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Upcoming Events

Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport, Atlanta, GA
www.lableadershipsummit.com

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Dealing with the FDA: 12 Best Practices for Responding to a Form 483

Laboratory diagnostic tests and affiliation with drug and device manufacturers have made labs a popular target for U.S. Food and Drug Administration (FDA) quality system inspection. Going through an FDA inspection can be an ordeal, especially if you are unprepared. And once the inspection ends, you may receive the dreaded Form 483 setting out the inspector's "observations," i.e., alleged violations of the Food Drug and Cosmetic Act spotted during the inspection.

You then have 15 days to respond. And if the FDA is not satisfied with your response to the 483, it may escalate and issue you a Warning Letter. Here are 15 best practices for responding to 483s and avoiding Warning Letters.

1. Respond within 15 Days

The FDA expects labs to respond in writing within 15 working days of receiving the 483, either by specifically addressing the observations cited or requesting clarification. In the latter case, the 15-day clock starts ticking again when clarification is received.

Continued on page 9

Brief Your CEO: 8 Changes in Trump Travel Ban

Although it applies to all industries, the Trump travel ban will have a disproportionate impact on labs and other health care providers. We recently outlined the major effects and the steps you can take to manage them (See *GCA*, February 2017). Although that guidance was based on the first version, it remains valid given how much the newly issued version looks like the original. Still, the new version does include a few key changes that you need to know about. Here's a quick rundown in the form of a briefing you can provide to your CEO.

1. 10-Day Grace Period

Old Version: The previous executive order (order) took effect immediately on the date it was issued, i.e., Jan. 27, 2017. Without notice or time to respond, many visa holders were left stranded abroad.

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Brief Your CEO: 8 Changes in Trump Travel Ban, *from page 1*

New Version: The new order will take effect on March 16, 2017, 10 days after it was issued, and exempts current visa holders.

2. Iraq No Longer on Restricted Countries List

Old Version: Covered seven countries—Iran, Iraq, Libya, Somalia, Sudan, Syria and Yemen.

New Version: Covers six countries—Iran, Libya, Somalia, Sudan, Syria and Yemen. In other words, Iraq has been removed from the list of restricted countries.

3. Elimination of Extra Restrictions on Syrians

Old Version: Imposed three different entry bans, based on nationality and entrant status:

Duration	Entrant Status	Entrant Nationality
90 days	Citizens, both immigrant and non-immigrant	Iran, Iraq, Libya, Somalia, Sudan, Yemen
120 days	Refugees	All nationalities (no exemptions)
Indefinite	Travelers and Refugees	Syria

New Version: Removes the indefinite ban on Syrians. The new order treats Syrians the same as the other restricted nationalities:

Duration	Entrant Status	Entrant Nationality
90 days	Travelers	Iran, Libya, Somalia, Sudan, Syria, Yemen
120 days	Refugees	All nationalities (exemption for refugees granted status or scheduled for transit into US before March 16)

4. Exemption for Green Card Holders

Old Version: Wasn't clear about the impact on green card holders. The Department of Homeland Security issued a press release stating that it would "deem the entry of lawful permanent residents to be in the national interest." But it then added: "Absent the receipt of significant derogatory information indicating a serious threat to public safety and welfare, lawful permanent residence status will be a dispositive factor in our *case-by-case determinations*" (emphasis added). *Translation:* Although green card holders would get the benefit of the doubt, the DHS could still bar entry if it had evidence that the individual posed a serious threat.

New Version: Makes a clear exemption for green card holders and persons with valid visas.

5. Exemption for Dual Citizens

Old Version: Covered dual citizens of both a restricted and non-restricted country outside the US, including a US ally like the UK, Canada, Australia or Germany.

G2CA

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New Version: Makes a clear exemption for citizens of restricted countries who are dual citizens of a non-restricted country.

6. Exemption for Previously Granted Refugee Status

Old Version: The 120-day travel ban into the US included no exemptions.

