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Inside this issue

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3 Things We Learned from New OIG Report on 2015's Top 25 Lab Tests by Medicare Payment

Buried in the back of the Office of Inspector General (OIG) recent report on 2015 Medicare payments for Part B lab tests are three key revelations about the new *Protecting Access to Medicare Act of 2014* (PAMA) payment system scheduled to take effect on Jan. 1, 2018.

1. Hospital Labs Will Not Report

The report confirms what the lab community has long suspected: that the private payer data the Centers for Medicare and Medicaid Services (CMS) will use to set the new payment rates will *not* come from hospital labs except for the handful of hospital outreach labs that have their own National Provider Identifier. Just about all of the data will come from (1,398) independent labs and (11,149) physician office labs which, together, constitute only 5% of all labs. These 12,547 labs accounted for 69% of Medicare payments for lab tests in 2015, the report notes.

2. Payment Rates for at Least Some Tests Will Go Up in 38 States

Although lab payments will be generally lower, the report states that rates for 22 of the 25 top most frequently ordered lab tests will go up in some parts of the country, with 38 states seeing higher rates for at least one of the top 25 tests. Increases will range from $0.02 to $30.27 per test, according to the report (see the graphic on page 4).

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Lab Institute 2016 Recap: Convergence and Compliance Dominate Discussions

Attendees at G2 Intelligence's 34th annual Lab Institute were treated to a history lesson about diagnostics as well as forward-looking discussions that illuminated the current state and the future of the laboratory industry and clinical diagnostics.

Convergence with Life Sciences, Patients

Opening keynote speaker, Kristin Pothier, EY's Global Head of Life Sciences, Transaction Advisory Services, highlighted key areas of life sciences that are driving convergence among various, previously independent sectors within the health care marketplace: pharmaceutical research and development, precision medicine and patient information. Pothier's presentation demonstrated how new technologies

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Be a part of the conversation next year! Join us for **Lab Institute 2017**, October 25-27, 2017 at the Hyatt Regency Capitol Hill, Washington D.C.

Lab Institute 2016 Recap, *from page 1*

and business models, precision medicine and the increasing prevalence of companion diagnostics are highlighting the value of diagnostics and driving alliances and acquisitions involving in-vitro diagnostics companies. Big data and increased access to patient information, mobile technology and rising consumerism are also revolutionizing patient care, according to Pothier.

In his keynote addressing the state of the laboratory industry, Dr. Gregory Henderson, president of BioReference Laboratories, discussed a convergence of a different kind – the convergence of diagnostics and health care providers with patients and their data. He emphasized the importance of the patient and patient access to data in an increasingly mobile and data-intense age. Henderson discussed the lab industry's need to educate and involve patients in the health care delivery process—providing "actionable medical knowledge" and explaining for patients the data generated in health care. He discussed this challenge in the context of the diagnostic industry's history. He began his presentation highlighting the differing viewpoints of chemists and vitalists about the need for lab testing to assist diagnosis roughly 200 years ago to gain perspective on the industry's current challenges. He concluded that labs must confront similar challenges faced those many years ago to demonstrate the value of diagnostic testing and manage utilization.

Compliance Issues Permeate Discussions Throughout Lab Institute

During three days of presentations, compliance issues for laboratories and pathologists permeated many of the discussions. Beginning with a workshop on workforce issues, speakers addressed compliance risks that can arise in recruiting, hiring, managing and terminating members of the workforce. Panel discussions prepared laboratories for the compliance challenges they'll face with new payment methodologies, regulation and oversight of new technologies such as next generation sequencing, laboratory developed testing and direct-to-consumer testing. Throughout the conference, concurrent and general sessions addressed compliance issues relating to reimbursement, managing data generated by diagnostics, and ensuring patient access to test results.

Health care attorney Karen Lovitch capped off a morning of general sessions addressing regulatory, reimbursement and policy issues by highlighting three key compliance hotspots for labs to watch out for—medical necessity, arrangements with physicians, and increasing coverage restrictions. Within those key issues, she also discussed increased individual accountability under the Yates memo, private payer enforcement, waiver of copayment amounts and surprise medical bill legislation that addresses patient bills for out-of-network services.

