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G2 Compliance Advisor

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Inside this issue

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Evaluate, increase your lab's compliance budget

The Health Care Compliance Association's (HCCA's) compliance officer and staff compensation survey sheds light on how your colleagues are faring from a salary standpoint (See *G2 Compliance Advisor*, November 2015). However, it doesn't address whether the compliance officers surveyed believed that their budgets for those salaries and other resources were sufficient or how to ask for more money to carry out their duties.

The survey, released Nov. 9, 2015 found that the typical compliance budget was $220,000 annually. However, two-thirds of the compliance officers/departments had an annual budget of less than $500,000. Fully a third of respondents (34 percent), the largest percentage represented, had an annual compliance budget of less than $100,000. The survey also found that more than half of the compliance officers handle at least 76 percent of the organization's legal and regulatory risk, and 57 percent of them had been in their job for at least six years. The survey did not indicate whether or how the size of the health care organization correlated with the compliance budget it had to work with.

Continued on page 9

Could Pharmasan Settlement Be Harbinger for More Corporate Admissions of Wrongdoing?

A Wisconsin firm and an affiliated company that provisionally operate as laboratories have agreed to pay a hefty sum and enter into a corporate integrity agreement to settle federal allegations of health care fraud—but a phrase in its settlement was quite rare.

"Pharmasan agreed that the United States could prove that: Pharmasan falsely billed Medicare for ineligible food sensitivity testing for nearly five years; Pharmasan employees knew that Medicare prohibited payment for food sensitivity testing; and Pharmasan employees submitted false information to Medicare disguising the type of test that Pharmasan was performing so that Medicare would pay for the services. Pharmasan also agreed that the United States could prove that it knowingly submitted claims for laboratory services that violated Medicare billing rules," said a statement issued by the U.S. Department of Justice. In addition to that admission, Pharmasan Labs, Inc. and the affiliated NeuroScience, Inc. in Osceola, Wis., and the owners of the two companies, Gottfried and Mieke Kellermann, agreed to pay

Continued on page 2

Could Pharmasan Settlement Be Harbinger?, *from page 1*

$8.5 million to settle False Claims Act allegations. That included $2.85 million seized by federal agents in March of last year, and another $5.66 million the businesses and the Kellermanns will pay directly.

Most settlements lack such a direct admission. The settlement agreement does further state, however, that agreement that the government could prove such facts is not an admission "that liability arises from the facts" and the parties agree that the Settlement Agreement and the facts agreed to are not an admission of liability. Pharmasan and the Kellermanns also reserved the right to contest the admissibility or use of the Settlement Agreement in any future litigation and the right to argue the statement of facts isn't admissible to prove liability under federal evidence rules.

> ***"It is rare.... I have seen that [language] before in a deferred prosecution agreement in a criminal case, not in a settlement of a civil case."***
>
> **—Jeremy Sternberg, Esq., Holland & Knight**

"It is rare," said Jeremy Sternberg, a partner in the Boston office of Holland & Knight and a former federal prosecutor who specializes in government enforcement cases for corporate clients. "I have seen that before in a deferred prosecution agreement in a criminal case, not in a settlement of a civil case."

"I am not sure what it reflects," he said. "It may just be that the case was so strong that the government just wasn't willing to allow a denial."

However, Sternberg noted that such a change in tack by the Justice Department could make it more challenging to represent clients.

According to the complaint, the two corporate entities sold naturopathic and homeopathic products, as well as a lab kit for customers to help market additional sales of the supplements. Medicare bars reimbursement of any tests not authorized by a physician, take-home tests performed by individual patients, or tests that are not medically necessary. The government alleges the companies submitted claims to Medicare for tests with specific billing codes omitted or incorrect codes. In one example, allergy tests were submitted with CPT code 86256, which covers fluorescent antibody assays.

The complaint also asserts that in a prior unrelated matter Gottfried Kellerman was convicted of making false statements to a government agency and conspiracy to make false statements with the intent to defraud, and has evaded deportation related to the conviction for nearly 20 years. The complaint further alleges that Pharmasan and Neuroscience were founded "to defraud Government Healthcare Programs."

