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INSIDE THIS ISSUE

The Newest PAMA Controversy: The GAO Report & Intervention of a Powerful Senator

The recent moves by CMS to include certain hospital outreach labs as "applicable laboratories" for purposes of PAMA reporting and pricing (see *National Intelligence Report (NIR)*, Dec. 31, 2018) has done little to calm the PAMA controversy. The American Clinical Laboratory Association (ACLA) is still pursuing its federal court case challenging the legality of the CMS PAMA system (see *NIR*, Dec. 14, 2018). And a recent government report suggesting that PAMA is too generous to labs has raised the temperature even higher. Here's what's going and what to expect.

The GAO Report & Industry Response

The new controversy began last November when the U.S. Government Accountability Office (GAO) issued a report suggesting that the new PAMA system will result in billions of dollars' worth of Medicare overpayments for lab tests. This conclusion flies directly in the face of what the lab industry and other critics have been saying about PAMA.

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CMS Says Big Changes Are in Store for Stark Law by End of Year

The Stark Law is like the weather: Everybody talks about it but nobody does anything about it. But that all may be about to change if CMS Administrator Seema Verma is to be believed. During her recent speech at the Federation of American Hospitals conference, Ms. Verma suggested that by the end of the year, the Stark Law will get the biggest makeover it's ever had since its inception back in 1989.

A Jurassic Law for a Modern Problem

The objective of preventing physician self-referrals remains and ensuring that physicians order services based on patient needs rather than the physician's own financial interests remains as valid today as it was nearly three decades ago. The problem is that the Stark Law

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The Newest PAMA Controversy: The GAO Report & Intervention of a Powerful Senator, *from page 1*

According to a January statement from American Clinical Laboratory Association (ACLA) President **Julie Khani**, "The GAO's conclusions on overbilling of laboratory services in the Medicare program are fundamentally flawed and inaccurate. The underlying assumptions for GAO's analysis and recommendations reflect a serious misunderstanding of standard industry practice for laboratory reimbursement and ignore unprecedented cuts to lab tests that pose serious harm to beneficiaries."

In February, the ACLA and AdvaMedDx, College of American Pathologists, National Independent Laboratory Association, and Point of Care Testing Association sent a joint letter to GAO expressing "strong disagreement with key assertions" in the GAO report and citing the "flawed approach to data collection that excluded large portions of the laboratory market."

Lab industry pushback against PAMA is nothing new. But now there are more voices, not to mention actual outcomes that can be cited resulting the "flawed" CMS process. "Payment rates for the vast majority of laboratory tests are not based on market prices and as result, cuts have far exceeded initial projections," the letter notes. The five organizations signing the letter have requested a meeting with GAO.

The Grassley Factor

Unfortunately, one person apparently didn't get the lab industry memo. And that person just so happens to be one of the country's most powerful lawmakers. Senator **Charles Grassley** (R-Iowa) is the last person you'd ever want to pick a fight with. Elected to the Senate in 1980, he has become a fierce advocate for lower health care prices and a thorn in the side of the drug companies. And this January, he became one other thing: Chairman of the powerful Senate Finance Committee.

Senator Grassley read the GAO report; and he apparently believed it. And now he's determined to find out what CMS intends to do to fix the "overspending" on lab tests problem. In a recent letter, he poses a series of specific questions.

Senator Grassley's 6 Questions to CMS on Supposed PAMA Lab Overpayments

1. What steps have been taken to ensure that all labs who are expected to report data to HHS actually do so?
2. Does HHS agree with the GAO recommendation that CMS phase in payment-rate reductions based on actual rather than maximum rates? If so, what steps have been taken to amend relevant HHS rule(s) and implement the GAO recommendation?
3. Does HHS believe it has the authority to create CPT codes for panel tests where they don't currently exist, or take other steps to ensure the completion of a bundled payment while remaining compliant with the provisions of PAMA and other relevant federal laws?

NIR

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4. Did CMS make a systems edit to its claims processing system that prevented CMS from detecting whether individually billed tests should have been bundled? If so, why?
5. What's the status of efforts to detect panel tests where CPT codes do exist but haven't been correctly billed by labs? When does CMS believe it will be able to effectively detect and correct the billing problems?
6. Did CMS know how many labs billed individual tests and received a higher reimbursement rate when they should have billed as a panel code during the time the claims processing system was unable to detect when a panel CPT code was appropriate? Is CMS able to perform an audit to determine that number and the cost in excess reimbursement?

