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INSIDE THIS ISSUE

Health Reform: The Latest Twist in the Legal War on Obamacare

The Affordable Care Act, aka Obamacare, remains alive but certainly not well. When last we left the melodrama, a federal district court in Texas had ruled in favor of Republican Governors challenging the law's constitutionality (see *National Intelligence Report*, Jan. 15, 2019). That case is currently with the Fifth Circuit Court of Appeals. And while a ruling isn't expected until the end of the year, a new twist has occurred with the Justice Department deciding to switch sides in the fight and urge full repeal of Obamacare. Here's the latest and what it means.

Recap

In the 2012 case called *NFIB v. Sebelius*, we all thought that the U.S. Supreme Court had decided once and for all that Obamacare was constitutional. But things changed, including the federal laws on which the *Sebelius* ruling was based, namely the penalty on employers for not offering health insurance to their employees which the Court said was a form of tax that the Congress had a right to impose. But in

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From Blood Screen to Silver Screen: The Theranos Story Goes Hollywood

Clinical labs are not usually the stuff of Hollywood. But the story of Theranos and its charismatic leader has attracted filmmakers the way regular law-abiding labs never do, spawning not one but a pair of new movies—including an HBO documentary and a feature length film starring Oscar winner Jennifer Lawrence in the role of its woman-in-black, Elizabeth Holmes.

The Theranos Storyline

In case you've forgotten, Holmes is the Stanford University dropout who founded a company that was poised to disrupt the blood-testing business. With her black turtlenecks, Holmes charmed the industry and venture capitalists into believing that they were talking to the

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2019, the Republicans got rid of the penalty. With the tax gone, Obamacare was once more exposed to constitutional challenge.

Republicans seized the opportunity. Round 1 of the new case, *Texas vs. United States*, went to the challengers in December when Texas U.S. District Court Judge Reed O'Connor ruled that not just the individual mandate but all of Obamacare was unconstitutional. To prevent panic in the insurance industry, the DOJ asked Judge O'Connor to "stay," i.e., freeze his ruling, which he agreed to do on Dec. 30, effectively leaving Obamacare in effect unless and until the Fifth Circuit affirms the ruling. And that's where we are right now—waiting to hear from the Fifth Circuit, which may take until the end of the year.

The DOJ Flip-Flop & What It Means

After initially defending the law, the U.S. Department of Justice has jumped ship and called on the courts to strike down not just the individual mandate but all parts of Obamacare. So, instead of helping the Democratic Governors defend the case, it will issue a brief asking the Fifth Circuit to uphold the lower court ruling.

So, what does it mean? Probably not all that much. Many, including people within the Trump Administration, see the DOJ flip-flop as nothing more than politics. The theory is that the DOJ neither expects nor wants the entire law to be declared invalid, at least until a replacement plan is in place and is just posturing for the 2020 election.

What's At Stake

But even if it's a bluff, nobody denies that the stakes are high with about 20 million Americans who stand to lose their health insurance caught in the middle. House Speaker, Nancy Pelosi, has promised new health care legislation to lower costs and protect pre-existing condition provisions. But even if it passes in the House, a Democratic Obamacare bill has little chance of becoming law before 2020. And hopes of a bipartisan resolution are about as unrealistic as hopes can get, especially with a Presidential election looming.

Meanwhile, if the Fifth Circuit calls the DOJ's bluff and rules all of Obamacare unconstitutional and there's no replacement in effect, the impact will be devastating with the first casualties including:

- Protections for people with pre-existing conditions;
- ACA Medicaid expansion;
- Requirements for employers to provide health insurance;
- Insurance for children under 26 who get insurance through their parents' plans.

Other effects:

- Annual and lifetime limits on coverage would again be permitted;
- Caps on out-of-pocket expenses could be eliminated; and
- Insurers could again charge more based on age, gender and profession.

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Medicaid Fraud Enforcement Trends By the Numbers

A new report from OIG details Medicare Fraud Control Unit (MCFU) enforcement activity in fiscal year 2018. **Bottom Line on Top:** The numbers were pretty consistent with previous trends with little in the way of any dramatic changes. Here are the key numbers for FY 2018:

- **1,503:** Total convictions, including;
  - **1,109:** Convictions due to fraud; and
  - **394:** Convictions due to patient abuse or neglect;
- **974:** Individuals or entities excluded from federally funded health programs;
- **810:** Civil settlements and judgments;
- **$859 million:** Total amount recovered, including;
  - **$314 million:** Criminal recoveries; and
  - **$545 million:** Civil recoveries.

