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PAMA: MedPAC Explores Simplified PAMA Reporting to Cut Burdens & Restore Lab Prices

The upcoming report of the Medicare Payment Advisory Commission (MedPAC) gives the lab industry new hopes for relief from the administrative burdens of *Protecting Access to Medicare Act of 2014* (PAMA) price reporting obligations. The even better news is that straightening out PAMA reporting will also go a long way toward fixing the pricing disconnect and establishing something more akin to the market-based pricing for Part B lab tests that PAMA was designed to create. Here's a sneak peak of what the MedPAC report may contain based on the April 1 Commission meeting and remarks of its marketing representatives.

The PAMA Pricing Controversy

Previously, Medicare Part B Clinical Laboratory Fee Schedule (CLFS) payment rates were based on local, historical lab charges, updated for inflation, and capped at certain amounts. In 2014, Congress passed the PAMA bill mandating CMS to establish market-based CLFS rates based on what private payors charge for

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Reimbursement: OIG Sounds the Warning on Improper COVID-19 Vaccination Billing

Labs and providers that furnish COVID-19 testing and vaccination services need to look ahead and prepare for the massive federal false billing crackdown that is sure to come if and when the pandemic crisis finally tails off. The latest rumblings from the federal enforcement volcano occurred on April 15 when the OIG issued a relatively rare "Message From HHS-OIG Leadership" (Message) to let it be known that the agencies are hearing reports of false billing and "remain vigilant and committed to holding perpetrators of [COVID-19-related] fraud schemes accountable."

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those tests. The agency was also given the authority to qualifying labs to submit pricing information that it could refer to in determining what the market rates for particular tests actually are.

The controversy over PAMA pricing stemmed not from the statutory scheme but the warped way in which CMS implemented it, specifically in excluding hospital labs from the definition of qualified labs required to report and collecting pricing data mostly from independent labs. In omitting hospital labs who not only provide many if not most of the tests but also have the leverage to command higher rates from payors, the pricing data CMS received reflected artificially deflated prices not representing the true state of the private payor market. After repeated delays, the new "market-based" CLFS went into effect in 2018.

For nearly a decade, the lab industry has pushed back and tried to hold CMS accountable for hijacking PAMA market-based pricing. While court challenges have thus far proved unavailing, direct negotiations and working with Congress have resulted in some success. Most notably, in 2019 when CMS agreed to broadened its definition of "applicable laboratories" to include some hospital labs. But PAMA prices still remain artificially low. Meanwhile, the full brunt of PAMA cuts will be felt in 2025 when previously deferred cuts are finally phased in.

The MedPAC Report on PAMA Pricing

Another avenue of potential relief is MedPAC, an independent, non-partisan agency created by the *Balanced Budget Act of 1997* to advise Congress on Medicare reimbursement to private health plans and providers, care quality and other issues. Congress has charged MedPAC with reviewing the methodology used by CMS to implement market-based pricing of Clinical Laboratory Fee Schedule (CLFS) tests under PAMA, as well as the reporting methods the agency uses to gather the data on which it bases those prices, and submit a written report of its findings in June 2021.

As bad as things are now, the distorted CMS scheme will drag prices down even further when the deferred cuts take effect in 2025. MedPAC Senior Research Assistant Carolyn San Soucie said payment rates will decrease by an estimated 24 percent once the rates are implemented.

In addition, private payor rates reported by labs were generally lower than Medicare's 2017 average payment rates for 77 percent of tests, but higher for about 23 percent of tests. MedPAC noted that although lab test utilization was stable overall from 2017 to 2019, there were "sharp increases in the use of new, high-cost tests," such as complex genetic tests. As a result, Medicare Part B lab spending actually increased from $7.1 billion to more than $7.5 billion.

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Spending on chemistry tests declined 14 percent, in line with PAMA expectations, while molecular pathology spending increased due to higher use of the tests. Panel test spending didn't decline as expected, which MedPAC attributed to unbundling and a "generous phase-in of payment rate reductions under PAMA."

MedPAC and PAMA Reporting

MedPAC is also looking into ways to reduce the reporting burden on labs and asked a third-party contractor, RTI, to perform an analysis of the different survey methodologies that could be used to collect representative and statistically valid samples. RTI evaluated multiple sampling techniques based on two criteria:

- The extent to which a survey could produce accurate estimates of private payer prices for each type of lab; and
- How many labs would have to report data to generate accurate price estimates.