Lab Industry Concerns

While Grassley's letter does ask some important questions, it also overlooks lab industry concerns. Indeed, some of the questions flat-out ignore key points. For example, Grassley asks whether CMS can create new CPT codes for panel tests and enforce existing panel test codes so it can continue to make bundled payments while remaining compliant with PAMA. He also asks whether CMS plans to amend a rule so it can base pricing reductions on average instead of maximum Medicare payment rates.

Takeaway:The uphill battle to peel back PAMA has become that much steeper now that Senator Grassley has joined the fray. Disabusing him of his misconceptions about lab reimbursement, if that's what they are, will not be a simple task; the good news is that the Senator is as fair and intelligent as he is tough and determined in his quest to secure lower medical prices for patients.

Enforcement Trends: CMS Looks to Recover $66.3 Million in Improper Specimen Validity Test Payments

The opioid crackdown has made urine drug testing an even greater priority for federal health fraud enforcers. One principle target is specimen validity testing (SVT) billed in combination with urine drug tests. In February 2018, the OIG issued a report saying that Medicare made $66.3 million worth of improper payments for such tests and calling on CMS to get that money back. Rather than waiting to hear from their Medicare contractor, a number of labs have stepped up and voluntarily self-disclosed receiving improper payments for SVTs.

Urine Drug & Specimen Validity Testing

SVT analyzes the urine specimen to ensure that it hasn't been tampered with or adulterated. While Medicare deems urine drug testing medically

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Enforcement Trends: CMS Looks to Recover $66.3 Million in Improper Specimen Validity Test Payments, *from page 3*

necessary to detect and quantify the presence of drugs in a patient's body, SVT is not considered medically necessary if its sole purpose is to validate the specimen since the test results aren't actually being used to manage the patient's treatment.

Exception: SVT is medically necessary in limited cases when it's used in combination with a urine drug test done on the same day for purposes of diagnosing certain conditions such as kidney stones or urinary tract infection. However, the latter cases are relatively rare; or at least CMS thinks they *should be*. So why are they being billed so frequently?

Indications of Improper Billing

With that question in mind, the OIG audited $67+ million in Medicare Part B payments for SVTs billed in combination with urine drug tests, i.e., on the same dates of service, from 2014 through 2016. The findings: $66.3 million of the payments were improper. Those payments were received by 4,480 clinical labs and physician offices. The OIG report cited two reasons for the improper payments:

- Providers' failure to follow existing Medicare guidance; and
- The inadequacy of CMS system edits designed to prevent payment for SVTs billed in combination with urine drug tests, in spite of revised edits implemented in 2016.

The OIG urged Medicare contractors who made the $66.3 million in improper payments to implement better edits and make an effort to recover the money already spent.

The Fallout

Many of the 4,480 labs and physician offices that received improper SVT payments have gotten a repayment request from their Medicare contractor. But for contractors, recovery isn't that simple. One problem is that the audit looks only at specific claim lines. Consequently, contractors must conduct medical review of the entire claim to determine whether it includes a relevant diagnosis code.

Meanwhile, some labs have decided to do their own internal audits and voluntarily self-disclose any improper SVT payments they identify. There have been at least two such reported self-disclosure cases in the past month, each totaling six figures:

- $126,799 paid by The Northern Kentucky Center for Pain Relief (Jan. 24, 2019); and
- $111,706 paid by Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD in Ohio (Feb. 6, 2019).Requirements for employers to provide health insurance.

Gottlieb Resigns as FDA Chief: Lab Industry Loses a Good Frenemy

Scott Gottlieb, M.D., is resigning as FDA commissioner, the position he's held since 2017.

But while his reign lasted just two years, Gottlieb has been a longtime friend and foe of the lab industry having served as deputy commissioner during the George W. Bush administration. The key question: Will the initiatives and policies he championed during his tenure continue after he's gone?

Why Gottlieb Is Leaving

The first clue to answering that question is that Gottlieb is not being forced out. He's resigning for personal rather than political reasons, namely his desire to be closer to his wife and three young daughters in Westport, CT.

His Legacy & Impact on Labs

Gottlieb will be remembered for his commitment to making one of the federal government's most opaque agencies more transparent and his energy in advocating reforms designed to simplify and speed up the cumbersome FDA approval process and ending the "shenanigans" that thwart competition.

Historically, becoming FDA commissioner has proven a less than effective way of winning friends in the lab industry. But Gottlieb was different. What the industry really appreciated (and may sorely miss when he's gone) was Gottlieb's willingness to tackle the controversial lab-developed tests (LDTs) issue. "The agency helped support major legislative efforts to secure a more modern framework for the efficient regulation of diagnostic tests," Gottlieb said in his resignation letter.

