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INSIDE THIS ISSUE

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Brief Your CEO: Explaining How Trump Budget Will Affect Your Lab

As lab manager, you may want to ensure your CEO understands how President Trump's 2018 budget proposal may affect your laboratory. Here are four things to cover in your briefing.

What the Budget Proposal Is—And Is Not
Technically, the proposal is not a budget. Only Congress has the constitutional authority to make budgets and appropriations. But while presidents do not "make" budgets, they play a leading role in the process by establishing spending priorities. The 2018 budget proposal is best understood as a "blueprint" of President Trump's spending priorities.

1. NIH Budget Cuts

The proposal requests $69 billion for HHS, $15.1 billion (or 17.9 percent) less than current levels. The NIH stands to lose $5.8 billion (almost 20 percent) in funding. To put things into perspec-

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Another Decision in the HDL Case Highlights Kickback Risks of Patient Responsibility Waivers Involving Private Payers

The Health Diagnostics Laboratory, Inc. (HDL) and Singulex saga continues. The latest chapter involves not the labs themselves but BlueWave Healthcare Consultants, their marketing firm. And it raises new and potentially troubling implications for labs that waive copayments and deductibles for patients covered by private payers.

A Quick Recap

The HDL case has been described as the mother of all clinical lab fraud schemes because of the massive dollars involved. For those of you unfamiliar with it, the case began as a *qui tam* lawsuit accusing HDL, Singulex and one other lab (the now defunct Berkeley Heart Lab) of working with BlueWave to induce blood testing referrals, including medically unnecessary large

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multi-assay panels, by paying physicians sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving co-payments and deductibles.

In 2013, the FDA issued a warning letter to 23andMe requiring that it stop marketing its DTC Personal Genome Service. The FDA had concluded that the $99 saliva test was a class III medical device requiring FDA approval. But a little less than two years later, the company won FDA approval for a DTC genetic carrier test for Bloom Syndrome.

In 2015, HDL paid $47 million to settle False Claims Act (FCA) charges against it; Singulex settled for $1.5 million. Both labs also entered into corporate integrity agreements with the government. The settlement forced HDL into Chapter 11 but the embattled lab giant's legal woes continued. In addition to its creditors, HDL is being sued by Cigna for $84 million in damages the private payer allegedly suffered as a result of the scheme. Adding insult to injury, BlueWave has also sued its former partner for millions in unpaid consulting fees.

The Newest Case

Now BlueWave is in the hot seat. The most recent case centers on the waiver of copayments and deductibles by HDL and Singulex. In the case it was argued that the waivers were kickbacks to induce referrals even though they applied to patients of private insurers. BlueWave disagrees and asked the South Carolina federal court to throw out the charges without a trial.

Ruling: The court refused.

Reasoning: Waivers of private insurance copays and deductibles may amount to kickbacks under the Anti-Kickback Statute (AKS). And there was evidence suggesting that the waiver arrangements in this case did cross the line:

- BlueWave's agreement with HDL and Singulex allegedly required the labs to agree not to charge patients for copays and deductibles; and
- BlueWave then leveraged the labs' no-balance billing practices to induce referrals by highlighting those practices in the marketing pamphlets it gave to physicians.

Bottom Line: BlueWave will have to stand trial for its role in the kickbacks scheme. And remember that committing a kickback violation can make a defendant guilty of FCA violations if it submitted false claims for services provided as a result of those illegal referrals.

What It Means

The concept of finding a kickback violation based on an arrangement involving services paid by private insurers is nothing novel, notes Baker Donelson attorney Robert Mazer. For example, the OIG has stated that improper physician discounts on private pay business can be used to unlawfully induce referrals of Medicare tests.

G2CA

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But, Mazer suggests, the relationship between forgiveness of a private patient's cost sharing responsibility and financial benefit to a physician related to his referrals of federal health care program appears much more attenuated.

Be mindful that waiver arrangements can raise kickback red flags even when they involve private payers.

TEST YOURSELF

How Much Time Does OSHA Have to Cite Labs for Recordkeeping Violations?

GROUND RULE

OSHA Recordkeeping Regulations (Section 1904.33) require labs and other employers to retain accurate illness and injury records) for 5 years. OSHA has a 6-month window to issue citations for recordkeeping violations.

SCENARIO

On July 1, 2017, a staff lab technician complains to OSHA that ConnSeel Laboratories is deliberately covering up work-related illnesses to employees. A week later, OSHA sends over an inspector who checks ConnSeel's 2016 illness and injury reports, i.e., OSHA Form 300 Logs, Form 300A Summary and Form 301 Reports. Sure enough, she finds at least 3 cases in which ConnSeel didn't report recordable illnesses, in violation of recordkeeping rules.