Using Medicare claims and private payer data to simulate the results of a survey, RTI concluded that setting Medicare payment rates using a survey is feasible and could substantially reduce the reporting burden on labs. RTI found that a survey could produce accurate estimates of private payer rates for all three types of labs that generate the vast bulk of CLFS tests, i.e., independent, hospital outpatient and physician office labs. Even a survey with a minimum as low as 10 labs reporting data for each particular test could reduce the number of labs required to report private payor data by up to 70 percent.

Setting Medicare payment rates on a representative sample of labs would increase program spending by 10 to 15 percent, as compared to the spending that would result from Medicare's current rates. This increase varied depending on different parameters for different labs, such as only including tests from hospital outpatient labs that were furnished to non-patients.

Although the estimates "should not be considered precise point estimates," the MedPAC representative noted that going from rates based largely on independent labs to rates based on data from a broader assortment of labs will likely increase Medicare spending significantly.

MedPAC also noted examples where basing payment rates on a sample of private payor rates may not be ideal, namely for routine tests and genetic tests. For routine tests, RTI found that policymakers should exclude high private payor rates resulting from negotiating power rather than the actual costs of providing the test. Medicare should instead set payment rates to ensure beneficiary access while maintaining incentives on laboratories to make better use of taxpayer and beneficiary resources. Policymakers could

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focus on "efficient laboratories" instead of all labs to exclude these high private payor rates.

For high-cost tests, MedPAC said private payors may have a limited ability to negotiate rates because they're more complex and proprietary. As a result, the representative suggested that in the future the Commission would "consider alternative ways to set payment rates for new, high-cost technologies, including certain pharmaceuticals, devices, and laboratory tests."

Takeaway

MedPAC has asked for comments on its findings and intends to use the feedback in the final report it issues to Congress in June. And when that report does come out, it will likely have significant influence. Just as important is the timing. While the devastation wrought by PAMA pricing in the past three years can't be undone, there's still time to fix the mess before the bottom falls out in 2025.

HIPAA Enforcement: New OCR Data Shed Light on the Costs of Privacy Noncompliance

HIPAA enforcement isn't nearly as fat a cash cow as enforcement of False Claims Act (FCA) and other healthcare fraud laws is, it still takes a lot of money out of the pockets of providers and into the hands of the federal government. But tracking the economics of HIPAA enforcement is tough because the government doesn't publish data on HIPAA recovery amounts the way it does with the FCA. However, new data from the HHS Office of Civil Rights (OCR) has recently emerged that offers some rare insight into the dollars and cents of HIPAA enforcement over the past two decades. Here are some of the key figures, which encompass April 2003, when HIPAA first began being enforced, through 2020:

- **$129,722,482:** Total amount of civil penalties and settlements collected by OCR for HIPAA infractions;
- **$26 Million:** Highest one-year total collected in past five years (2018);
- **$12 Million:** Lowest one-year total collected in past five years (2019);
- **$16 Million:** The highest ever settlement for a HIPAA violation, paid by Anthem in 2018 for a massive 2015 data breach affecting 79 million people;

- **250,367:** Total number of HIPAA complaints received by OCR;
- **3,992:** Number of HIPAA complaints that remain open (2 percent of total complaints filed); and
- **$129,722,482:** Total amount of civil penalties and settlements collected by OCR for HIPAA infractions.

Top 5 HIPAA Complaints

The OCR report also lists the top 5 most frequent reasons that people file HIPAA complaints:

1. Impermissible use or disclosure of an individual's protected health information (PHI);
2. Lack of adequate safeguards for PHI;
3. Lack of patient access to their PHI;
4. Lack of proper administrative safeguards for electronic PHI; and
5. Use or disclosure of more than the necessary amount or type of PHI.

Takeaway

From a lab compliance officer's perspective, perhaps the most meaningful number listed in the OCR report is 69, which is the percentage of HIPAA complaints that have resulted in a corrective action being taken against a provider. In other words, nearly 7 in 10 HIPAA complaints result in a fine and/or imposition of a corrective action. That's a factoid you might want to cite to your lab executives the next time you encounter resistance to HIPAA compliance initiatives.

Technology & Innovation: CMS Delays New Rule Providing Automatic Medicare Coverage of Breakthrough Devices

A CMS final rule providing for automatic Medicare coverage for new medical products cleared by the FDA as breakthrough devices under Section 510(k) was supposed to take effect on March 15, 2021. But now that CMS is under new management, the rule has been put on ice for at least 60 days pending further study. While no doubt disappointing to some manufacturers, the potential demise of the Medicare breakthrough status coverage rule is hardly unexpected. Here's a briefing on the situation.