The two companies agreed to enter into a five-year corporate integrity agreement, the scope of which was more than 40 pages long. That will include Pharmasan and NeuroScience hiring a compliance officer, a minimum of three hours of compliance training for each of its employees, and a mechanism for employees to report any compliance issues outside of their chain of management command. And both companies would have to notify the Office of the Inspector General of the Department of Health and Human Services if it sells any of its assets or plans to acquire another business. The companies could be fined as much as $2,500 a day for failure to comply with any of the provisions of the agreement.

"As this settlement demonstrates, health care fraud will be aggressively pursued in Wisconsin," said John W. Vaudreuil, United States Attorney for the Western District of Wisconsin, in a statement. "We will continue to work with our law enforcement partners to ensure that health care providers who lie to the United States, and place profits ahead of their legal and ethical responsibilities, are held accountable."

The settlement ends what had been a particularly fractious saga for Pharmasan, which included accusations that a laboratory manager had engaged in the illegal billing and a failed attempt to keep many of the documents pertaining to the case sealed as privileged. The case began as a *qui tam* action, brought by Richard Forrest, the Kellermans' insurance billing manager. The DOJ statement didn't name Forrest but said he would receive $1.12 million from the settlement.

"We are glad to resolve these issues with the government and be moving forward," said Gottfried Kellermann in a statement. "We are committed to continuing to provide our patients and doctors with the diagnostic testing services that they need to address patient medical issues."

"As this settlement demonstrates, health care fraud will be aggressively pursued in Wisconsin. We will continue to work with our law enforcement partners to ensure that health care providers who lie to the United States, and place profits ahead of their legal and ethical responsibilities, are held accountable."

—John W. Vaudreuil, US Attorney, Western District of Wisconsin

The statement also suggested Forrest had played a role in the problematic claims, indicating the companies sued him for "diverting billing reimbursements to his own accounts, among other causes of action." NeuroScience and Pharmasan won a $548,477.32 judgment last year against Forrest, records show, although that is the fraction of what it and Pharmasan agreed to pay the federal government.

Court records also indicate that Forrest, who is not an attorney, represented himself in the matter and lost by default—the legal equivalent of not contesting a legal matter at all. Forrest could not be reached for comment.

In another settlement announced in late November, Piedmont Pathology Associates, Inc. and Piedmont Pathology, P.C. in Hickory, N.C., agreed to pay $500,000 to settle false claims charges. That case also began as a *qui tam* suit, brought by a former Piedmont sales person who alleged that the two entities exchanged licenses for electronic medical record software in exchange for physician referrals, in violation of federal anti-kickback statutes.

"Financial relationships between physicians for referrals can alter a physicians' judgment as to what's necessary and appropriate for a patient," said Bill Nettles, the U.S. Attorney for the District of South Carolina. "Our goal in this settlement was not only to recover money for improper health care claims, but to deter similar conduct and, in turn, promote health care affordability."

In this case, the whistleblower received $75,000 of the settlement—the maximum allowed under federal law—as well as attorneys fees and other legal costs.

Takeaway: The Pharmasan/NeuroScience settlement was particularly tough, and could potentially signal a change in strategy regarding how the U.S. Justice Department negotiates civil false claims settlements. G2

HHS' Top Ten Management Problems Include Labs

The OIG's FY 2015 Top Management and Performance Challenges target clinical laboratories among other providers as a necessary focus of efforts to fight fraud, abuse and waste in Medicare. Specifically, the report notes that while "[f]raud schemes shift over time, … certain Medicare services have been consistent targets"—namely, clinical laboratories. The OIG report notes "CMS is not realizing the full potential of contractors to proactively identify fraud and address other program integrity concerns."

Among the steps the OIG says need to be taken are providing "clear guidance for providers on program requirements" and developing systems to ensure models are successfully implemented and problems or inefficiencies are identified and addressed. Data is also a concern.