What MFCUs Are

MFCUs are state government agencies that investigate and prosecute Medicaid provider fraud and patient abuse or neglect within the particular state. Under the Social Security Act (SSA), each state is required to operate a MFCU unless it meets specific exemption criteria. In FY 2018, 49 states and the District of Columbia operated MFCUs. The OIG also certified the territories of Puerto Rico and the U.S. Virgin Islands also to operate MFCUs for the first time.

Convictions Trends

The total number of convictions has remained relatively steady for the past four years, after a jump from 2014 to 2015.

Year	Medicaid Convictions
2014	1,318
2015	1,553
2016	1,564
2017	1,528
2018	1,503

Source: U.S. Department of Health and Human Services, Office of Inspector General

For the past five years, fraud convictions have accounted for approximately 73% of all convictions.

Convictions of personal care service (PCS) attendants and agencies for fraud were significantly higher than for any other provider type in FY 2018: 496 convictions.

Other 2018 Data

Criminal recoveries, which spiked in 2017, are back in line with previous years.

The number of civil settlements and judgments is slightly lower than

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Medicaid Fraud Enforcement Trends By the Numbers, *from page 3*

in previous years. Similarly, in FY 2018, civil recoveries decreased in comparison to what happened in three of the last four years.

Other Noteworthy Numbers

In FY 2018, MCFUs:

- Had a conviction rate of 90.3%; and
- Recovered $2.92 for every $1 they spent.

The President's Proposed 2019 Federal Budget: The 6 Things Labs Must Know

While President Trump's proposed $4.75 trillion budget may be the largest in U.S. history, it calls for important cuts affecting health care in general and labs in particular. Here are the six things lab managers need to know about it:

1. Medicare & Medicaid Cuts

The part of the Trump budget with the most direct impact on labs are probably the deep cuts to Medicare and Medicaid, including $181 billion from Medicare and nearly $1.5 trillion from Medicaid over projected 10-year spending levels.

2. Payment Cuts to Health Providers

Medicare cuts would reduce payments to providers. The New York Times projects that cuts to hospitals over 10 years would amount to:

- $136 billion for unpaid bills and uncompensated care; and
- $131 billion in payments to hospital outpatient departments (including labs).

3. More Funding to Combat Opioids

The budget requests more than $30 billion for "drug control funding," including money for:

- Prevention and treatment;
- New resources for the Dept. of Health and Human Services (HHS); and
- States to help them respond to the crisis.

Significantly, the budget also calls for Medicaid and Medicare program changes to prevent drug abuse, e.g., via monitoring of providers and changes to current payment methods.

4. Increased Health Care Spending for Veterans

The budget requests an increase of nearly 10% in health care spending to enhance and expand veterans' access to health care and provide them with more treatment options, including allowing them to use walk-in clinics for minor illnesses and injuries.

5. Repeal & Replace Obamacare

The budget includes a section called "Repeals & Replaces Obamacare and Reforms Medicaid Financing" that highlights the negative aspects of the Affordable Care Act (ACA). After proposing the budget, the Administration reversed its previous position that at least part of the ACA should be retained and is now seeking full repeal (see the related story on page 7). In so doing, the Administration indicated that it would ensure that some form of replacement coverage is offered to the approximately 20 million Americans who'd lose their coverage if the ACA were repealed. But the budget itself includes no such replacement coverage plans, calling instead for turning over management of health care to the states.

6. Greater State Control Over Medicaid

The budget proposes empowering states to "modernize Medicaid benefits and eligibility," basically a code word for cracking down on what's perceived as Medicaid abuse. The budget notes that it "would give states additional flexibility around benefits and cost sharing, allow states to consider savings and other assets when determining Medicaid eligibility, and reduce waste by counting lottery winnings as income for Medicaid eligibility."

Takeaway: Keep in mind that the proposed budget is just that—a proposal. Under the U.S. Constitution, budgets are created by Congress, not the President. Still, budget proposals are significant for staking out the Administration's position on health care and other federal spending issues even if they exert only minimal influence on what eventually emerges from Congress, especially in times where each party controls one chamber.