The Final Rule

Medicare covers only medical services and products that are "reasonable and necessary." The *Social Security Act* (Section 1862((a)(1)(A), to be precise) gives the HHS Secretary authority to determine whether a particular service or product meets the standard. However, HHS has never

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established a formal regulation to define "reasonable and necessary." The rule, which was finalized on Jan. 12, creates such a definition, one that would enable breakthrough devices to qualify as reasonable and necessary.

Specifically, the rule would grant national Medicare coverage of breakthrough devices for a four-year period starting on the date of FDA market authorization. Once the period ends, CMS would then re-evaluate the device based on clinical and real-world evidence of improved health outcomes to determine whether to make Medicare coverage permanent.

The idea is to give Medicare beneficiaries better access to new medical technologies. Technically, the rule applies only to devices that pass through the Medicare Coverage of Innovative Technology (MCIT) pathway, which doesn't include laboratory developed tests (LDTs). However, CMS had made it clear that the MCIT rule would serve as a template that could be extended to breakthrough diagnostics, drugs and/or biologics that aren't currently in the MCIT pathway.

The Biden Brake

Immediately upon taking office, the Biden administration signaled its suspicion and skepticism of the health care policies of its predecessor and imposed a blanket freeze on new regulations adopted in the regime's final days. (To find out about the other regulations affected, see G2 Blog, How the Transition from Trump to Biden Will Affect Federal Regulation and Reimbursement, Feb. 19, 2021). However, critics have attacked the rule for throttling CMS' clinical scrutiny and opening the door scientifically unproven devices as part of the Trump administration's general disdain for science and regulation. This criticism was bound to resonate with the new President who has expressed similar views on Trump policy.

Takeaway

Although the delay in implementation comes as no surprise, the final rule's ultimate demise is by no means a forgone conclusion. On the contrary, lack of a clear Medicare coverage definition of "reasonable and necessary" has been a problem for decades, serving not only as a thorn in the side of the medical device and lab industry but also in blocking the access of Medicare patients. The attempt to address the problem also enjoys bipartisan support in Congress.

But the Biden administration refuses to be rushed. In announcing the final rule's delay, CMS initiated a new 30-day comment period to gather public feedback on operational issues, overlapping rules, breakthrough device volume, patient protection and commercial insurance. And if the final rule does make it through, the door will be opened to extending it to LDTs. Stay tuned.

Enforcement Trends: Silicon Valley Becomes Epicenter of Lab Investment Scams

On paper, the Silicon Valley venture capital and innovation that have lifted so many other industries seem like the perfect elixir for medical labs. Perhaps one day it will prove to be just that. But so far at least, things haven't gone well. Instead of driving game-changing diagnostic innovation, the infusion of Silicon Valley can-do into the lab sector has yielded mostly massive Wall Street scandals.

Stanford dropout Elizabeth Holmes has become the literal face of the beauty and perversion of the Silicon Valley-ization of lab diagnostics. The Steve Jobs-wannabe who appeared on the cover of *Forbes* magazine and became a media sensation transcending the white coat world of the testing lab with a breathtaking new modality capable of performing a full menu of rapid tests from a single drop of blood. But, alas, Ms. Holmes and her startup, Theranos, turned out to be smoke and mirrors.

Unfortunately, by the time it became clear that the technology didn't support the vision, investors from across the nation, including not only notable wealthy backers but also retirement funds supporting many from middle class America, had made Theranos a $9 billion company. What can't be calculated is the medical harm inflicted on the patients who were diagnosed based on results from tests performed with Theranos technology.

Ms. Holmes is still awaiting criminal trial on wire fraud, investment fraud and other charges, with pregnancy being the source of the latest delay. Odds are that the Theranos feature film will appear on movie screens before Ms. Holmes appears in the defendant's docket.

The Theranos Formula

In retrospect, the Theranos fraud seems so obvious. So, how were Ms. Holmes and her partner Ramesh "Sunny" Balwani able to rise so quickly to stardom? According to John Carreyou, The Wall Street Journal writer who broke the story and subsequently turned it into the Pulitzer prize-winning book *Bad Blood: Secrets and Lies in a Silicon Valley Startup*, what made the scandal not only possible but predictable was the Silicon Valley culture of "faking it until you make it." It's a culture where hype and overpromise win funding and it's okay to go to market with a buggy product, as long as you get to market quickly.