New Version: States that the 120-day travel ban does not apply to individuals formally granted refugee status or scheduled for transit to the US by the State Department before the order's effective date of March 16, 2017.

7. Individual Exemption Process

Old Version: Allowed the DHS and State Dept. to grant individual exemptions on a "case-by-case" basis. The courts said the provision violated "due process" because it didn't establish clear standards or processes.

New Version: Changes the wording to hint that there will be a formal process for banned individuals to apply for a "waiver" but doesn't list specifics.

8. Elimination of Post-Ban Religious Preferences

Old Version: Upon restoring refugee entry after the ban, the order directed the DHS and State Dept. to give priority to refugees claiming religious persecution, "provided that the religion of the individual is a minority religion in the individual's country of nationality."

New Version: Eliminates the controversial "religious test" language which was criticized as expressing preference for Christians in Muslim countries.

At A Glance: The Differences between the New & Original Travel Ban

Provision	Original Ban	New Ban
Effective Date	Took effect immediately	Takes effect after 10-day grace period (March 16)
Restricted Countries	Iran, Iraq, Libya, Somalia, Sudan, Syria, Yemen	Iran, Libya, Somalia, Sudan, Syria, Yemen (Iraq removed)
Duration of Restrictions on Syrians	Indefinite	Same as other restricted countries, i.e., 90 day travel, 120 day refugee
Impact on Green Card Holders	Covered	Exempt
Impact on Dual Citizens	Covered	Exempt
Pre-Existing Refugee Status	Covered	Exempt
Individual Exemptions	Granted case-by-case without specific process or standards	Waivers to be granted via formal process, which isn't described
Religious Preferences for Post-Ban Refugees	Priority for Christians in Muslim countries	None expressed

COMPLIANCE CORNER

Managing Kickback Risks in Lab Sales & Marketing Arrangements

As with any other business, labs need sales and marketing expertise to survive and grow in the competitive diagnostics market. But to the extent you serve patients in Medicare, Medicaid and other government health programs, your sales and marketing arrangements can expose you to liability risks under health care fraud laws. Here's a look at the risks and the practical measures you can take to manage them.

The Danger

Lab managers need to be sure that their sales and marketing activities, both internal and external, don't run afoul of federal fraud laws. There are two key laws that need to be navigated:

Anti-Kickback Statute (AKS): The AKS makes it a crime to "knowingly and willfully" offer, pay, solicit or receive remuneration:

- To induce referrals of lab and other health services reimbursed by federal health care programs; or
- For referring, recommending or arranging the referral of patients for services reimbursed by such programs.

Note that "remuneration" need not actually be paid. Merely *offering* it is enough to trigger liability.

Stark Law: The federal Physician Self-Referral Law, aka Stark Law, bans:

- Physicians from referring patients for lab and other health services payable by federal health care programs to entities with which the physician or immediate family member has a financial relationship; and
- Labs or other entities on the receiving end of banned referrals from billing those programs for the services they provide as a result of the referral.

Sales and marketing agreements between a lab and third-party vendors raise red flags under both the AKS and Stark Law, especially when the vendor receives a commission or other payment based on the volume or value of sales generated.

The 2 Safe Harbors

The AKS and Stark Law carve out safe harbors or exceptions giving labs room to engage in otherwise problematic business arrangements involving remuneration of referral sources provided that the transaction meets specified conditions. There are two basic safe harbors in play for contracts between labs and outside sales and marketing vendors:

1. The Bona Fide Employee Safe Harbor

Arrangements between labs and *individual* vendors may qualify for protection under the AKS "bona fide employee" safe harbor. For the safe harbor to apply, the vendor must:

- Be a bona fide W-2 employee, rather than an independent contractor; and

- Receive compensation that is:
  - Reasonable;
  - Reflective of fair market value;
  - Negotiated at arm's length; and
  - Not based on the number or value of referrals.