Lovitch was only one of several speakers to address the challenges raised by surprise medical bill legislation. This legislation protects patients from unexpected bills from out-of-network providers after they sought services from an in-network facility. For example, a patient seeking treatment at an in-network hospital might be billed separately by out-of-network labs, radiologists or anesthesiologists. New York and California both have passed related legislation within the last two years and the issue is gaining national attention. Lovitch and other speakers cautioned labs to make sure they understand state laws and reimbursement policies that govern such out-of-network billing.

Continuing Rise of Genetic Testing

Increasing diagnostic options for providers and patients was a common theme throughout the conference. Speakers noted that more opportunities also require more education

and better resources to help providers and patients understand their options, select the most appropriate diagnostics, and properly manage utilization.

Keynote speaker Mara Aspinall, chief executive officer of Health Catalysts and Executive Chairman of GenePeeks, said diagnostics will change with the rising importance of genetic testing. She explained that identification of genetic mutations rather than site of a tumor will drive cancer treatment in the future. The future of diagnostics, Aspinall predicted, will involve algorithms and integrated data gathered from multiple sources—in short, "an information business with a wet lab on the side."

The final presentation, by Gillian Hooker, vice president of clinical development at NextGxDx, similarly addressed the explosion in the genetic testing market with tens of thousands of tests currently on the market and new genetic tests being introduced every day. NextGxDx research indicates there are more than 65,000 genetic testing products on the market compared to less than 13,000 just three years ago. Hooker addressed challenges providers face in identifying the right test and a need for standardization in terminology not only to simplify ordering but to facilitate coding and reimbursement as well.

Takeaway: Industry leaders indicate the future of diagnostics is patient- and data-focused yet brings both new and familiar compliance and business challenges.

G2 Awards Recognize Diagnostics Leaders and Innovators

Amidst three days of networking, workshops, panel discussions and presentations focused on the challenges and opportunities facing laboratories and pathologists, two leaders in diagnostics were honored for their commitment to the laboratory industry, public service and innovation in diagnostics.

Mark Ziebarth, G2 Intelligence president and publisher; Gregory S. Henderson, M.D., Ph.D, president of BioReference Laboratories; and Scott Liff, chief executive officer of Kellison & Company

Public Service Distinguished Leadership Award sponsored by Kellison & Company

Gregory S. Henderson, M.D., Ph.D. was awarded the 2016 G2 Laboratory Public Service Distinguished Leadership Award, sponsored by Kellison & Company, a revenue cycle management solutions company. Kellison's Chief Executive Officer Scott Liff presented the award at G2's 34th Annual Lab institute Conference at the Hyatt Regency Capitol Hill, Washington, D.C. on Thursday, October 27, 2016.

This annual award is presented to a diagnostic laboratory industry executive exemplifying the traits of leadership, excellence, and service to the industry. Dr. Henderson was named President of BioReference Laboratories, a division of OPKO Health, Inc. in March 2016. He has served as a leader in pathology and laboratory medicine as a pathologist, executive and innovator. He has guided business growth and operations of one of the largest laboratory outreach programs in the United States, served on a team charged with rebuilding healthcare infrastructure in New Orleans after Hurricane Katrina, co-developed the first cloud based anatomic pathology information system, and founded a company that leverages cloud technology solutions to provide digital pathology consultations that afford access to quality diagnostics in the developed and developing world.

Mark Ziebarth, G2 Intelligence president and publisher; Analyte Health Chief Executive Officer Dr. Frank Cockerill; and Jack Redding, senior vice president, sales and marketing, for Halfpenny Technologies

Lab Innovation Award Sponsored by Halfpenny

Dr. Frank Cockerill, Chief Executive Officer of Analyte Health received G2 Intelligence's Lab Innovation Award, designed to recognize innovation in the field of diagnostics. The award, sponsored by Halfpenny Technologies Inc., was presented by Jack Redding, senior vice president, sales and marketing, for Halfpenny, on Friday, October 28 at Lab Institute in Washington, D.C.

Cockerill was recognized for his leadership of Analyte Health in innovating patient access to diagnostic testing. As CEO, Cockerill is leading Analyte Health in pioneering online diagnostic services aimed directly to consumers—including education, diagnostic testing, personalized results and recommendations about next steps. Cockerill previously led the Department of Laboratory Medicine and Pathology at Mayo Clinic and was Chief Executive Officer of Mayo Medical Laboratories, a global reference laboratory operating within Mayo Clinic. He was also the Ann and Leo Markin Professor of Microbiology and Medicine at the Mayo Clinic College of Medicine, having extensive experience and expertise in infectious diseases and antimicrobial resistance.