The formula worked for Steve Jobs and Apple Computer. And Holmes and Balwani felt it would work for Theranos. The problem, of course, is that laboratory diagnostics isn't the same as consumer electronics. "Iterating and debugging once you are already commercial may be okay in the world

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of computer hardware and software, but that way doesn't transfer well to medicine," Carreyrou told G2 Intelligence in an interview.

The "Formula" Plays Out during COVID-19

Sure enough, the Theranos scandal would prove to be only the first in a pattern of scandals generated by the wedding of diagnostics and the Silicon Valley "formula." Only, this time there would be a new twist: COVID-19. Tests that detect the SARS-CoV-2 virus don't command high reimbursement. Even so, the global pandemic has created the desperate demand for breakthrough COVID-19 diagnostics. Thus, the seeds were sown for Theranos-type Wall Street scandals involving bloated claims about the capabilities of COVID-19 tests to lure investors.

Sure enough, in June 2020, another executive of a publicly traded Silicon Valley medical tech firm was charged with swindling investors and insurers by misrepresenting the diagnostic capabilities of a SARS-CoV-2 test using finger stick blood collection. The defendant is Mark Schena, president of Sunnyvale, California-based Arrayit. According to a criminal complaint filed by the U.S. Department of Justice (DOJ), Arrayit sought to cash in on the COVID-19 pandemic to sell more of its high-reimbursing allergy tests. Starting in March, Schena and colleagues distributed marketing emails claiming that the company's unapproved blood test based on finger prick technology, was capable of rapid novel coronavirus detection when used in combination with the allergies test kit.

However, the DOJ claims that the test didn't exist. It was only on the day that the emails were sent that Schena actually ordered the COVID-19 antigens. The company later developed and self-validated the test and submitted it the FDA for emergency use authorization (EUA). But the agency denied EUA clearance after finding the test's performance wanting.

Of course, none of this was known to investors. Nor did investors know that Arrayit was actually broke. All they heard were the company's claims that it was generating millions of dollars in billings for a rapid COVID-19 detection test. Thinking they had spotted a pearl in a pandemic, investors caused Arrayit's stock price to double—albeit it remained a low-priced penny stock. The federal Securities and Exchange Commission (SEC) suspended trading for the stock for two weeks in April 2020.

On June 9, the DOJ dropped the hammer charging Schena with criminal securities fraud and conspiracy to commit healthcare fraud by transmitting email communications and marketing materials that misrepresented Arrayit's ability to provide accurate, fast, reliable and cheap COVID-19 tests in compliance with applicable regulations and instructing its patient recruiters and medical clinics to add on or bundle Arrayit's much more lucrative allergy test with its COVID-19 test regardless of medical necessity.

uBiome Becomes the Most Recent Theranos

The next scandal was revealed in March 2021, when federal prosecutors filed criminal charges against the co-founders of a San Francisco biotechnology start-up firm for defrauding investors by making bloated claims about a revolutionary diagnostics product. This time the role of Theranos was played by uBiome Inc, a business created in 2012 to develop and commercialize tests to detect microbiomes in the gut and other parts of the body. uBiome's Gut Explorer, Smart Gut and SmartJane were sold in mail-order kits that patients could use to collect samples from home, complete surveys and get results online in a few weeks. According to prosecutors, uBiome's co-founders Zachary Apte and Jessica Richman were able to raise over $76 million in a pair of fundraising rounds by misleading investors about the firm's revenue growth and ability to secure coverage from payors even though many tests weren't clinically validated or medically necessary. uBiome filed for bankruptcy in 2019.

Acting U.S. Attorney Stephanie Hinds is in charge of the criminal prosecution. If the name sounds familiar, it may be because Ms. Hinds' office is also prosecuting Elizabeth Holmes and Theranos. "The innovation that emerges from our Bay Area companies is unparalleled," noted Ms. Hinds, "but all innovation must exist within the boundaries of the law. In addition to the criminal charges, Apte and Richman have been hit with civil charges of stock fraud from the Securities Exchange Commission (SEC).

Takeaway

The Silicon Valley playbook is "ill-suited" to health care, Carreyou warns. "Increasingly medical technology and the traditional Silicon Valley are going to converge," he told G2. "It's inevitable that convergence will accelerate and the people involved in that convergence need to adjust their behavior for anything that touches medicine, where ultimately the product affects people's lives."