2. The Personal Services or Management Safe Harbor

Sales and marketing arrangements between labs and vendors who are agencies and/or individuals acting as independent contractors may be permitted under the safe harbor for personal services or management contracts. To qualify for the safe harbor, the arrangement must meet six conditions:

- There must be a written agreement signed by both parties;
- The agreement must specify the services to be provided by the vendor;
- If the services are to be provided on a periodic, sporadic or part-time rather than full-time basis, the agreement must specify the precise schedule, including the exact length and charge of each interval;
- The aggregate term of the agreement must be at least one year;
- The aggregate compensation paid over the agreement's term must be:
  - Set in advance;
  - Consistent with fair market value in arm's length transactions; and
  - Not based in any way on the volume or value of referrals or business generated;
- The services performed may not involve counseling or promotion of business arrangements or activities that violate state or federal laws.

The services performed may not involve counseling or promotion of business arrangements or activities that violate state or federal laws.

Beware of Commissions & Percentage Sales Fees

Failing to qualify for a safe harbor doesn't necessarily make an arrangement illegal. However, it does leave you at the mercy of OIG review. The personal services and management contracts safe harbor has proven especially dicey over the years.

While acknowledging that "many advertising and marketing activities warrant safe harbor protection," the OIG has consistently taken the position that commission-based compensation to contract sales force will not meet the personal services and management contracts safe harbor because it "is not fixed in advance and is determined in a manner that takes into account the value or volume of business generated between the parties, including federal health care program business."

The HDL Case

The Health Diagnostics Laboratory (HDL) case is a striking example of the trouble labs can get into by not heeding the OIG's warning against percentage-based sales arrangements. The case, which began as a series of *qui tam* suits, accused HDL and two other labs (including Singulex, Inc.) of paying

On April 9, 2015, HDL agreed to pay $47 million to settle the FCA claims.

physicians sham processing fees in exchange for blood testing referrals, including medically unnecessary large multi-assay panels.

At the center of the case was the labs' marketing arrangement with their outside sales consultant, BlueWave Consultants. The DOJ contended that the sales contract was illegal noting that in addition to a monthly consulting fee, BlueWave received a commission up to 19.8% of lab revenue. The other problematic aspect was the marketing tactic of BlueWave's sales force, alleged to have encouraged physicians to order medically unnecessary blood testing via panels and offering doctors a fee per blood test (up to $20 from HDL and $10 from Singulex) for processing and handling samples. The result was billing of Medicare for millions of dollars in unnecessary tests.

On April 9, 2015, HDL agreed to pay $47 million to settle the FCA claims. Roughly two months later, it filed for Chapter 11 bankruptcy. Singulex shelled out $1.5 million to settle charges stemming from its role in the scheme. Both labs also entered into CIAs with the government.

Alternatives to Consider

Alternatives to percentage-based structures tied to volume or value of lab testing may include fair market value compensation that is set in advance and based upon other production-related values not determined by the volume or value of lab referrals that result from the individual or vendor's marketing activities, such as:

- The amount of time spent;
- The number of attendees at marketing presentations;
- The number of sales presentations made;
- The overall financial performance of a region or division of the lab organization; and/or
- Other pre-set financial performance targets not linked to specific customers or test volumes.

Any of these payment methodologies should be carefully spelled out in the sales and marketing agreement (or employment contract if the sales and marketing services are supplied by an individual employee).

Takeaway: While enlisting individuals and entities to furnish sales and marketing services for your lab may be crucial to success, you also need to be keenly aware of the AKS and Stark Law risks. The best way to manage these risks is to ensure that your arrangements satisfy a safe harbor:

1. *Structuring arrangements as bona fide employment agreements when hiring individuals; and/or*
2. *Structuring arrangements as bona fide personal services and management contracts when hiring agencies or individuals acting as independent contractors; and*
3. *In all cases, ensuring that compensation is reasonable, reflective of fair market value and **NOT** based on commissions or the value or volume of sales or business generated.*

TOOL

Model HIPAA Breach Notification Letter to Patient

Data security breaches involving patient records can occur despite your best efforts to prevent them. If prevention fails, your lab needs to switch to incident response mode and take measures to control the privacy damage. In some circumstances, that may include providing written notification to each individual patient affected by the breach. Patient notification must be provided within 60 days of discovering the incident and meet the requirements of the HIPAA Breach Notification Rule. Here is a Model Patient Notification Letter listing the required information that you can adapt for your own use. (Note that the bold-faced subheads are illustrative only and need not be included as part of the actual letter.)