3 Things We Learned from New OIG Report on 2015's Top 25 Lab Tests, *from page 1*

Medicare Lab Test Pay Increases by State	
Number of Top 25 Lab Tests that Will Have Higher Medicare Payment Rates	**States**
0	Alaska, Arkansas, California, Florida, Minnesota, Montana, Nevada, New Jersey, Pennsylvania, Virginia, Wisconsin
1	Colorado, Delaware, Georgia, Hawaii, Louisiana, Maine, Maryland, Massachusetts, New Mexico, North Carolina, North Dakota, Oklahoma, South Dakota, Texas
2	Arizona, Connecticut, Idaho, Illinois, Iowa, Mississippi, Missouri, Oregon, South Carolina, Tennessee, Utah, Washington
3	Indiana, New Hampshire, Rhode Island, Vermont, West Virginia
4	Alabama, Kansas,
5	Ohio, Kentucky, Nebraska
6	New York
7	Michigan, Wyoming

Source: OIG analysis of Medicare's 2015 Clinical Laboratory Fee Schedule.
Note: New York has three local fee schedules, and California, Kansas, and Missouri each have two local fee schedules. For States with more than one fee schedule, the number shown is an average for the State's fee schedules.

3. 3 Red Flags OIG Intends to Monitor

Ominously, the OIG warns that certain aspects of the new system "could limit potential savings" and will be subject to "monitoring going forward." The report cites three examples:

- Switching to a single national fee schedule could lead to higher prices for certain tests in locations where Medicare currently pays less than the new national rate for the test;
- Elimination of bundled rates for blood test profiles under the new system in favor of individual pricing might lead to higher payments than Medicare would have paid for the profile; and
- The fact that 95% of labs (including about half of independent labs, most physician office labs and virtually all hospitals) will not report their private payer data may limit Medicare fee decreases for certain tests, according to the report.

Industry Reaction

Perhaps not surprisingly, the early reaction to the OIG report from the lab industry has been less than enthusiastic. From the beginning, industry has argued that omitting hospital labs from the private payer data reporting pool would artificially suppress rates. In addition to confirming the industry's fear about hospitals being kept out, the OIG's contention that narrowing the reporting pool may actually result in *lower* fees adds insult to injury.

One industry group, the American Clinical Laboratory Association, has also "taken exception" to the OIG's suggestion that "ongoing monitoring" may be necessary in cases where payment rates increase. "In enacting PAMA, Congress was clear in its intent that Medicare reimbursement for lab tests are to reflect true market rates," bristles ACLA President Alan Mertz in a recent statement, adding that ACLA has worked closely with Congress, CMS, the PAMA Advisory Panel and other stakeholders in implementing CLFS payment reform.

COMPLIANCE PERSPECTIVES

Zero Tolerance of Workplace Violence: From Moral Stand to Workable Policy

Although workplace violence has become an epidemic, health care settings are at especially high risk. One of the most popular approaches to the problem is the so-called "zero tolerance" policy. Zero tolerance has appeal because it claims the moral high ground and makes organizations feel like they are taking a real stand. But is it really an effective way to combat workplace violence?

Defining Our Terms

Workplace violence is a broad concept that may encompass threats and attacks against employees by strangers, customers, clients and others from outside the organization. But this article focuses on one aspect of the problem: violence by one employee against another.

The so-called OSHA general duty clause (GDC) ... requires employers to provide a workplace "free from recognized hazards that are likely to cause death or serious physical harm." For decades, OSHA has made it abundantly clear that violence may be such a "recognized hazard" and that failure to protect against it may constitute a GDC violation.

Workplace Violence & OSHA

Although workplace violence has always occurred, awareness of the problem is relatively recent. This gap between awareness and existence explains why there are relatively few laws on the subject. The federal agency entrusted with protecting workers from job hazards, the Occupational Safety and Health Administration (OSHA), has yet to formulate a specific standard for workplace violence—although many states, most notably Cal-OSHA, have.

