it's also slow and results in the buildup of significant appeals backlogs over time, especially at the third, ALJ level. Right now, it may take an additional two to three years after the first two levels just to get before an ALJ, according to Azia.

2017 Reforms

In Jan. 2017, CMS issued a Final Rule to streamline the appeals process, reduce pending appeals and encourage resolution of cases still in the pipeline earlier in the appeals process by:

- Permitting designation of final Medicare Appeals Council decisions as precedential to provide more consistency in decisions;
- Expanding the Office of Medicare Hearings and Appeals (OMHA) available adjudicator pool;
- Simplifying proceedings involving CMS or CMS contractors;
- Clarifying regulations that may result in unnecessary appeals;
- Creating process efficiencies by eliminating unnecessary steps; and
- Addressing areas for improvement previously identified by stakeholders.

New Proposals

The 2017 changes have had only marginal impact with appeals still taking several years. The Oct. 2 Proposed Rules pick up where the 2017 reforms

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left off. Most of the proposals are technical changes but there are a few substantive items as well, notes Baker Donelson attorney **Kathleen Salsbury**:

- Let appellants submit Medicare Parts A and B claims and Part D coverage determinations appeals without signatures;
- Reduce timeframe for vacating a Part A or B claims or Medicare Part D coverage determinations dismissal from 6 months to 180 days;
- Presumption that date of receipt of ALJ (or attorney adjudicator) decision or dismissal is 5 calendar days after the date of the notice of decision or dismissal, unless there's evidence to the contrary.

Final Take

The Proposed Rules, the comments for which end on Dec. 3, are positive news to the extent they signal the government's seriousness in tackling the appeals backlog. Azia also notes that efforts are being made to hire more ALJs. "There's a real problem with the system," he says. "You're supposed to have a quick, efficient hearing and that's not happening."

MACRA: QPP Year 1 By the Numbers

On Nov. 8, CMS posted Merit-based Incentive Payment System (MIPS) performance results for 2017, the first year of the Quality Payment Program (QPP) which it will use to determine 2019 Medicare payment adjustments for physicians and other clinicians. As expected, the 2019 adjustments, both up and down, were quite modest. But that's expected to change in the years ahead as the QPP is phased in. Here are the key numbers for 2017:

1 million+:	Number of clinicians participating in the QPP
95:	Percentage of physicians that avoided MIPS penalties
1.88:	Maximum positive adjustment percentage
93:	Percentage of clinicians that earned a positive adjustment
71:	Percentage of clinicians that earned a positive adjustment and bonus for exceptional performance
2:	Percentage of clinicians that earned a "neutral" adjustment
5:	Percentage of clinicians that earned a negative adjustment
4:	Maximum negative adjustment percentage
Nearly 100,000:	Clinicians that earned APM participant status

Anti-Kickback: Feds Continue Roundup of Physicians on Receiving End of Millennium Labs Test Cups Freebie

The Millennium Laboratories free point of care test (POCT) cups scandal has been described as the biggest kickback scandal involving lab services in history. And its legacy has now entered a new stage. In October 2015, Millennium agreed to pay $256 million to settle claims of offering the freebies to physicians as an inducement for referrals of custom profile panels and other tests before ultimately declaring bankruptcy shortly thereafter.

Now that the giver has been brought to justice, the feds have turned their attention to the takers, namely, the myriad physicians who accepted Millennium's largesse. The roundup, which began in September 2017, is now into its 13th month. The eighth and most recent physician to settle Stark and kickback charges for its involvement in the scheme is the owner of a Phoenix pain management practice. While the settlement amount, $75,409, is in the middle of the pack, the case is notable in that it is the first in which the individual physician was the only defendant. Previous cases have targeted the physician's business and, in a few cases, the physician principles as well. Here's the rundown:

Providers Targeted in Millennium Laboratories POCT Free Test Cup Kickback Scandal (from most to least recent)

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
Oct. 3, 2018	Ronald Burns, M.D	$75,409	YES
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Abbott Pays $25 Million to Settle TriCor Kickback & Off-Label Marketing Claims

Case: The case began when a sales rep accused Abbott Laboratories and AbbVie Inc. of paying kickbacks to induce or reward physicians for prescribing TriCor to patients with abnormal cholesterol levels. Improper inducements allegedly included gift baskets, gift cards and other items offered via sales reps as well as consulting and speaking fees. The whistleblower will collect $6.5 million for her share in bringing the case.