The OIG does commend the Health Care Fraud and Abuse Control Program for its ability to return $7.70 for every $1 invested in fighting fraud and abuse, the Fraud Prevention System, which achieved $133 million in adjusted actual and projected savings and a $2.84 return on each $1 invested, as well as the establishment of the ICD-10 Coordination Center and appointment of an ICD-10 ombudsman as successful efforts by HHS to address the above challenges.

However, the report asserted "more needs to be done" and the Centers for Medicare and Medicaid Services needs to identify and recover improper Medicare payments "in a timely manner" and implement safeguards to prevent recurrence.

"[M]eaningful and secure exchange and use of electronic information and health information technology" was another top concern. Specifically, the OIG advised "[t]o make use of the benefits of the growing amounts of data in the health care context, data must be available, subject to appropriate privacy and security safeguards, where and when needed." The report indicates this lack of information sharing can have patient safety implications; for example, if a patient undergoes additional invasive testing because prior results from a different provider aren't shared.

Not surprisingly reforming payment programs was also included among the top ten challenges facing HHS—including implementation of the "new market-driven payment system for laboratory services beginning in 2017." The report warned that CMS "must establish policy, infrastructure, data systems, and oversight mechanisms to successfully implement these substantial changes."

Among the steps the OIG says need to be taken are providing "clear guidance for providers on program requirements" and developing systems to ensure models are successfully implemented and problems or inefficiencies are identified and addressed. Data is also a concern.

Takeaway: Laboratory compliance continues to cited as a subject of concern for government agencies.

Congress Asks CMS to Delay PAMA Implementation

Forty-four members of Congress signed a letter sent Dec. 16, 2015, to Acting Administrator Andy Slavitt at the Centers for Medicare and Medicaid Services expressing concern "that laboratories will be unable to comply with the proposed implementation timeline."

The letter notes rulemaking delays leave labs little time to prepare to report "upwards of millions of data points based on a yet-to-be-released set of agency requirements." It also said proteins should be included in the criteria defining Advanced Diagnostic Laboratory Tests and the number of labs reporting should be "more inclusive" and "allow any laboratory to voluntarily report."

The American Clinical Laboratory Association praised the letter for its bipartisan nature and the commitment to "ensuring a smooth PAMA implementation."

Yates Memo Creates Additional Compliance Risk for Labs and Their Executives

Bruce E. Reinhart, Esq.
Member, McDonald Hopkins LLC

On Sept. 9, 2015, Deputy Attorney General Sally Quillian Yates issued a memorandum to all federal prosecutors and civil enforcement attorneys mandating a new emphasis on prosecuting individual defendants who are legally responsible for corporate wrongdoing. The so-called Yates Memo represents a major shift in federal enforcement policy that could have a wide-ranging impact for diagnostic labs.

The United States Department of Justice (DOJ) recently has come under significant criticism from Congress and the public for not prosecuting individuals involved in corporate crimes. The perception (rightly or wrongly) was that too many corporate officers escaped prosecution, particularly for crimes occurring in the financial sector. The Yates Memo appears to be a reaction to that criticism.

Many diagnostic labs are currently the subject of federal investigations, either initiated by the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), the Federal Bureau of Investigation (FBI), or a *qui tam* whistleblower. Frequently, the investigations involve potential liability for both the lab entity and one or more of its employees. The Yates Memo creates new complications that must be considered in responding to a governmental investigation. It creates more questions than it answers, all of which create additional compliance risk for labs.

Details of the Yates Memo

The Yates Memo applies to all DOJ enforcement proceedings. These include traditional criminal prosecutions, *qui tam* whistleblower cases, and actions seeking civil monetary penalties. The Yates Memo changes the process by which cases will be evaluated and also the process by which they can be resolved.

On the case evaluation side, the Yates Memo requires the DOJ attorneys to focus on potential individual defendants from the onset of the investigation. If, after conducting the investigation, they determine that no individuals should be charged, that decision must be documented, justified in writing, and approved by a supervisor. The Yates Memo also calls for expanded information sharing between criminal and civil investigators during investigations. These changes will create greater institutional pressure for DOJ lawyers to bring charges against individuals. These changes do not, however, directly affect how a lab can or should respond to an investigation.