But do not confuse lack of a specific standard with lack of a legal obligation. The so-called OSHA general duty clause (GDC) (Section 5(a)(1) of the Occupational Safety and Health Act) requires employers to provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm." For decades, OSHA has made it abundantly clear that violence may be such a "recognized hazard" and that failure to protect against it may constitute a GDC violation. (See, for example, OSHA Interpretation Letter, 12/10/92.)

Zero Tolerance

When a hazard is or should reasonably be recognized, employers must take reasonable steps to combat it. In many cases, workplace violence is treated as an HR problem for which a "zero tolerance" policy is the preferred solution. Zero tolerance means that employees who engage in it are subject to immediate discipline up to termination without second chances. In other words, under zero tolerance, workplace violence is a fire-able transgression even for a first offense.

This signals that the organization considers workplace violence more serious than other offenses. Few would argue with that logic. But adopting a zero tolerance *policy* isn't necessarily a no-brainer. The biggest obstacles include fear of antagonizing a union or the misconception that discipline won't be upheld in a court and labor

arbitration. But in fact, courts and arbitrators will sustain discipline if they think it's necessary to protect the workforce.

In the words of one arbitrator: "An employer made aware of physical violence and threats of physical violence has little alternative but to take all disciplinary steps up to and including discharge, to protect its staff from acts tantamount to workplace terrorism."

The case law more than backs this up.

Easy to Adopt, Hard to Enforce

Theoretically, a zero tolerance policy is enforceable, provided that termination is necessary to protect others in the workplace. But as a practical approach for combating workplace violence, it has its limitations. Simply put, zero tolerance is often too inflexible to implement.

Zero tolerance works best in the most serious cases involving physical assault. After all, it is hard to defend giving individuals who engage in such acts a second chance. The problem is that workplace violence often takes more subtle forms including threats and verbal abuse. The severe penalties provided by zero tolerance may be too harsh for these offenses.

In addition, there may be mitigating circumstances or reasons that if they do not justify at least explain an employee's violent behavior. For example, maybe the employee was acting in self-defense or just engaging in horseplay. Organizations should be free to consider all of these circumstances in their decisions and not be boxed in by a zero tolerance policy.

Example: A lab worker picks up an object and swings it at a co-worker's head stopping at the very last second. Everybody realizes that it is just a joke, albeit a stupid and dangerous one. The lab thinks the worker should be warned and perhaps suspended but considers termination too harsh. But the zero tolerance policy calls for immediate termination of workers who engage in or threaten

TOOL
Model Workplace Violence Policy

Definition. Workplace violence means more than just physically assaulting a person. It means the attempted, threatened or actual conduct of a person that causes or is likely to cause injury to another person in the course of employment. It includes, among other things:

- Actual physical assaults or attacks
- Threats or intimidation
- Harassment, abuse or bullying
- Gestures of a violent nature
- Any other conduct that might reasonably give a worker cause for fear, affront his or her dignity or create a hostile work environment

Zero Tolerance. Acts of violence will not be tolerated and will be responded to with appropriate disciplinary action based on a thorough investigation of the incident and the surrounding circumstances. Such disciplinary action may include immediate termination, even if the person committing the act has committed no prior offenses or engaged in previous acts of violence.

violence against other workers. So the lab has to choose between ignoring the policy and ignoring the offense.

It might seem easy to simply ignore the policy and give the worker a break. But that could lead to unforeseen legal consequences: Letting one worker get away with an offense undermines the legitimacy of a zero tolerance policy and makes it harder to enforce on future occasions. Thus, as with all disciplinary policies, labs should consistently apply policies and impose disciplinary action to increase the chance the court or arbitrator will find the disciplinary action valid.

Solution: How to Tailor a Workable Policy

Labs need to recognize that workplace violence is a safety issue and adopt a plan to manage it. The first step is to ban violent behavior. Two bits of advice:

Avoid Knee-Jerk Zero Tolerance. Do not make termination automatic. Like the Model Policy on page 6, you should give yourself leeway to investigate all the circumstances and impose whatever disciplinary action you consider appropriate up to immediate termination.

Define Violence. Your workplace violence policy should also clearly describe the forms of behavior that you consider unacceptable. Many people think of workplace violence as the use or threat of physical force. But the problem is much broader than that. It includes bullying, harassment, intimidation, affronts to dignity and the creation of poisonous work environment. It also includes a wide array of conduct including acts, gestures and verbal comments.