Significance: The suit wasn't just about kickbacks. The government also accused Abbott of marketing TriCor, a drug approved by the FDA to help patients raise their HDL and lower their LDL, in conjunction with diet, for off-label, i.e., non-approved uses including use:

- In treating, preventing or reducing cardiac health risks
- In combination with statin drugs
- As a first-line treatment for diabetes.

Provider Fined for Not Taking Compliance Measures Required by Its CIA

Case: Nearly 10 years ago, a new Affordable Care Act rule requiring labs and other providers to investigate their credit balances for potential Medicare overpayments took effect. In 2015, Pediatric Services of America (PSA) made the wrong kind of history by becoming the first provider to settle claims for violating the overpayment rules. In addition to a $6.88 million fine, PSA had to enter into a requiring it to enter into a corporate integrity agreement (CIA) And now the OIG has fined PSA $22,500 for not meeting its compliance obligations under the CIA, specifically:

- Not having its Chief Compliance Officer make a quarterly report directly to the Board of Directors in the first quarter of 2017.
- Not ensuring that the Compliance Committee met at least once a quarter during 2017.

Significance: The CIA is something like healthcare enforcement's version of the scarlet letter, a penalty whose legacy seems to continue perpetually after the transgression that prompted it. Providers that enter into a CIA as part of a settlement are compelled to take draconian compliance measures for a number of years and subject to review and pre-determined fines for not implementing those measures. The PSA case is the latest example of just how onerous the CIA can be.

Shareholders Sue Illumina for Stock Fraud

Case: A pair of investors brought a class action lawsuit accusing lab

giant Illumina of artificially inflating stock prices by making "overwhelmingly positive statements" about its sales before releasing its earnings for the third quarter of 2016. Although Illumina did post 10% growth in Q3, its $607.1 revenues came in far short of both average Wall Street estimates ($628.1 million) and the firm's own guidance of $625 to $630 million. The investors claim that this was no accident and are suing on behalf of shareholders who bought Illumina stock between July 26, 2016 and Oct. 10, 2016.

Significance: The suit, the latest pitting a publicly traded lab against its own shareholders, contends that Illumina was pumping up expected sales while failing to disclose the serious flaws in its internal controls and forecasting processes. "Prior to and during the third quarter of fiscal 2016, Illumina had been experiencing a material decline in sales of its traditional HiSeq sequencing instrument," according to the complaint. "The decline in sales, which defendants would later refer to as a 'trend' that had been 'building' for some time and 'didn't show up suddenly' during the third quarter, went unnoticed during the forecasting process."

Lab CEO Pleads Guilty to Distributing Medically Unnecessary Opioids

The CEO of Tri-County Wellness Group and owner of labs and pain clinics in Michigan and Ohio, pleaded guilty to criminal charges for his role in $300 million health care fraud scheme

Case: The CEO of Tri-County Wellness Group and owner of labs and pain clinics in Michigan and Ohio, pleaded guilty to criminal charges for his role in $300 million health care fraud scheme involving distribution of over 6.6 million doses of medically unnecessary oxycodone, hydrocodone and other controlled substances to Medicare patients, some of whom were drug addicts. to narcotics. Some of these opioids were allegedly resold on the street. In addition to $51 million in cash, the CEO will forfeit the other fruits of the scheme including $11.5 million in real estate and Detroit Pistons season tickets.

Significance: The Tri-County case is one of the earliest and biggest of the opioid schemes involving labs and pain clinics. In September 2017, a 72-year-old physician pleaded guilty to conspiring with two other Detroit-area providers, to carry out the scheme by:

- Prescribing the drugs;
- Directing physicians to make Medicare patients that wanted an opioid prescription to first undergo medically unnecessary facet joint injections and lab tests; and
- Telling physicians to refer those services to labs, clinics and other facilities in which he had secret ownership interests.

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new OIG Advisory Opinion signals the government's willingness to accept this practice provided that proper safeguards are in place.

The Proposed Arrangement

A Managed Care Organization (MCO) wants to pay providers incentives to increase EPSDT services to enrolled Medicaid patients under age 21.