The Yates Memo's directives on the resolution side will have significant implications for how labs and individuals react to a Government investigation. These changes are:

1. the lab cannot qualify for leniency based on cooperating with law enforcement unless the lab provides to the Government "all relevant facts relating to the individuals responsible for the misconduct."
2. absent extraordinary circumstances, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with the corporation.

The goal of this process would be to help management decide quickly whether to vigorously defend the investigation or to approach the Government about cooperation and/or a quick settlement.

3. civil suits will be brought against individual defendants without regard to their ability to pay.

Impact of the Memo

Perhaps the easiest way to examine the Yates Memo's impact on how to react to a Government investigation is through a case study of a typical lab enforcement matter. Assume the following facts:

XYZ Lab learns of a Government investigation into possible violations of the Stark Law and the Anti-Kickback Statute related to Medicare billings. In particular, the Government is investigating allegations that XYZ's marketing staff, at the direction of senior management, was offering improper financial inducements in return for referrals from physicians. XYZ's Director and Officer Liability Insurance carrier declines to provide coverage for legal fees or investigative fees.

Before the Yates Memo:

XYZ would initiate an internal investigation through outside counsel. Counsel would interview all relevant employees, review documents, and prepare a confidential and privileged report of the facts. Counsel would also provide management with an analysis of XYZ's potential civil and criminal liability.

The goal of this process would be to help management decide quickly whether to vigorously defend the investigation or to approach the Government about cooperation and/or a quick settlement. Among the factors management would take into account were the direct costs of litigation, the business disruption involved in responding to investigative demands, and the reputational and marketplace loss from having an investigation hanging over XYZ's head.

If XYZ decided to pursue a settlement, it could withhold the results of its internal investigation and decline to implicate its own senior managers. XYZ could also offer to absorb a more severe sanction at the corporate level in return for leniency on behalf of senior management. Senior managers separately could seek to avoid liability by showing that they lacked the financial ability to pay a meaningful penalty. Also, by achieving a resolution that did not implicate them individually, the senior managers could more easily avoid being excluded from the Medicare program.

After the Yates Memo:

XYZ is almost immediately in a conflict position with its own senior management because, if XYZ later needs to seek leniency for itself, it may be obligated to provide the Government with information that implicates the managers. Therefore, even before commencing the internal investigation, XYZ must consider what it will do with the results of the investigation.

If the investigation shows likely criminal or civil exposure for XYZ, it will be in XYZ's best interest to seek leniency through cooperation. After the Yates Memo, however, that course of action requires XYZ to implicate any of its employees, officers, or directors who are responsible for the illegal conduct. Making that disclosure may also require XYZ to waive its attorney-client privilege with investigative counsel. The individuals who could be implicated may be the same people who have to decide on behalf of XYZ whether to initiate an investigation.

If they decide not to investigate, the Government may draw an adverse inference that XYZ is stone-walling the investigation; it therefore may try to impose more severe sanctions on XYZ. As you can see, there is an inherent conflict of interest between XYZ and its senior managers.

How can XYZ resolve this conflict? Who will make the decisions for XYZ? XYZ may need to designate an impartial senior manager or a special committee of its governing Board to decide whether to conduct an internal investigation, to receive the results of that investigation, and to make decisions on behalf of the lab based on the information received. For small labs, there may not be any such independent person or body to make that decision.

The Yates Memo is clear: The Government is going to punish more individuals for corporate wrongdoing.

Another difficult issue is XYZ's ongoing relationship with the individual potential defendants. In many cases, these individuals continue to be employed by XYZ, and may be running XYZ's day-to-day operations. XYZ's General Counsel (or outside corporate counsel) represents XYZ, not the individual officers, directors, or employees of XYZ. That lawyer must recommend the course of action that is best for XYZ.