Under Gottlieb, the agency has made several proposals to make it easier to bring new tests to market. Specifically, it has worked with industry and Congress to generate support for the VALID Act, a bill aimed at resolving the longstanding controversy around FDA regulation of LDTs that would bring all diagnostics under a single regulatory pathway using more modern and technologically realistic approval criteria.

Meanwhile, the volume of test approvals has increased markedly during Gottlieb's tenure, including:

- Two new flu tests;
- First NGS residual cancer detection test to gain FDA approval
- New point-of-care tests for Ebola; and
- First approved objective blood test for concussion evaluation

Under Gottlieb, the FDA also softened its previous resistance to genetic tests, most notably in allowing 23andMe to engage in direct to consumer marketing of its products. So, it's not that biotechnology stocks fell on the day he announced his resignation.

Of course, lab tests are just part of the story. Gottlieb has also won praise for

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Gottlieb Resigns as FDA Chief: Lab Industry Loses a Good Frenemy, *from page 5*

his determination to speed approval of new generic drugs and the agency's handling of the opioid crisis. Of course, he's not without critics. One problem area is his support for e-cigarettes, which the anti-tobacco groups contend has contributed to the growth of vaping among teens. Gottlieb has also managed to tick off the other side by pushing to regulate the amount of nicotine in cigarettes and proposing a ban on menthol cigarettes.

His Successor

Norman Sharpless, M.D., director of the National Cancer Institute has been named acting commissioner. He will oversee the agency until President Trump nominates and the Senate confirms a permanent successor.

Genomic Data Sharing: From Utopian Principle to Practical Reality

> *"Publicly available data should be treated as open data, a shared resource with unrestricted use for analysis, interpretation, and publication."*
> --The journal *Science* report on genomic data sharing

As a principle, it's hard to take issue with *Science*'s recommendation; but as the article itself notes, actually achieving genomic data sharing remains highly difficult due to the lack of clear guiding rules for data usage. The good news is that recent progress in standards and software development has made it achievable.

Criteria for Data Sharing

A number of organizations are working to facilitate the process of and establish standards for data sharing. Among them is ClinGen, a National Institutes of Health (NIH)-funded resource whose mission is to build a genomic knowledge base to improve patient care. ClinGen has established a minimum standard of data sharing for clinical labs that meet the following criteria:

- The lab's submissions are registered in ClinVar (a free government resource for the medical community) as "Single Submitter, Assertion criteria provided;"
- A complete list of the lab's test offerings is publicly available either through a registry such as Genetic Test Registry (GTR) or Orphanet, or on the lab's website (Requirement modified February 2019 to any public display of the lab's complete list of test offerings, not limited to GTR);
- The lab submits at least once per year adding new variants and updating reclassified variants as necessary;

- The lab submits all categories of variants reported to patients (labs are also encouraged to share B/LB variants and VUS if not reported);
- The lab has attested to submitting at least 75% of all sequence and/or copy number variants reported in the past year;
- The lab has submitted at least 100 variants; and
- The lab is CLIA certified (USA) or meets an equivalent standard in another country.

ClinGen lists the labs that meet its standard on its website.

Tools for Data Sharing

Another barrier to achieving data sharing is the lack of available tools to facilitate the process. However, medical software providers are working to solve that problem.

For example, ApolloLIMS has developed a product called eXchange that allows a lab to send and receive data using common protocols and file formats. While this solution in and of itself does not create the "open data" for which some, including the authors of the *Science* article advocate, it does highlight an important component. The technology to share data is readily available.

Takeaway: While much work remains to be done, genomic data sharing has become achievable thanks to standards like the ClinGen criteria and software like eXchange.

Labs IN COURT

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

$1.99 Million Settlement for False Billing of Genetic Tests

Case: In a case that began as a whistleblower suit filed by two ex-employees, GenomeDx Biosciences has agreed to shell out $1.99 million to settle charges of improperly billing Medicare for its Decipher Biopsy which predicts the probability of prostate cancer metastasizing after surgery and classifies the tumor's aggressiveness. The feds claim that over a nearly two-year period, beginning in September 2015, the San Diego-based genetic testing company made claims for Decipher tests performed on patients who didn't have risk factors making the tests medically necessary. The whistleblowers will get $350K of the settlement.