Other key details of the arrangement: The MCO pays on a capitation basis, i.e., providers receive a set amount for each enrolled Medicaid patient regardless of services actually utilized. The MCO would provide per-enrollee incentive payments to providers that meet benchmarks for increases in EPSDT services provided. Providers would be eligible for one of three different levels of incentive payments, based on the percentage increase:

Incentive Amount	Incentive Trigger
$1 per patient	10% to 19% year-over-year increase in screenings
$2 per patient	20% to 29% year-over-year increase in screenings
$3 per patient	30% or higher year-over-year increase in screenings

Although the arrangement clearly incentivizes higher utilization of testing, it does so to further the state's objective of detecting ailments early before they become more complex and expensive to treat. The arrangement provides no incentives to providers for recruiting new Medicaid beneficiaries nor for participating in the MCO's Medicare Advantage Plan or other lines of business. The MCO would also cover the payments out of its own pocket and not pass them on to the state Medicaid agency.

Question

The MCO asks the OIG for an advisory opinion on whether the proposed arrangement would violate anti-kickback rules.

OIG Response

While it would certainly implicate the Anti-kickback Statute, the OIG gives the green light.

OIG Reasoning

The OIG says the proposed arrangement is allowed under the Eligible Managed Care Organization (EMCO) safe harbor because:

- Payments would be based solely on the provision of Medicaid services to existing enrollees; and
- The arrangement wouldn't inappropriately increase or shift costs to federal health care programs.

Takeaway

While not technically binding (nor applicable to the Stark Law), the new Advisory Opinion is potentially significant to not just payors but also labs and other providers considering arrangements incentivizing utilization of EPTSD testing. The OIG has now provided a blueprint on how to structure these arrangements so as to fall into the EMCO safe harbor, notes ***Henry Casale****, partner with the Pittsburgh law firm of Horty, Springer & Mattern, P.C.*

Innovation: Using Digital Technology and AI to Fight Cancer

It has the makings of a Hollywood movie. Three recent college grads start a medical testing software company that uses a digital pathology platform, meet with success, and then go on to utilize artificial intelligence (AI) to change the field of pathology, facilitating breakthrough advancements in the treatment of cancer.

Step three is still in the works, but the company, Proscia, has received a total of $8.3 million from five venture capital firms that support the direction the Philadelphia-based startup is taking. The funding has already put the company on the map, and on track to meet the demands of a changing field.

The Process

Proscia was actually launched when the founders were still in college. Reportedly, the three young men created test management software in a Baltimore dorm room. Today, that software has evolved into a cloud-based digital pathology platform used by thousands of pathologists, scientists, histotechnicians, and lab managers at more than 300 clinical and research facilities worldwide, including Johns Hopkins Department of Pathology and Thomas Jefferson University Hospitals, among others.

Three recent college grads start a medical testing software company that uses a digital pathology platform, meet with success, and then go on to utilize artificial intelligence (AI) to change the field of pathology, facilitating breakthrough advancements in the treatment of cancer

Unlike Theranos, another startup that was supposedly destined for success, Proscia doesn't collect samples. Instead, its software is used to sort information collected on digital imaging and testing equipment and move that data efficiently among labs, doctors, insurers, and patients so they can make accurate decisions quickly.

The Proscia platform makes storing, viewing, and sharing slide images possible from anywhere in the world, on nearly any device. It is also designed to work with any slide-scanning hardware, and can be set up to upload automatically and directly to a lab's digital workflow.

Moving Forward

The company indicates that proceeds from the financing will be used to expand the deployment of its digital pathology software and accelerate the use of artificial intelligence (AI) applications to drive accuracy and efficiency in cancer diagnosis. The capital raised will fuel the development and commercialization of new, clinical AI-enabled workflows targeting high-volume, high-impact cancers, the first of which will be available later this year.

Proscia says it will also use the funds to ramp up sales and marketing of its existing cloud-based digital pathology platform, which will serve as the foundation for its AI-based applications. It indicates that, combined, these technologies will redefine the field of pathology and be the impetus that moves human healthcare forward.

"Digital pathology and artificial intelligence are unlocking new possibilities for pathologists in the fight against cancer," said David West, CEO at Proscia. "Pathology has been historically underserved by technology, and we believe that powerful software tools will push the boundaries of how modern pathology is practiced.