Although they still work for XYZ, the potential individual defendants may need their own lawyers because their legal interests diverge from XYZ's. Because there is no insurance coverage, XYZ must decide whether to pay for lawyers to represent these individuals. Once they have lawyers, XYZ normally would enter into a joint defense agreement the individual potential defendants. After the Yates Memo, there is a risk that the Government would consider the joint defense arrangement to be inconsistent with XYZ's obligation to provide cooperation. If they believe XYZ may ultimately "throw them under the bus" in exchange for leniency, will the individuals sign a joint defense agreement?

In the past, XYZ could encourage voluntary cooperation with its internal investigation by assuring senior managers that XYZ would do its best to resolve the matter in a way that protected the managers from individual liability, even if it meant a more severe penalty for XYZ. After the Yates Memo, that trade-off is no longer available. Is XYZ prepared to compel those managers to cooperate with the internal investigation under the threat of dismissal? From a business perspective, can XYZ afford to lose the individual potential defendants?

In the past, individuals could also protect themselves from civil liability or civil penalties by showing an inability to pay a judgment. The Yates Memo eliminates "ability to pay" as a determining factor in a civil enforcement action. It states, "The Departments' civil enforcement efforts are designed not only to return government money to the public fisc, but also to hold wrongdoers accountable and to deter future wrongdoing ... [T]he fact that an individual may not have sufficient resources to satisfy a significant judgment should not control the decision on whether to bring suit ... [P]ursuing individual actions in civil corporate matters will result in significant long-term deterrence." Also, as a policy matter, the Government generally prohibits a third-party, such as an insurance company or an employer, from indemnifying an individual for any monetary settlement.

Exclusion – The Other Shoe Drops

The Yates Memo is clear: The Government is going to punish more individuals for corporate wrongdoing. Corporations are expected to sacrifice their own. There will be increased

pressure for individuals to admit culpability, even if they cannot pay a financial penalty. For many in the lab field, admitting civil liability (with or without a corresponding financial penalty) is not the worst case scenario. The big hammer is exclusion.

The Yates Memo is a game-changer. It raises difficult questions.

The HHS-OIG has statutory authority to exclude individuals from federal health benefit plans. Exclusion is mandatory upon conviction of certain health care-related fraud crimes, including Medicare or Medicaid fraud. As DOJ more aggressively pursues criminal charges against lab officials, the number of mandatory exclusion cases will rise.

Similarly, the risk of permissive exclusion also will rise for both individuals and labs. HHS-OIG can exclude an individual even in the absence of a criminal conviction. For example, permissive exclusion authority exists for "Any individual or entity that the Secretary determines has committed an act" involving fraud or kickbacks. 42 U.S.C. 1320a-7(b)(7). An entity may be excluded if one of its officers or directors commits certain healthcare-related acts that result in a conviction or a civil monetary penalty. 42 U.S.C. 1320a-7(b)(8). So, a lab could face vicarious exclusion based on the actions of an officer or director.

To avoid exclusion, a lab has a powerful incentive to turn over its employees. In the past, one of the strongest factors that helped avoid lab exclusion was that the lab fully cooperated with the Government's investigation. Now, cooperation requires the lab to identify and provide evidence against its culpable employees. While full cooperation as envisioned by the Yates Memo may avoid vicarious exclusion, there is no guarantee. It is conceivable that a lab could be excluded even after fully cooperating with the Government and turning over its culpable senior manager.

The OIG also has the authority to exclude an officer or managing employee of a sanctioned entity. 42 U.S.C. 1320a-7(b)(15). Given the Yates Memo's emphasis on individual responsibility, it is entirely possible the OIG would attempt to exclude a lab officer or owner even if that person did not personally violate the law. This approach would mirror the "Responsible Corporate Officer" doctrine under the Food, Drug & Cosmetic Act. That doctrine imposes misdemeanor criminal liability on corporate officers if they fail to properly supervise or control underlings who then violate the law. The officers need not have criminal intent, and may not even know about the illegal conduct. It is not difficult to envision a scenario where the OIG attempted to exclude a lab officer who it believed was indifferent to the lab's compliance obligations, even if the official was not the person who violated the health care laws.