6 Ways to Hold Labs Liable for Workplace Violence

1. **OSHA Violation.** Although there's no specific standard on workplace violence, OSHA imposes a general duty on employers to take all reasonable precautions to protect employees. Failing to guard against workplace violence may violate that general duty.
2. **Vicarious Liability.** A worker who engages in workplace violence might be considered an agent of the employer for whom the employer is legally responsible.
3. **Negligence.** If the person who engages in violence had a criminal record or violent background, the employer might be found negligent for hiring him. If the violent person acted violently on the job before but didn't get properly disciplined, the employer might be found negligent for retaining him on the payroll.
4. **Breach of Contract.** Some courts believe that employers have an implied contract to treat workers with respect and dignity so they can do their job. A victim of workplace violence might be able to claim that an employer violated this contract.
5. **EEOC Violation.** If victims of violence are members of a minority protected by the fair employment laws, such as a woman, Muslim or Asian, they might be able to claim that the employer's failure to protect them against violence was illegal discrimination.
6. **Infliction of Mental Distress.** If the complained-of conduct was outrageous, victims of workplace violence might be able to sue their employers for intentionally inflicting mental distress on them.

PAMA Update: OIG Status Report on Implementing New Medicare Fee Schedule for Part B Lab Tests

Transition to the new Medicare Part B payment system for lab tests under the *Protecting Access to Medicare Act of 2014* (PAMA) is in full swing and about to heat up. With D-day set for Jan. 1, 2018, the Office of Inspector General (OIG) just issued a report documenting the progress the Centers for Medicare and Medicaid Services (CMS) is making in implementing the different aspects of the new payment system. Here is what lab managers need to know about the report to keep on top of their own PAMA implementation efforts.

What CMS Has Done So Far

CMS has already reached a few of the most important implementation milestones: In December, it completed the IT system that labs will use to report their private payer data; and on June 17, 2017, it issued the final rule. And as we reported last month (see *GCA*, Sept. 2016, p. 5), CMS has since issued guidance materials on the final rule, including:

- The HCPCS reporting codes;
- Guidance for collecting and reporting private payer data; and
- The data reporting template.

The Remaining Implementation Timetable

As a lab manager, you need to be prepared for the next moves. The good news is that the information contained in the new OIG report enables us to outline a pretty definitive implementation timetable:

- October 2016: CMS to complete independent validation of data collection system;
- Late October, Early November 2016: CMS to make system available for labs to begin registering;
- By Dec. 31, 2016: CMS must:
  - Finish educating labs on the new reporting requirements; and
  - Publish guidance describing the new Advanced Diagnostic Laboratory Tests (ADLT) application procedure;
- Jan. 1, 2017: Labs begin reporting of private payer data;
- April to August 2017 (roughly): CMS must:
  - Conduct testing to verify the accuracy and completeness of reported data; and
  - Use the data to calculate preliminary pricing rates;
- September 2017: CMS to publish preliminary pricing rates and seek public input on their accuracy;
- November 2017: CMS to finalize pricing rates;
- Jan. 1, 2018: New pricing rates take effect.

The 6 Implementation Tasks and the Progress Being Made on Each

A good way to monitor progress is by considering the six discrete things CMS must do to implement the new PAMA lab fee schedule. The OIG report explains what each of these "tasks" involves and describes the progress CMS has made on each one so far, as summarized by the chart on page 9.

PAMA Briefing: Current Status of Part B Payment Changes Implementation Final Implementation Deadline: Jan. 1, 2018