In the News: Federal Court Nixes Appeal of Physician Convicted of Participating in Urine Drug Test Billing Scam

Before the pandemic began, fraudulent utilization and false billing of medically unnecessary urine drug screening had climbed to the top of the agenda for federal enforcement. (See *National Lab Report*, May 13, 2019, page 1). One of the many providers to feel the fury was the Florida physician/medical director of a pair of sober home clinics who in February 2019 was convicted for his role in a massive fraud scheme

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involving billings for millions of dollars of unnecessary urine drug tests on recovering addicts.

The Jury Conviction

He was just a patsy in the 20-member conspiracy, the physician had claimed. But after an 8-day trial, the Florida federal jury found him guilty of conspiracy to commit health care fraud and distribute controlled substances, as well as seven counts of unlawfully dispensing controlled substances. As a result, the physician was sentenced to 11 years in prison and ordered to pay $1 million in restitution. The owner of the clinics who served as ringleader of the scheme is also serving a 27-year sentence after being convicted of multiple charges.

The Failed Appeal

The physician appealed, claiming that the jury didn't have enough evidence to convict. But now the U.S. Court of Appeals for the 11th Circuit has ruled that there was more than enough evidence to support the verdict and sentence and tossed the appeal. The physician played a central role in the scam, reasoned the Court. It wasn't just *that* he ordered all of those medically unnecessary drug tests but also *the way* he ordered them that made him guilty. Examples:

- For one lab, he issued a standing order authorizing as medically necessary two to three scheduled and up to two random tests on a single patient per week; and
- For the second lab, he pre-signed blank requisition forms for drug tests leaving the patient information blank so that others could enter it later.

In each case, staff photocopied the documents and used them to maximum advantage, often ordering tests and providing their own urine samples for patients who didn't show up for appointments [*U.S. v. Abovyan*, 2021 U.S. App. LEXIS 5030, 988 F.3d 1288, 28 Fla. L. Weekly Fed. C 2452].

Takeaway

It's hard to understand the defense's legal strategy without knowing all of the details of the case. But the severity of the sentence in Abovyan is a pretty good reminder of why the vast majority of false claims cases are settled rather than taken to trial. Of course, it's easy to second-guess, especially when representing defendants who firmly believe—and perhaps accurately so—that they haven't done anything wrong.

Reimbursement: OIG Sounds the Warning on Improper COVID-19 Vaccination Billing, *from page 1*

Compliance managers at labs and vaccination facilities are well advised to audit whether their organizations are currently meeting the billing and reimbursement rules the Message summarizes.

6 Things to Check to Ensure Proper Billing of COVID-19 Vaccination

The Message specifically reminds providers is being provided by the federal government at no cost to recipients. It then runs down the six ground rules of billing and reimbursement under the CDC COVID-19 Vaccination Program under which participating providers:

1. **Must** administer the vaccine with no out-of-pocket costs to the recipient: YES [ ] NO [ ];
2. **May not** vaccination to anyone based on the person's coverage or network status: YES [ ] NO [ ];
3. **May not** charge for an office visit or other fee if COVID-19 vaccination is the only medical service provided: YES [ ] NO [ ];

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4. **May not** require a recipient to get additional medical services to receive the vaccination: YES [ ] NO [ ];
5. **May** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fee for the vaccine recipient, such as: YES [ ] NO [ ]
   - The vaccine recipient's private insurance company;
   - Medicare or Medicaid reimbursement;
   - HRSA COVID-19 Uninsured Program for non-insured recipients;
6. **May not** seek any reimbursement, including via balance billing, from the vaccine recipient.

The OIG is "aware of complaints" that providers are charging recipients when they get their vaccines, the Message warns. It then calls on providers that have been charging impermissible fees to refund them and stop charging them in the future. However, the CDC does allow providers to bill payors for an administration fee in accordance with payor program rules.

Takeaway

Almost from the moment the pandemic began, the OIG has been sounding the warning on COVID-19-related fraud and abuse. The agency is currently investigating a series of rumored coronavirus billing ripoffs, including:

- *Bundling of COVID-19 and non-COVID-19 tests;*
- *Performing medically unnecessary add-on tests on COVID-19 test recipients; and*
- *On a larger scale, use of telemarketing, text messages, social media platforms, and door-to-door visits to perpetrate scams to steal money and personal information from vulnerable people.*