Conclusion

The Yates Memo is a game-changer. It raises difficult questions. Many of these questions must be addressed immediately upon learning of a Government investigation. Those decisions could have profound effect on the ongoing business operations of the lab and the manner in which the legal process proceeds.

***Bruce E. Reinhart**, Esq. is Co-Chair of McDonald Hopkins' Government Compliance, Investigations and White Collar Defense Practice Group. He represents laboratories and health care providers in Government investigations and compliance matters. He can be contacted at McDonald Hopkins LLC, Flagler Center Tower, 505 South Flagler Drive, Suite 300, West Palm Beach, FL 33401; (561)472-2970, or breinhart@mcdonaldhopkins.com.*

EVALUATE, INCREASE YOUR LAB'S COMPLIANCE BUDGET, *from page 1*

What's particularly striking is how the findings in the compensation survey dovetail with those in HCCA's most recent report on compliance officers and stress. That survey, released in 2012, found that compliance professionals operate under so much job-related stress that more than half often lost sleep from job-related worry, which the survey called "unhealthy" and HCCA chief executive officer Roy Snell deemed "unacceptable."

The stress survey also found that while the causes of the stress were widespread, inadequate budgets deserved much of the blame. Almost three-quarters of respondents (73 percent) reported that their budgets were not enough for them to do their jobs.

At the same time, compliance work and recognition of its importance are both increasing. HCCA's membership is growing about 15 percent a year, conference attendance is up, and the number of people getting certified in compliance is rising, says Snell.

First do your homework

So how does the compliance officer determine what his or her compliance budget for staff and resources should be? And how does one make that pitch to the board of directors or owners of the lab?

> ***"If you know you have a compliance issue and ignore it, you get into more trouble. It's thumbing the government in the face."***
>
> **—David Zetter, President, Zetter Healthcare Management Consultants**

The first step is evaluating where the lab is compliant and what areas are in need of improvement, says David Zetter, president of Zetter Healthcare Management Consultants in Mechanicsburg, Pa. and a member of the National Society of Certified Healthcare Business Consultants (NSCHBC) who regularly advises labs on compliance issues. "Do an assessment," he suggests.

Then you need to prioritize what areas of compliance are riskier if not in compliance, since regardless of your budget you may not be able to cover everything. "Determine which laws you most want and need to be in compliance with," Zetter says. This will vary somewhat from lab to lab, says Snell.

For example, if your lab has gone through a number of billing audits and is regularly repaying overpayments, you may want to focus your compliance efforts and resources on dealing with this issue. Not only would the lab be on the government's radar, but the Centers for Medicare and Medicaid Services (CMS) has begun to enforce the Affordable Care Act's requirement that overpayments be returned within 60 days of being identified. That deadline is likely not being met in this situation.

CMS has also begun to crack down on providers with practices or patterns of billing noncompliance by revoking their enrollment in the federal health care programs, another power granted to CMS courtesy of the Affordable Care Act.

"If you know you have a compliance issue and ignore it, you get into more trouble. It's thumbing the government in the face," says Zetter.

Then do some homework about the costs of compliance, see where you're currently spending money, and whether it's money being well spent. "Generally speaking, I would spend most of my time looking for, finding and fixing problems rather than writing and rewriting policies and reports, meeting and talking," suggests Snell.

For instance, providers are supposed to check to see if employees and others they do business with are on the Department of Health and Human Services' Office of Inspector

General's lists of exclusion from participating in the Medicare and Medicaid programs. For some labs, it may be cheaper and just as effective to conduct that check in-house; for others, it would be better to outsource that obligation.

Discussion with C-suite is key

Once you have a good grasp of what your budgetary needs are, go to the decision makers to pitch for those resources.

"You need to make your case [for a bigger budget]. Address the risk of noncompliance and give [the decision makers] a plan to mitigate the risks," says Zetter. Include in your presentation the increased number of state and federal laws that involve compliance, because they create more obligations on compliance personnel. "Those who [are working] in compliance are having to spend more [to be compliant]," he adds.