QUESTION

Can OSHA cite ConnSeel for recordkeeping violations?

A. No, because ConnSeel committed the violations more than 6 months ago

B. Yes, as long as the citations are issued within 6 months after the inspector discovered the violations

ANSWER

A. No because OSHA didn't discover the violations until after the 6-month window for issuing citations had closed. **Note:** If you got this one wrong, don't feel too bad. Up until a few weeks ago, the rules were different and B *would have been* the right answer.

EXPLANATION

OSHA recordkeeping regulations give the agency 6 months to issue citations for violations but don't specify when the window period begins to run. In

The rule change doesn't affect the substance of OSHA recordkeeping requirements. Your lab will still need to maintain the same OSHA illness and injury records as before.

2013, OSHA purported to resolve the problem by adopting a new rule clarifying that OSHA recordkeeping violations are "ongoing" and that the window period begins to run not when the violation *occurs* but when OSHA first *discovers* it.

But on April 3, 2017, the new President signed a congressional action (H.J. Res. 83) nullifying the OSHA rule and specifying that the 6-month window period begins when the employer *commits the* violation.

IMPACT ON YOU

The rule change doesn't affect the substance of OSHA recordkeeping requirements. Your lab will still need to maintain the same OSHA illness and injury records as before. But resetting the window start to the date of violation means that OSHA will now have only 6 months to uncover violations. This will make it much harder for OSHA to enforce the rules.

The above scenario, which is purely hypothetical, illustrates how this may play out. Remember that ConnSeel committed the recordkeeping violations in 2016 and that OSHA discovered them on July 8, 2017.

- **Before:** Under the previous rules, ConnSeel's 2016 recordkeeping violations would have been considered ongoing and OSHA could have cited the lab despite not discovering them until 7 months after they were committed.
- **Current:** Under the new rules, the 6-month window period for recordkeeping violations committed in 2016 would end on June 30, 2017 and OSHA couldn't cite ConnSeel for the violations since it discovered them in July 2017.

How to Comply with New OSHA Electronic Injury Recordkeeping & Reporting Rules

- Does your lab facility have 250 or more employees?
- Has your employee count reached 250 or more at any time during the 2016 calendar year?
- Is your lab part of a hospital that has had 20 to 249 employees at any time during the calendar year?

If you answered YES to any of the above questions, make sure you mark July 1 on your compliance calendar. That's the date by which you must make your first electronic filing to OSHA under new illness and injury recordkeeping rules. Here's a look at the rules, who they affect and what you must do to comply with them.

Background

OSHA requires labs to maintain accurate records of work-related injuries and illnesses. In November 2013, OSHA proposed the so called "Improve Tracking of Workplace Injuries and Illnesses" rule to require electronic recordkeeping and reporting. OSHA issued the Final Rule on May 12, 2016 (Rule) and the first electronic filing deadline is July 1, 2017. Here are the 13 things lab managers need to know about the Rule to ensure that their facility complies with it.

1. How It Changes OSHA Log Requirements

The Rule changes OSHA Recordkeeping Regulations (Section 1904), specifically, the provisions requiring you to keep OSHA logs to track work injuries and illnesses. It doesn't affect the kind of information you track and how you record it. You'll still need to maintain the same OSHA logs you always have. But starting July 1, some labs will have to start reporting information from their injury and illness records electronically each year so that OSHA can post the data on a publicly accessible website.

2. Why OSHA Issued the Rule

Mandatory electronic reporting and disclosure of OSHA injury records is designed to give labs and other employers a safety "nudge." OSHA's logic: Knowing that their OSHA logs will be accessible to potential investors, customers, employees and the public, will give employers an incentive do more to prevent work-related injuries and illnesses. The availability of online data on other labs will also enable labs to benchmark and compare their health and safety performance to others in the sector.