From Blood Screen to Silver Screen: The Theranos Story Goes Hollywood, *from page 1*

Steve Jobs of lab medicine. Her pitch centered on a supposed miniaturization technology capable of testing microscopic samples as accurately and a lot more conveniently than any other lab on the planet could.

Convinced that Theranos' finger stick technology was a real technological breakthrough that would revolutionize the face of lab testing, investors piled billions into the company. Holmes also charmed the media, which heralded Theranos as a Silicon Valley success story, and powerful partners like Walgreens, which entered into what would turn out to be a disastrous consumer alliance with the firm. At its height, Theranos was valued at more than $9 billion.

The Ugly Truth

The Theranos storyline turned out to be a lie. The supposed groundbreaking technology proved nothing of the sort. Theranos not only used analyzers from other manufacturers but did so in ways that weren't approved or didn't meet federal guidelines. The results were all too often unreliable and inaccurate test results.

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Federal and state regulators soon swooped in, resulting in a series of costly settlements that the company would never be able to pay off. As a result of testing issues, the agreement with Walgreens, which had been the company's stepping stone to the consumer market, also unraveled. The drugstore chain sued Theranos for breach of contract and was awarded damages.

The company was forced to lay off most of its staff.

Then things got really ugly. Holmes and her ex-boyfriend, Ramesh "Sunny" Balwani, who served as Theranos president and chief operating officer until he retired from the company in May 2016, were indicted on nine counts of wire fraud and two counts of conspiracy to commit wire fraud.

With its founders awaiting trial, the company dissolved, owing creditors approximately $60 million.

In the Movies

The HBO investigative documentary, "The Inventor: Out for Blood in Silicon Valley," premiered at the 2019 Sundance Film Festival and recently aired on HBO. It shares the Holmes story in a straightforward manner, complete with interviews including of John Carreyrou, The Wall Street Journal investigative journalist whose story blew Theranos' cover and raised the red flags that would result in its undoing.

The other film, "Bad Blood," reportedly based on Carreyrou's book of the same name, is currently in production, starring Jennifer Lawrence as Holmes. It remains to be seen if Hollywood will stick to the facts in "Bad Blood."

It also remains to be seen whether Holmes will get to see the movie on a big screen. She's still awaiting trial for criminal charges, although a date for the trial hasn't even been set.

Meanwhile, Holmes has moved on with her life—a life that doesn't include the lab industry. The television show "Inside Edition" reports that Holmes is engaged to a hospitality heir, and that she has stopped wearing black turtlenecks.

GAO: $77.3 Billion in Improper Medicare/Medicaid 2017 Payments, Including $1.82 Billion to Labs

Medicare made $36.2 billion and Medicaid $41.2 billion in improper payments in fiscal year 2017. That's the finding of a report from the Government Accountability Office (GAO) based on CMS estimates published on March 27.

The Context

Each year, CMS uses estimates of fee-for-service (FFS) improper payments to identify Medicare and Medicaid overpayments for lab tests and other services and their causes during the previous fiscal year. The latest findings, which cover fiscal year 2017, may get more attention than in past years given the Administration's citation of fraud and abuse as justification for making deep cuts in both programs (see the related Budget story on page 4).

Improper Payment Totals

The improper payment totals for each program are attributable to different types of errors, including insufficient documentation and no documentation. Here are the breakdowns for FY 2017:

- **Total Medicare improper payments:** $36.2 billion, including $23.6 billion due to insufficient documentation + $0.6 billion due to no documentation; and
- **Total Medicaid improper payments:** $41.2 billion, including $4.3 billion due to insufficient documentation + $2.5 billion due to no documentation.

Improper Payments Made to Labs

The GAO report also breaks down improper payment amounts by sector, including lab, home health, durable medical equipment and hospice. Findings for FY 2017:

- **Total Medicare improper payments to labs:** $1.05 billion, including $1.02 billion due to insufficient documentation and only $4 million due to no documentation; and
- **Total Medicaid improper payments to labs:** $77 million, including $76 million due to insufficient documentation and less than $1 million due to no documentation.

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Labs IN COURT

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

Kentucky Lab Pays $125K to Settle Self-Disclosed SVT False Billing Charges

Case: VerraLab JA, LLC, has agreed to pay $125,983 after self-disclosing that it billed Medicare for specimen validity tests (SVT) performed to authenticate urine samples for drug testing. Unlike the underlying urine drug test which is actually used to manage treatment, SVT is not considered medically necessary by Medicare where its sole purpose is to validate the specimen, i.e., verify that it hasn't been adulterated.