Task	Status	What CMS Has Done	What CMS Still Must Do
1. Issue final rule and lab industry guidance	**Almost complete**	▪ June 17, 2016: Final rule issued ▪ Issued guidance on data reporting procedures and requirements	▪ By January 2017: issue guidance on process for labs to apply to have a test designated as an ADLT ▪ Determine if additional regulations or guidance is needed
2. Establish and consult with advisory panel	**Complete**	▪ April 2015: Panel created ▪ 2015-2016: Panel met four times ▪ Panel has formed 2 subcommittees: i. One advises CMS on payments for automated "profile" tests ii. Other advises on ADLT application process	▪ Through April 2017: Continue to receive and consider recommendations of panel and subcommittees
3. Collect private payer data reported by labs	**Significant progress**	▪ December 2015: Completed building of data collection system used by labs to report private payer data ▪ Testing of data collection system user experience, security and capacity partially completed—stress testing of user capacity hindered due to limitations of CMS's Presentation Zone	▪ Finish testing of data collection system user experience ▪ October 2016: Independent validation of system ▪ October 2016: Data collection system to be made available for labs to begin registering ▪ By January 2017: Finish educating labs about reporting requirements ▪ January 2017: Reporting begins ▪ January to March 2017: Collect first set of labs' private payer data
4. Ensure accuracy and completeness of reported data	**In progress**	▪ Creation of preliminary plans to conduct checks in mid- to late 2017 after labs submit first round of data ▪ Automated data verification and certification features incorporated into CLFS module	▪ April to August 2017: Conduct checks on first round of data labs submit ▪ September 2017: Publish pricing and volume data ▪ Starting September 2017: Seek public input on accuracy of preliminary Medicare payment rates ▪ CMS does **not** plan to independently verify whether all applicable labs submit their private payer data as required or the accuracy and completeness of the data of the labs that do report their data—*Result:* Risk of inaccurate payment rates
5. Determine and publish new Medicare payment rates	**In progress**	▪ Capacity to calculate new rates from data labs report incorporated into data collection system	▪ Early 2017: Collect data reported by labs ▪ Calculate Medicare payment rates from data ▪ November 2017: Publish the new payment rates ▪ January 2018: New payment rates take effect
6. Identify ADLTs	**In progress**	▪ June 2016: Publication of criteria for test to qualify as ADLT (as part of final rule) ▪ July 2016: Advisory panel subcommittee recommends ADLT application procedure	▪ By January 2017: Decide and issue guidance describing ADLT application procedure ▪ Thereafter: Review applications and decide whether tests qualify as ADLTs

Takeaway: 5 Things You Should Be Doing to Get Ready for PAMA. At this point, there are five things labs should be doing to get ready for the new Medicare Part B lab test payment system:

1. *Familiarizing themselves with the Final PAMA Rule;*
2. *Getting ready to register on the CMS's new data collection system when registration begins;*
3. *Looking out for the two sets of materials CMS intends to release by year's end before reporting begins on Jan. 1, 2017:*
   a. *Educational materials explaining the payer data reporting process; and*
   b. *Guidance explaining the process to follow when applying to have CMS designate a test as an ADLT;*
4. *Preparing for the release of the preliminary lab test fee schedule in September 2017 and, if warranted, providing feedback on its accuracy; and*
5. *Being on the lookout for the final PAMA fee schedule which CMS intends to issue in November 2017.*

G2 Compliance Corner

MODEL SECTION 1557 CIVIL RIGHTS GRIEVANCE PROCEDURE
How to Comply with New ACA Non-discrimination Requirements

Background
Section 1557 of the Affordable Care Act (ACA) requires covered entities to take certain actions to ensure they comply with their duty not to discriminate on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 92.7 of the ACA final rule specifies two things entities must do to meet their non-discrimination obligations:

- Section 92.7(a) requires designation of an employee responsible for carrying out Section 1557 compliance efforts (which, for simplicity's sake, we will refer to as "1557 coordinator"); and
- Section 92.7(b) requires the establishment of a grievance procedure to ensure fast and fair resolution of grievances under Section 1557.

Here are two user questions we received regarding these Section 1557 requirements, which took effect on July 18, 2016.

Question 1: Must the 1557 Coordinator Be an Attorney?
Can we designate a manager, technologist or pathologist to be the 1557 coordinator, or does it have to be an attorney?

Answer
No, the 1557 coordinator does not necessarily have to be an attorney. You can make any employee the coordinator as long as he/she can perform the role without a conflict of interest.

Explanation
Note that you may not have to designate a 1557 coordinator at all if your lab or pathology practice is really small. The 1557 coordinator requirement applies only to covered entities that employ 15 or more persons.

Moreover, Section 92.7(a) of the final rule says that the 1557 coordinator must be an employee but does not specify the kind of employee he/she must be or position he/she must hold. In fact, its comments to the final rule, the Dept. of Health and Human Services Office of Civil Rights (OCR) confirms that the rule "does not prescribe" who within the entity may serve as 1557 coordinator.