3. How to Determine If Your Lab Is Covered

If you're currently exempt or partially exempt from OSHA recordkeeping requirements, you're not covered by the new electronic reporting and disclosure rules either (unless OSHA expressly notifies you otherwise). But if

you are required to keep OSHA illness and injury records, you may also be subject to the new rules depending on your lab's size and facility type. Specifically, you're covered if:

- You had 250 or more employees at any time during the previous calendar year; or
- You had 20 to 249 employees at any time during the previous calendar year **and** you're in one of the industries designated as high-risk listed in Appendix A of the Rule. For labs, the relevant listings could include:

High-Risk Industries Listed in Appendix A Relevant to Labs

NAICS	Industry
6219	Other Ambulatory Health Care Services
6221	General Medical & Surgical Hospitals
6222	Psychiatric & Substance Abuse Hospitals
6223	Specialty (except Psychiatric & Substance Abuse) Hospitals
6231	Nursing Care Facilities
6232	Residential Mental Retardation, Mental Health & Substance Abuse Facilities
6233	Community Care Facilities for the Elderly
6239	Other Residential Care Facilities
6242	Community Food & Housing, and Emergency & Other Relief Services
6243	Vocational Rehabilitation Services

4. Which Information Is Subject to Electronic Reporting & Disclosure

Electronic reporting and disclosure rules apply to injury and illness information listed in a lab's OSHA recordkeeping forms, i.e.:

- The OSHA Form 300 Log of Work-Related Injuries and Illnesses (OSHA 300);
- The OSHA Form 300A Summary of Work-Related Injuries and Illnesses (OSHA 300A); and
- The OSHA Form 301 Injury and Illness Incident Report (OSHA 301).
- **If you're covered because your lab has 250+ employees**, you must report information from all 3 forms.
- **If you're covered because your lab has 20 to 249 employees and is high-risk**, you must report information only from your OSHA 300A.

5. Which Information from Each OSHA Form You Must Report

Basic rule: You must report all information listed in the particular form except information that reveals or could be used to reveal the identity of the injured or ill employee:

OSHA Form	Required Information
OSHA 300	Everything except employee name (column B)
OSHA 300A	Everything
OSHA 301	Everything except: Employee name (field 1); employee address (field 2); name of physician or other health care professional (field 6); facility name and address if treatment given away from worksite (field 7)

6. How Often You Must Report

Electronic reporting is required once a year.

7. The Deadline for Reporting

The new reporting rules officially took effect on January 1, 2017 and will be phased in over the next 2 years. Reporting deadlines vary depending on why you're covered:

If you're covered because your lab has 250+ employees, follow this timetable:

- *July 1, 2017:* Deadline to report 2017 OSHA 300A information;
- *July 1, 2018:* Deadline to report 2018 OSHA 300, 300A and 301 information;
- *March 2, 2019 (and every year thereafter):* Deadline to report information from that particular year's OSHA 300, 300A and 301.

If you're covered because your lab has 20 to 249 employees and is classified as high-risk, follow this timetable:

- *July 1, 2017:* Deadline to report 2017 OSHA 300A information;
- *July 1, 2018:* Deadline to report 2018 OSHA 300A information;
- *March 2, 2019 (and every year thereafter):* Deadline to report information from that particular year's OSHA 300A.

8. How to Report the Required Information

OSHA will provide a secure web site for employers to electronically submit the required injury and illness information. The site will have web forms for direct data entry and instructions for other means of submission, e.g., uploading of files.

9. How Long Reporting Will Take

OSHA claims that it will take about 10 minutes to create an account and another 10 minutes to enter the required 300A information. If you have to file information from the other two OSHA forms because your lab has 250+ employees, OSHA estimates it will take 12 minutes to enter the required information for each injury or illness recorded on your OSHA 300 and 301.

10. The New Workers' Reporting Rights Notification Requirement

OSHA is worried that once OSHA logs become publicly accessible, employers may try to keep workers from reporting work injuries and illnesses. Thus,

while it's already against the law to punish a worker for reporting an injury or illness, the Rule requires employers to notify workers that they have the right to report work injuries and illnesses without retaliation by August 10, 2016.

Model Notification Tool: Even though the deadline for initial notification has passed, you can reinforce that notification by posting the GCA version of the OSHA "*Job Safety & Health—It's The Law*" workers' rights poster on page 9.

11. The New 'Reasonable' Reporting Procedure Rule

OSHA already requires employers to establish a policy for workers to report work injuries and illnesses. But the Rule expressly states what the previous regulations only implied: the reporting procedure must be reasonable and not discourage or deter workers from reporting injuries and illnesses.

12. How to Ensure Your Reporting Procedure Complies with the Rule

Although the Rule doesn't define "reasonable," OSHA has provided guidance to help employers determine if their reporting procedure is acceptable:

- Rigid prompt reporting requirements that discipline workers for reporting late are problematic especially with regard to injuries and illnesses that take time to develop like musculoskeletal disorders;
- Incentive programs that reward workers for being injury- and illness-free are okay as long as they don't discourage reporting;
- Drug testing workers after they report an injury or illness is okay as long as testing meets federal and state requirements and isn't designed to intimidate, discourage or punish reporting.