Significance: In February 2018, the OIG issued a report saying that Medicare made $66.3 million in improper SVT payments to nearly 4,500 labs and physician offices. CMS has ordered Medicare contractors to recover those payments. Meanwhile, labs are proactively coming forward to self-disclose. VerraLab is the fourth settlement involving SVT payments that OIG has reported in the first quarter of 2019. The other three also involve providers from the Ohio Valley area:

Self-Disclosed SVT Payment Settlements (January thru March 2019)		
Date	**Lab**	**Settlement Amount**
Jan. 24	Northern Kentucky Center for Pain Relief	$126,799
Feb. 6	Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD (Ohio)	$111,706
March 13	VerraLab JA, LLC (Louisville, KY)	$125,983
March 13	Medical Specialist of Kentuckiana, PLLC (MSK) (Louisville, KY)	$69,776

Federal Jury Finds Trio Guilty of $3.5 Million Lab Kickback Conspiracy

Case: Three men from the Chicago area were convicted of taking bribes for sending blood, urine and saliva samples to St. Louis lab AMS Medical Laboratory, Inc. for testing subsequently billed to Medicare and Medicaid. Under the elaborate scheme which generated $3.5 million in false test billings, the defendants sent AMS samples collected at health fairs held at churches and businesses in Illinois and Indiana under the names of doctors who didn't order the tests or even know the patients; in exchange, they received a cut of 50% of the profits—up to $200 per sample—from AMS' managing partner.

Significance: The Chicago three are among 10 defendants in the case, including the managing partner who pled guilty last year and a physician convicted by a jury last October for pocketing kickbacks in connection with the scheme. They'll be sentenced in July.

Co-Owner of Kentucky Lab Pleads Guilty to Reference Lab Conspiracy

Case: This story is about a medical billing firm T. Monroe Medical Billing and its toxicology lab client Compliance Advantage LLC (CAL) that were partially owned by the same gentleman. The problems began in 2016 when Medicaid, Aetna and Humana accused the lab of improper billings and cut payments to the facility. Aetna also demanded that CAL repay $750K. To get around the ban and generate revenue, the co-owners cut a reference lab agreement with a third lab (not named in the court papers) enabling Monroe and CAL to bill the payors for tests that were actually performed by CAL in the name of the third lab. **The cut:** 60/40 with the third lab taking the 40%. The reference lab agreement was backdated to further the deception.

Significance: One of the co-owners pled guilty to one count of conspiracy and now faces up to five years' in prison when he's sentenced in June. The other co-owner who had a partial ownership interest in both CAL and Monroe will answer to a higher authority, having died in 2017.

Healthcare 'Trial of the Century' Ends in Guilty Verdict against Esformes

Case: After a seven-week trial, a federal court convicted Florida healthcare executive Philip Esformes of 20 charges in carrying out a $1.3 billion Medicare fraud scheme, the biggest in history. In addition to paying doctors to refer patients to his elaborate nursing homes, labs and home health agency network from 2009 to 2016, Esformes paid a regulatory official thousands of dollars to sound the warning when government inspectors were planning to inspect the facilities.

Significance: Although not strictly about labs, the Esformes case has been called the healthcare trial of the century due to the sheer size of the scheme. And it's not over. Esformes' attorneys say they plan to appeal the verdict.

Lab Technician Gets 56 Months' Jail for Role in Texas Toxicology Scheme

Case: A former toxicology testing company account rep pled guilty to conspiring with a medical clinic lab technician to steal patient identities and urine specimens from the clinic and send them to the testing company without a physician order or patient consent so they could pocket commissions and collection fees. Along the way, they forged patient consent signatures, falsified medical records and created registration forms and other fictitious documents to make it look like the unapproved toxicology screens were properly ordered. As a result of the scheme, Medicare was billed $836,788 between May and December 2015.

Significance: The account rep was sentenced to 56 months followed by three years of supervised release. In exchange prosecutors dropped the remaining 17 charges against him and the lab technician, who'll be sentenced on April 17. Each defendant will also pay $166,866 in restitution.