Significance: Decipher, which is based on the level of expression for 22 RNA biomarkers involved in prostate cancer pathways, has gained favor with a growing number of payors, including Cigna. In 2015, Medicare approved coverage but only for a limited subset of patients, i.e., those with: i. pathological stage T2 disease with a positive surgical margin; ii. pathological stage T3 disease; or iii. rising prostate-specific antigen levels after an initial PSA nadir. The patients GenomeDx billed for allegedly lacked the risk factors spelled out in the coverage policy.

Atlanta Medical Group Execs Jailed for $8.5 Million Allergy Testing Scheme

Case: The two owners of now defunct Primera Medical Group pled guilty to criminal charges for their role in billing insurers for allergy blood tests that weren't medically necessary, ordered by a physician or, in many cases, even performed. **Details:** Primera hired market research firms to pay fees to recruit privately insured patients to undergo allergy testing regardless of whether they had symptoms indicating the tests were medically necessary, generating over 4,500 claims seeking $8.5+ million from private insurers. The owners even fabricated false lab reports for tests that were never completed and sent them to not only insurers but also directly to patients, in one case sending phony results to the family of a 5-year-old girl suffering from an unknown reaction. Both owners were fined over $1.5 million and sentenced to 81 months and 93 months in jail, respectively, followed by three years of supervised release.

Significance: In addition to health fraud, the owners committed aggravated identity theft by billing insurers for the tests and allergy immunotherapy injections administered to nearly every patient using National Provider Identifiers of other doctors without their knowledge.

Lab Settles Specimen Collection Fee Kickback Charges for $2.275 Million

Case: Cleveland HeartLab (CHL) has agreed to pay $2,275,094 after self-disclosing to the OIG that it paid remuneration in the form of payments to physicians and physician groups for collecting, processing and handling blood specimens. The offenses occurred during a four-year period between 2010 and 2014, three years before CHL

was acquired by current owner Quest Diagnostics.

Significance: OIG Advisory Opinions and court cases, including the notorious Health Diagnostics Laboratory (HDL) case involving the payment of a $10 to $17 per test processing fee to physicians have made it abundantly clear that processing fee arrangements raise bright red flags under the Anti-Kickback Statute and Stark Law. More legally sound alternatives to help physicians manage the costs of specimen collection and processing include:

- Establishing a collection station near the offices of your physician clients; and/or
- Placing a phlebotomist or staff member compensated by your lab at fair market value within their facilities.

Device Company Pays Nearly $20 Million to Settle MD Bribe Claims

Case: Former sales managers of Covidien LP filed a whistleblower suit accusing the firm of providing free or discounted marketing and practice development services to California and Florida physicians to get them to buy Covidien's ClosureFAST™ radiofrequency ablation catheters. In addition to kickback violations, Covidien violated the False Claims Act by billing Medicare and Medicaid for the devices, the claim alleges. Covidien denies the charges. But once the DOJ decided to pick up the case, it decided that discretion was the better part of valor and agreed to settle for $17,477,947, of which $3,146,030 will go to the whistleblowers. In addition, Covidien will have to pony up $1,474,892 to California and $1,047,160 to Florida to settle the related Medicaid claims.

Significance: Although Covidien is a medical device company, this case is also extremely relevant for labs. The Antikickback Statute ban on offering referring physicians free or cut-rate practice and marketing services, e.g., accounting, technology, EHR, consulting and other forms of support, also applies to labs.

PacBio Settles Lawsuits with Shareholders Over Illumina Acquisition

Case: In November 2018, Illumina agreed to acquire Pacific Biosciences for $1.2 billion. Disappointed with the $8 per share acquisition price, PacBio shareholders filed five different class action lawsuits against the financially troubled long-read, high-resolution sequencing firm claiming that the board of directors deliberately concealed important financial information to secure shareholder support for the deal. On Feb. 1, 2019, PacBio announced that it had settled all five of the cases.

Significance: Although the terms of the settlement weren't disclosed, as part of the deal, PacBio has agreed to pay $300K worth of attorneys' fees.

CMS Says Big Changes Are in Store for Stark Law by End of Year, *from page 1*

was designed in and for the fee-for-service context of 1989. And that world no longer exists.

Today, medical dollars are spent on outcomes, not individual services. "In a system where we're transitioning and trying to pay for value, where the provider is ideally taking on some risk for outcomes and cost overruns, we don't have nearly as much of a need to interfere with who's getting paid for what service," Verma noted in her speech.