The OCR also says that it is okay to combine the coordinator's function with other related duties, e.g., the person in charge of your civil rights compliance under Section 504 of the Americans with Disabilities Act can serve as 1557 coordinator, "as long as there is no conflict of interest."

Question 2: Can We Rely on Our Existing Grievance Procedure?
What has to be in the grievance procedure? Can we rely on our existing Section 504 procedure or do we have to create a whole new one for Section 1557?

Answer
You can extend your current Section 504 procedure as long as it meets the OCR's criteria.

Explanation
After OCR first proposed the Section 92.7(b) grievance procedure rule, several commenters asked the agency to specify what the procedure should contain. But the agency declined saying it wanted covered entities to show "flexibility" in implementing the rule. But the OCR did offer guidance and even published a model at the end of the final rule that we adapted and improved to create the Model Section 1557 Grievance Procedure on page 11.

How to Create a Section 1557 Grievance Procedure
While not officially binding, the Model Procedure is a useful template that you can use to develop a grievance procedure for your own lab. Like the Model, your procedure should:

- State your lab's general non-discrimination policy (Model, par. 1);
- Clarify that the procedure is intended to serve that policy (Model, par 2);
- List the nitty-gritty procedural details, starting with the deadline for submitting a grievance (which we set at 60 days in accordance with the OCR model) (Model, par. 3(a));
- Say that the grievance must be in writing and specify the information it must contain (Model, par. 3(b));
- Explain that the 1557 coordinator will investigate grievances internally (Model, par. 3(c));
- Indicate that the 1557 coordinator will take steps to preserve the confidentiality of the grievor and related grievance records (Model, par. 3(d));
- Require the 1557 coordinator to issue a decision within 30 days (Model, par. 3(e));
- Describe the appeal rights of the person who files the grievance (Model, par. 4);
- Explain that the grievance procedure is not intended to be exhaustive and that persons filing grievances have the right to pursue other remedies (Model, par. 5);
- Indicate that appropriate accommodations will be made so that persons with disabilities and/or limited English proficiency can participate in the grievance process (Model, par. 6); and
- Specify that individuals will not be subject to retaliation for filing grievances or taking part in grievance investigation under the procedure (Model, par. 7).

For more on discrimination, see "Job Interviews: How to Ask Personal Questions Without Committing Discrimination," *GCA*, Aug. 2016.

TOOL: MODEL SECTION 1557 CIVIL RIGHTS GRIEVANCE PROCEDURE

Section 1557 of the Affordable Care Act (ACA) requires covered entities to adopt safeguards to avoid discriminating on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. One of those safeguards, which is set out in Section 92.7(b) of the ACA final rule, is to establish a grievance procedure ensuring fast and fair resolution of Section 1557 grievances. Although the final rule does not offer a specific formula, it does include a model grievance procedure as an attachment. We took the government's model and improved it to create the Model Section 1557 Grievance Procedure below that you can use to develop a grievance procedure for your own lab.

ZZZ Laboratories
Model Section 1557 Civil Rights Grievance Procedure

1. Commitment to Nondiscrimination

ZZZ Laboratories is committed to providing equal opportunity for all and to ensure a workplace and work environment in which no person is subject to discrimination on the basis of race, color, national origin, sex, age or disability. This commitment includes but is not limited to full compliance with Section 1557 Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services, which prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. To that end, ZZZ Laboratories has designated [name, title] as its Section 1557 Compliance Coordinator ("Section 1557 Coordinator").

Those wishing to examine Section 1557 and its regulations may do so at the office of the Section 1557 Coordinator at [list office address, contact info including fax and email]. Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure.

2. Purpose of Grievance Procedure

In pursuit of its commitment to compliance with Section 1557 requirements, ZZZ Laboratories has adopted the following internal grievance Procedure to provide for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557. Any person who believes that he/she or another person has been subject to discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities carried out or involving ZZZ Laboratories may file a grievance under this Procedure.

3. Procedures for Filing, Investigating and Resolving Grievances

(a) Submission Deadline: Grievances must be submitted to the Section 1557 Coordinator within [60 days—recommended minimum] of the date the person filing the grievance becomes aware of the alleged discriminatory action.