GAO: $77.3 Billion in Improper Medicare/Medicaid 2017 Payments, Including $1.82 Billion to Labs, *from page 7*

The Medicare v. Medicaid comparison of lab payments is a bit apples-to-oranges to the extent that what counts as a lab varies by calculation. Thus, labs counted for Medicare overpayments includes labs that are both clinically independent and which bill Medicare under Part B; Medicaid calculations, by contrast, include labs, X-ray and imaging services. GAO acknowledges that the categories aren't directly comparable and that it "used the estimated improper payments to examine factors that contribute to improper payments for laboratory services due to insufficient documentation."

Examples of Insufficient Lab Documentation

The report lists the following as examples of insufficient documentation in the Medicare lab category:

- Documentation from the referring physician did not support the order or an intent to order the billed lab tests; and
- Documentation from the referring physician did not support that the beneficiary currently has diabetes for a billed lab test for the management and control of diabetes.

Sneak Peek for FY 2018

CMS hasn't yet released its Medicaid FFS Supplemental Payment Data for FY 2018—it's scheduled to do so later this spring. But the FY 2018 Medicare data are out. And the GAO report for FY 2017 includes appendix offering an early glimpse into the FY 2018 numbers:

- Estimated total of $31.6 billion in improper Medicare payments made;
- Estimated $1 billion in Medicare overpayments made to labs; and
- Approximately 26% of improper payments to labs were the result of insufficient documentation.

Case of the Month: Milwaukee Clinic the Latest MD-Owned Lab Busted for Urine Drug Test Abuses

Fraudulent utilization and billing of urine drug screening has become a priority for federal enforcers since the $256 million Millennium settlement of 2016. Subsequent cases have targeted abuses committed by physician-owned drug abuse, rehab and pain clinics. The most recent $4.1 million settlement by the physician owner of a now shuttered Milwaukee mental health clinic is in many ways typical of what's been happening for the past three years.

The Acacia Case

Dr. Abraham Freund acquired the Acacia Mental Health Clinic LLC in 2009 recognizing its enormous potential as a source of Medicaid drug testing revenues. He soon implemented new rules requiring every patient to provide a urine sample for every type of visit, even when they weren't being seen for drug abuse issues, according to the government's lawsuit. Every sample collected was tested for the same drugs.

From Paper to Gold-Plated Technology

At first, Acacia used a simple "pee in a cup" test detecting the presence of several drugs which was reimbursable at $20 but often upcoded to nearly 10 times that amount. But in November 2012, Acacia bought a $40,000 analyzer which raised the level of reimbursement to $300 per test. Subsequent technological upgrades allowed Acacia to perform and bill for more complex and expensive tests to the point where the clinic was getting paid an average of $474.66 by 2013. Medicaid reimbursement grew from $332K in 2011 to $3.3 million (for nearly 9,000 urine drug screens) in 2014. Between 2011 and 2015, Acacia was accounting for an astounding 99% of all Wisconsin Medicaid payments for mental health and substance abuse counseling services.

The Whistle Blows

As is often the case, Acacia was undone by an inside source. In 2013, nurse practitioner Rose Presser filed a whistleblower suit accusing the clinic of requiring excessive drug screens and prescription refills as well as billing initial appointments as "assessments." After initially declining to intervene, the DOJ had a change of heart.

Last month, Freund agreed to settle the case for $4.1 million (of which

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Case of the Month: Milwaukee Clinic the Latest MD-Owned Lab Busted for Urine Drug Test Abuses, *from page 9*

the whistleblower will be entitled up to 30%) and a 20-year Medicare and Medicaid exclusion. The one part of the settlement that makes it different from previous cases is the inclusion of charges that Acacia, Freund and his son, Isaac, falsely billed Medicaid for telemedicine services provided by psychiatrists located outside the US.

Analysis: Why Physician-Owned Labs Have Become the Primary Target

Urine drug test abuse has attracted the attention of whistleblowers and prosecutors because it amalgamates two forms of high-priority misconduct:

- Traditional Medicare fraud, i.e., generation of enormous revenues in overcharges or services that aren't medically necessary; and
- Promotion of both legal and illegal opioid use.

Although big testing labs like Millennium have been involved, much of the recent focus has been on rogue physicians, particularly those who perform tests out of their own offices and labs. What makes these testing scams cases even more egregious is that the victims, which typically include the indigent, the mentally ill and patients with current or previous drug addictions, are often forced to undergo testing so that doctors can turn a profit.