If the board/owners push back on cost, offer different alternatives. For instance, if they balk at more money for compliance training, see if you can find a cheaper option, such as training via the internet rather than in-person, suggests Zetter.

You can also use the HCCA compensation survey to foster discussions about your budget and resources, says Zetter. "But don't just give them the report. You need to also offer specific solutions [to your budget issues]," he says.

It may also help to get the chief executive officer of the lab or other decisionmaker to attend a large compliance conference, suggests Snell. "There is nothing like seeing what best practices are to answer the question, 'is our budget adequate?' It's very hard to sell something to someone who has never seen what you are trying to sell. So if you can get someone in the group to see what others are doing and tell the rest, peer to peer, I think it will be easier," he explains.

Additional tips to help increase, maximize that budget

There are also several steps that compliance personnel can take internally to make better use of their budgets and resources:

- Use available tools to stretch your budget dollars. For instance, use Office of Inspector General alerts, guidance from HHS' Office for Civil Rights for HIPAA education, and other free, publicly available information to communicate issues with others in your facility and educate the workforce. Consider hiring outside help only when needed for audits or other specific functions, says Zetter.
- Document your activities. For instance, if you've handled a compliance problem, document what you did to resolve it so you can provide evidence of the amount of work being performed. Justify the worthiness of what you and your department are doing. At the very least, this will help if the board of directors/owners or financial head is thinking of reducing the compliance budget.
- Enlist others in your facility or organization. "I would like to see compliance officers use their budget wisely and then leverage everyone else in the organization to get more done. Get help from HR, legal, risk, audit or any other department to make sure all the elements of a compliance program are as robust as possible. ... Let leadership do what they can and then go get help from others until your program is effective," says Snell.

Takeaway: Compliance professionals need to review whether they have adequate funds to handle their compliance workloads. If not, they need to speak up and ask for more financial support. G2

AABB and A2LA Form Laboratory Accreditation Partnership

Providing laboratories with a three-for-one opportunity to streamline their accreditation processes, the AABB and the American Association for Laboratory Accreditation (A2LA) have partnered to provide a joint accreditation program. A2LA is an independent nonprofit accrediting body that assesses competence of laboratories as well as proficiency testing providers and other entities. AABB provides accreditation programs for entities involved in transfusion medicine, cellular therapies, and patient blood management.

The joint program will assess laboratories according to AABB accreditation standards, International Organization for Standardization 15189:2012, and the Clinical Laboratory Improvement Amendments (CLIA) requirements. In a statement announcing the partnership, AABB's Chief Executive Officer Miriam A. Markowitz asserted this "combined clinical laboratory accreditation program, drives operational excellence and is an important step for ensuring that clinical laboratories are prepared to provide the safest products, treatments and services for patients."

Touting the efficiencies afforded laboratories by the joint accreditation, A2LA President and Chief Executive Officer explained in a statement that the program means "less interruption to the laboratory's work and findings can be coordinated and addressed at one time, ultimately eliminating duplication of efforts and identifying opportunities for efficiency and quality enhancements."

The organizations also claim the program's benefits include application of ISO standards with recognition of the organization's "work culture and processes," educational opportunities for laboratories, and assessment by "uniquely trained technical experts." The accreditation receives Deemed Status from Centers for Medicare and Medicaid Services.

AABB also recently announced a separate partnership with The Joint Commission for a joint hospital certification program for patient blood management, beginning in 2016.

Takeaway: Laboratory accreditation options focus on efficiency and easing burden on laboratories. G2

G2 Compliance Corner

Make Sure Your PPE Matches the Hazard

Recently released U.S. Food and Drug Administration guidance regarding gowns is a good reminder to periodically evaluate personal protective equipment (PPE) used in the laboratory. The Occupational Health and Safety Act requires employers protect workers from hazards in the workplace. PPE such as a gown is one measure for protecting health care workers from exposure to hazards such as infected blood and other specimens. While the FDA indicated it doesn't intend to address exposure to specific diseases or pathogens, such as Ebola, its guidance concerning gowns used in health care settings calls attention to the inconsistent terminology regarding gowns that can create confusion.