13. OSHA's New Anti-Retaliation Enforcement Powers

Under previous rules, OSHA's authority to punish employers for retaliation didn't kick in unless and until the worker filed a complaint. The problem is that workers often lacked the time and knowledge—not to mention the courage—to file a retaliation complaint against their employer with OSHA. The Rule eliminates that barrier to enforcement by allowing OSHA to issue citations for retaliation even if workers *don't* file a complaint.

TOOL: MODEL OSHA JOB SAFETY POSTER & NOTIFICATION TO LAB EMPLOYEES

OSHA has long prohibited labs from retaliating against employees for reporting work-related injuries or illnesses. New rules up the ante by adding the requirement that employers notify employees in writing of their right to report injuries and illnesses without retaliation. While the August 10, 2016 deadline for initial notification has passed, you may want to reinforce the message. An excellent way to do that is in the context of a broader notification explaining employee and employer health and safety rights and duties. OSHA has published a "Job Safety & Health—It's The Law" poster to accomplish that. But like any other government document, the OSHA poster leaves a little to be desired. So we've taken the liberty of improving it in the form on page 9.

OSHA JOB SAFETY & HEALTH—IT'S THE LAW POSTER

Job Safety and Health
IT'S THE LAW!

All Workers Have the Right to:

- A safe workplace.
- Raise a safety or health concern with your employer or OSHA, or report a work-related injury or illness, without being retaliated against.
- Receive information and training on job hazards, including all hazardous substances in your workplace.
- Request an OSHA inspection of your workplace if you believe there are unsafe or unhealthy conditions. OSHA will keep your name confidential. You have the right to have a representative contact OSHA on your behalf.
- Participate (or have your representative participate) in an OSHA inspection and speak in private to the inspector.
- File a complaint with OSHA within 30 days (by phone, online or by mail) if you have been retaliated against for using your rights.
- See any OSHA citations issued to your employer.
- Request copies of your medical records, tests that measure hazards in the workplace, and the workplace injury and illness log.

Employers Must:

- Provide employees a workplace free from recognized hazards. It is illegal to retaliate against an employee for using any of their rights under the law, including raising a health and safety concern with you or with OSHA, or reporting a work-related injury or illness.
- Comply with all applicable OSHA standards.
- Report to OSHA all work-related fatalities within 8 hours, and all inpatient hospitalizations, amputations and losses of an eye within 24 hours.
- Provide required training to all workers in a language and vocabulary they can understand.
- Prominently display this poster in the workplace.
- Post OSHA citations at or near the place of the alleged violations.

FREE ASSISTANCE to identify and correct hazards is available to small and medium-sized employers, without citation or penalty, through OSHA-supported consultation programs in every state.

1-800-321-OSHA (6742) • TTY 1-877-889-5627 • www.osha.gov

Brief Your CEO: Explaining How Trump Budget Will Affect Your Lab, *from page 1*

tive, you might want to let your CEO know that the proposed $25.9 billion for NIH funding is actually below *2003* levels.

You can also give your CEO a sense of the potential impact by explaining what happened in 2013 when the NIH's budget was slashed 5 percent via sequestration cuts. *The result:* In fiscal year 2013, the NIH awarded 700 fewer competitive research grants. And the cuts Trump is proposing for fiscal year 2018 are five times greater than in 2013!

It is also worth mentioning that the proposal also refers to "a major reorganization of NIH's Institutes and Centers" without listing any details.

The proposal also calls for "reforms to key public health, emergency preparedness, and prevention programs"—such as changing preparedness grants to "reduce overlap," save expense and channel funding to states most in need.

2. More Money for Fraud Enforcement

Another item in the proposal directly affecting the diagnostics industry to tell your CEO about is the increase in federal enforcement funding, particularly with regard to Medicare and Medicaid fraud initiatives under the Health Care Fraud and Abuse Control Program (HCFAC). The proposed budget would raise HCFAC discretionary funding for 2018 by $70 million to $751 million.

The proposal declares the administration's commitment to "investing in activities to prevent fraud, waste, and abuse and promote high quality and efficient health care" and points to the high return on investment associated with fraud enforcement activities. "Additional funding for HCFAC program has allowed the Centers for Medicare & Medicaid Services in recent years to shift away from a 'pay-and-chase' model toward identifying and preventing fraudulent or improper payments from being paid in the first place," the proposal explains.