(b) Submission Guidelines: A grievance under this Procedure must be in writing and state: i. the name and address of the person filing; ii. a description of the problem or action alleged to be discriminatory; and iii. the remedy or relief sought.

(c) Internal Investigation: The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the grievance. This investigation may be informal, but it will be thorough and afford all interested persons an opportunity to submit relevant evidence.

(d) Records & Confidentiality: The Section 1557 Coordinator will maintain the files and records of ZZZ Laboratories relating to grievances under this Procedure. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will also take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.

(e) Initial Determination: The Section 1557 Coordinator will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.

4. Appeals of Grievance Determinations

The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the ZZZ Laboratories [indicate individual/office to direct appeals] within 15 days of receiving the Section 1557 Coordinator's decision. The [indicate individual/office to direct appeals] shall issue a written decision in response to the appeal no later than 30 days after its filing.

5. Grievor Rights to Pursue Other Remedies

The availability and use of this Procedure is not intended to and does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201. Complaint forms are available at: www.hhs.gov/ocr/office/file/index.html. Such complaints must be filed within 180 days of the date of the alleged discrimination.

6. Accommodations

ZZZ Laboratories will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this Procedure. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.

7. Protection from Retaliation

Employees are reminded that it is a violation of federal law and ZZZ Laboratories policy to fire, demote, reassign, discipline or subject to any other punishment or tolerate such adverse treatment from ZZZ Laboratories or its managers, supervisors and other representatives in retaliation for filing a grievance, participating in the investigation of a grievance or opposing discrimination.

Labs IN COURT

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

Ex-Hospital Exec Pays $1 Million for Role in Kickback Scheme. **Case:** Last fall, Tuomey Healthcare shelled out $72.4 million to settle claims of paying part-time specialists for referrals of hospital patients and falsely billing Medicare $39 million. Now the South Carolina system's former CEO Ralph "Jay" Cox III has agreed to pay $1 million of *his own money* and accept a four-year ban for his personal involvement in the scheme. Brushing aside warnings from attorneys, Cox allegedly caused Tuomey to enter into sweetheart deals with the physicians to keep them from referring outpatients to a new freestanding surgery center. **Significance:** The Cox settlement is the latest example of the Justice Department's policy of holding health care executives personally accountable for Medicare fraud committed by their organizations. A week earlier, the board chairman and Senior Vice President of North America Health Care paid $1 million and $500,000, respectively, to settle claims for their role in the skilled nursing company's billing of medically unnecessary rehabilitation services provided to residents. (For more on executive accountability, see "Yates Memo Creates Additional Compliance Risk for Labs and Their Executives," *GCA*, Dec. 2015).

Doctor Jailed for Taking Cash Bribes from Marketers. **Case:** A New Jersey osteopath pleaded guilty to accepting thousands of dollars in commissions from the sales reps of a marketing firm in exchange for referring patients to two different blood and DNA testing labs that were clients of the firm. The osteopath was sentenced to a year in prison, two years of supervised release and fined $26,000. **Significance:** While kickbacks tend to be enmeshed in complex business arrangements, this scheme was as subtle as a punch in the face. In addition to his monthly commissions check, the osteopath received cash payments calculated on the basis of the actual number of patient referrals he made to the client labs during the month. Similar to the Biodiagnostic Laboratory Services LLC case, this case highlights the government's intention to pursue individuals including physicians involved in improper referral arrangements.

Lab Fined $152K for Exposing Workers to Chemical Dangers. **Case:** Employees of a Connecticut lab complained to the Occupational Safety and Health Administration (OSHA) about suffering sore throats, headaches and other ailments on the job. OSHA inspected and cited the facility for 17 violations, including failure to implement an effective chemical hygiene plan carrying $152,435 worth of proposed fines [*Quest Diagnostics Corp., OSHA Region 1*, Sept. 1, 2016]. **Significance:** Although labs are subject to OSHA regulations, they are relatively low on the agency's list of priorities. Construction sites, manufacturing facilities and other high risk operations get most of OSHA's attention. But labs become an inspection target in certain situations such as when:

- Employees complain, which is what happened in this case;
- A health or safety incident occurs; and/or
- OSHA carries out a specific enforcement initiative targeting labs or lab operations.

(See "How (& When) to Comply with New OSHA Chemical Safety Requirements," *GCA*, Nov. 2015, for more on managing OSHA risk.)

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