Acknowledging that terminology for gowns "has evolved," the FDA noted that gowns are described using many different terms, including surgical gowns, cover gowns, comfort gowns, and isolation gowns. So it issued guidance to describe its "premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings." The guidance emphasizes that not only labeling or terminology used to describe the gown but claims about liquid barrier protection determine whether a gown requires FDA approval as a Class II medical device. It says that gowns claimed to provide moderate or high level barrier protection (e.g. ANSI/AAMI Level 3 or 4 barrier protection claims) will require premarket notification and a 510k filing.

That guidance and the clarity it seeks to bring, raises a good point about PPE. Periodically reevaluate the hazards in your laboratory and the PPE your staff are using. Is it appropriate for the current hazard? Does it meet current standards for that type of PPE? The FDA's announcement of its guidance notes that it's important "for both industry and gown users to have a clear and consistent understanding of the terms used to describe the protective ability of gowns." Make sure your personnel understand the protective qualities of PPE used in your lab and that it fits with the hazards your lab staff face.

News at a Glance

DOJ Reports $1.9 Billion in Healthcare False Claims Act Recoveries for FY 2015. The Department of Justice (DOJ) recovered $1.9 billion in Healthcare False Claims Act cases in fiscal year (FY) 2015. That's more than half of the aggregate $3.5 billion the DOJ reported recovering under all False Claims Act cases for the fiscal year ending Sept. 30. This year's $1.9 billion brings the total health care recoveries under the False Claims Act since January 2009 to almost $16.5 billion. Noting the Yates memo's call to hold individuals responsible for corporate wrongdoing, the DOJ highlighted the individuals being pursued as a result of the cases against cardiovascular testing laboratories Health Diagnostics Laboratory (HDL) and Singulex. The government settled with HDL and Singulex for $48.5 million and has intervened in *qui tam* actions brought against individual owners and founders of the entities involved.

FDA Workshop Addresses Security of Medical Devices. The U.S. Food and Drug Administration (FDA) warns of the cybersecurity risks relating to wireless, internet- and network-connected devices and electronic exchange of health information and is holding a two-day workshop Jan. 20-21, 2016, titled "Moving Forward: Collaborative Approaches to Medical Device Cybersecurity." The FDA explains the risks of compromised medical devices "could have a profound impact on patient care and safety." Thus, the workshop will include discussions of awareness, "cyber hygiene," information sharing, identifying and managing medical device cyber vulnerabilities, and vulnerability disclosures. Written comments on the issues can be submitted through Feb. 22, 2016. For more information and to register, visit the FDA website. Laboratorians are directly affected by these cyber risks as diagnostic technology becomes more mobile and laboratories and their data become more connected. A September FDA workshop focused on "semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records."

CMS Software Glitch Affects Reference Lab Claims. A glitch in updated software the Centers for Medicare & Medicaid Services (CMS) sent to its regional administrative contractors all but halted payments for reference lab claims submitted between Oct. 1 and the start of this month. Sector officials say the mishap was tied to CMS' decision last May to require any reference claims be submitted with not only the CLIA number of the referring laboratory, but also the NPI number for the clinician or laboratory contractor that performed the test. However, virtually all of those claims were being rejected as not recognizing the NPI, according to JoAnne Glisson, senior vice president with the American Clinical Laboratory Association. On Dec. 10, less than three weeks after being notified about the issue, CMS forwarded the following announcement to the MACs: "A claims processing issue affecting claims for reference lab services and services subject to the anti-markup payment limitation, which were billed on or after Oct. 1, 2015 has been resolved. Medicare Administrative Contractors (MACs) are reprocessing these claims. No further action is needed by providers/suppliers." G2

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Marla Durben Hirsch, Contributing Writer; Donna Pocius, Contributing Writer; Ron Shinkman, Contributing Writer; Stephanie Murg, Managing Director, G2 Intelligence; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Jim Pearmain, General Manager; Michael Sherman, Marketing Director; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher. ***Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.***