The Move for Stark Reform

Of course, talk of Stark Law reform is nothing new. Last year, the CMS solicited feedback on how the law should be changed for modern times and received more than 300 comments from hospitals and providers. Among the suggestions:

- Don't punish providers for inadvertent violations such as missing a signature or using an incorrect date; and
- Create an exception for providers in value-based arrangements.

Changes to Expect

Verma said that CMS is currently working on regulations designed to ensure Stark's workability for value-based and other modern conditions without compromising its effectiveness in deterring Medicare referral abuses and protecting program integrity. The changes will be unveiled later this year, she added, and are expected to include:

- Clarification of the regulatory definitions of volume or value, commercial reasonableness and fair market value;
- New rules addressing lack of signature, incorrect dates and other forms of technical noncompliance; and
- New provisions allowing for arrangements addressing cyber-security, EHR and other digital challenges

Big Deal: Danaher to Buy GE Biopharma

Danaher has entered into a definitive agreement with General Electric Company (GE) to acquire the biopharma business of GE Life Sciences, known as GE Biopharma, for approximately $21.4 billion in cash.

Deal Details

GE Biopharma is a leading provider of instruments, consumables, and software that support the research, discovery, process development, and manufacturing workflows of biopharmaceutical drugs. The business is comprised of process chromatography hardware and consumables, cell culture media, single-use technologies, development instrumentation and

consumables, and service. GE Biopharma is expected to generate annual revenue of approximately $3.2 billion in 2019, with approximately 75% of these revenues considered recurring.

The business will operate as a standalone company within Danaher's $6.5 billion Life Sciences segment. Other companies in the unit include Pall, Beckman Coulter Life Sciences, SCIEX, Leica Microsystems, Molecular Devices, and Phenomenex, along with IDT businesses.

Danaher has more than 20 operating companies in total, and approximately 71,000 employees worldwide. It holds the 162nd spot on the 2018 Fortune 500 list of the largest U.S. corporations based on revenue.

"GE Biopharma is renowned for providing best-in-class bioprocessing technologies and solutions. This acquisition will bring a talented and passionate team as well as a highly innovative, industry-leading product suite to our Life Sciences portfolio, providing an excellent complement to our current biologics workflow solutions."

— Thomas P. Joyce

Unloading GE Biopharma is part of a larger, ongoing restructuring plan by GE that has it exiting several sectors in order to focus on three core segments: aviation, power, and renewable energy.

Attractive Acquisition

In announcing the acquisition, **Thomas P. Joyce**, Jr., president and CEO of Danaher, explained the billion-dollar deal, indicating that it is about talent as well as technologies.

"GE Biopharma is renowned for providing best-in-class bioprocessing technologies and solutions. This acquisition will bring a talented and passionate team as well as a highly innovative, industry-leading product suite to our Life Sciences portfolio, providing an excellent complement to our current biologics workflow solutions," said Joyce.

"We expect GE Biopharma to advance our growth and innovation strategy in an important and highly attractive life science market. We see meaningful opportunities to harness the power of the Danaher Business System to further provide GE Biopharma's customers with end-to-end bioprocessing solutions that help enable breakthrough development and production capabilities. We look forward to welcoming this talented team to Danaher."

The transaction is expected to be completed in the fourth quarter of calendar year 2019, and is subject to customary conditions, including receipt of applicable regulatory approvals.

Funding the Deal

Meanwhile, Danaher is focused on raising additional cash to help cover the cost of the megadeal.

Immediately following announcement of the acquisition, Danaher announced that has priced concurrent offerings of 11 million shares of

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common stock at a price to the public of $123 per share and 1.5 million shares of 4.75% Series A Mandatory Convertible Preferred Stock at a price to the public of $1,000 per share (the offerings). The underwriters have separate 30-day options to purchase up to an additional 1.1 million shares of common stock, and up to an additional 150,000 shares of mandatory convertible preferred stock. The offerings are scheduled to be completed on March 1, 2019, subject to customary closing conditions.

The net proceeds from the common stock offering and the mandatory convertible preferred stock offering will be approximately $1.31 billion and $1.45 billion, respectively (or approximately $1.44 billion and $1.60 billion, respectively, if the underwriters exercise their options in full), in each case after deducting issuance costs and discounts.

The timing is not coincidental. A company press release confirms that Danaher intends to use the net proceeds from the offerings to fund a portion of the purchase price of its pending acquisition of GE Biopharma and to pay related fees and expenses. If for any reason the acquisition is not completed, Danaher indicates that it expects to use the net proceeds from the offerings for general corporate purposes.