3. Higher FDA User Fees

Your lab may also be impacted by the proposal's attempt to "recalibrate" medical product user fees, which could include doubling of what pharmaceutical companies and medical device manufacturers (including diagnostics companies) pay in review costs. Explain to your CEO that the FDA had decreased user fees in 2017 to what the Regulatory Affairs Professionals Society says are the lowest fees since 2013. The White House says the proposed increase in fees is "designed to achieve regulatory efficiency and speed." However, you may want to add that given the current shortage of FDA reviewers and the federal hiring freeze, experts are skeptical that the increase in fees would achieve its stated goal.

4. Public Health Emergency Funding

The proposal also calls for "reforms to key public health, emergency preparedness, and prevention programs"—such as changing preparedness grants to "reduce overlap," save expense and channel funding to states most in need. It also proposes a new Federal Emergency Response Fund to address public health crises such as the Zika virus outbreak. Finally, the Centers for Disease Control and Prevention would get a $500 million block grant designed to provide more flexibility and address state-specific needs.

Labs IN COURT

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

Theranos Pays $4.65 Million to Settle Arizona Consumer Fraud Case

Case: Although it's still under legal attack from multiple directions, Theranos did get some relief on one front: Arizona. The state claimed that Theranos committed consumer fraud by misrepresenting the reliability of its blood tests in its marketing and advertising. Theranos has agreed to settle the case by providing, among other things, full refunds to the more than 175,000 residents who used the blood testing services, $200,000 in civil penalties and $25,000 to cover the state's legal costs. Total settlement amount: $4.65 million.

Significance: The Arizona AG had also charged Theranos with failure to comply with federal CLIA requirements. While not admitting liability, Theranos has agreed not to own or operate a CLIA-licensed lab in the state for 2 years, starting March 28, 2017. Of course, that appears to be a moot point given the company's recently announced intentions to shift its business focus from lab testing to technology and development of its miniLab, a compact 2.5 cubic feet device containing a mini-robot processing single use cartridges.

Quest to Pay $1.15 Million for Self-Disclosed CMP Violations

Case: Quest Diagnostics, Inc., New Jersey has agreed to fork over $1.151 million for a trio of Civil Monetary Penalties Law violations that it voluntarily self-disclosed to the OIG. The allegations involve:

- Performance of services outside the scope of employment by Quest phlebotomists in Texas, Maryland, Ohio and New Jersey;
- Failure to meet documentation requirements in connection with Quest's donations of electronic health records software and information technology to clinical laboratory referral sources; and
- Failure to collect timely second-year payments from physician clients as required in electronic health record donation agreements.

Significance: This is the second reported case of an OIG fine against Quest in 2017 for self-disclosed violations. In February, Quest agreed to pay $315,093 for allegedly paying kickbacks to a referral source in a case involving rent payments at above fair market value to a medical practice made by a Quest lab in New Jersey.

Medicare Exclusion for Not Documenting Response to Urine Drug Test Results

Case: A Michigan physician and pain management specialist agreed to a 3-year Medicare and Medicaid exclusion for failing to meet medical necessity documentation standards. According to the OIG, the physician didn't adequately document his response to results of urine drug screenings and discussions with patients who:

- Tested positive for illicit drugs and/or controlled substances;
- Tested positive for noncontrolled substances he didn't prescribe; and/or
- Tested negative for controlled substances he did prescribe.

Significance: This case serves as a reminder of two important morals on physician documentation of medical necessity of lab tests:

- Proper documentation isn't just a favor to help the lab get paid for ordered tests—it's a core standard of health care quality that physicians must meet to participate in Medicare; and
- To document medical necessity properly, physician must show not simply why they ordered the tests but how they actually used the test results to treat the patient.

MD Practice Manager Fined, Jailed for Testing Ripoff

Case: The manager of an Oregon ophthalmology practice was fined $2.519 million and sentenced to a year and a day in prison for his role in a six-year scam targeting Medicare, private health insurers and even the IRS. The ophthalmologist, since deceased, who also happened to be the manager's father, performed medically unnecessary diagnostic tests and the manager sent out the invoices, often billing for tests that cost more than were actually performed and double billing insurers for the same test. As icing on the cake, the two concocted a scheme involving a straw company to conceal nearly $8 million in business revenue from the IRS and finance personal expenses including the construction of a posh home.

Significance: The manager was actually hit with a pair of fines—$1.702 million in restitution to Medicare, Care Oregon and several private health insurers and $817,378 to the IRS. And once he gets out of jail, he'll be subject to three years of supervised release.