FICTIONAL LABORATORIES, INC.

April 18, 2017
Via Certified Mail

Mr. John Q. Patient
123 Main Street, Nowhere, ST 99999

Re: Notice of Privacy Breach Affecting Your Personal Medical Records

Dear Mr. Patient:

Please be advised that on [*date breach discovered*], Fictional Laboratories (Labs) employees discovered that a data security breach occurred that may affect the privacy of your protected health information. The purpose of the letter is to offer our apologies and to describe the breach, its potential impact on you and the steps you can take to minimize the harm to your privacy.

Brief Description of Breach: The breach occurred on [*date of breach*] when [*explain what happened*] [*example:* a night-time custodial worker employed by one of our independent contractors gained unauthorized access to a database containing private test records on you and other patients of Labs.]

PHI Involved: As a result, of this unauthorized and unexpected intrusion, the worker was able to gain access to the medical records and protected health information of you and other patients, including [*list the type of PHI involved in the breach*, e.g., names, Social Security numbers, street addresses, dates of birth, test results and diagnoses.]

Labs' Response: On [*date*], [*X*] days after learning of the breach, Labs reported the incident to the police and began an internal investigation. Labs also plans to implement the following measures in response to the investigation's findings [*describe measures taken to limit the potential privacy impact of the breach and ensure that it never happens again*] [*example:* to limit the risk of financial damage, we are offering you and other patients affected by the breach one year's worth of credit monitoring and reporting at no cost to you. Please notify us at the below contact number if you want to accept this offer by [*date*].

Suggested Protective Measures: So far, Labs has obtained no evidence indicating that the worker has actually used or shared the patient personal health information to which he gained unauthorized access. However, we are offering you protection in the form of the free credit monitoring service noted above. We also suggest that you call the toll-free numbers of any one of the three major credit bureaus to place a fraud alert on your credit report:

- **Equifax:** 1-888-766-0008; www.equifax.com; P.O. Box 740256; Atlanta, GA 30374;
- **Experian:** 1-888-EXPERIAN (397-3742); www.experian.com; P.O. Box 9532, Allen, TX 75013;
- **TransUnion:** 1-800-680-7289; www.transunion.com; Fraud Victim Assistance Division, P.O. Box 6790, Fullerton, CA 92834-6790.

You need only contact one of the big three agencies. Once a fraud alert is placed with one agency, the other two will receive notification and place their own alerts. The credit bureau will also explain how to obtain a free copy of your credit report that you can examine for signs of fraud. You should also continue to monitor your credit report going forward to ensure no fraud or identity theft takes place.

Contact Information: If you have any questions or would like further information regarding the breach, please call Labs' special toll-free number [*phone number*] during normal business hours. Labs has also established a section on its web site [*URL*] where it will post updated information and links to other sites offering information to help you protect yourself against fraud and identity theft.

Closing Apology: Last but certainly not least, Labs would like to apologize to you for the inconvenience and personal stress you may suffer as a result of this breach. Please be assured that we are keenly aware of our obligation to safeguard the privacy and security of the personal health information our patients entrust to us and that we have adopted strict policies and technological solutions to meet that obligation. The breach, we believe, represents an aberration, one that we are determined to learn from and prevent from ever happening again.

Sincerely yours,
[*Privacy Officer/Lab Manager*]

For step-by-step guidance on responding to HIPAA breaches, see *GCA*, January 2017

Labs IN COURT

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

Family MD Faces Jail for Taking Blood Test Referral Bribes.

Case: It took the jury just four hours to find a 79-year-old New Jersey family physician guilty of all 10 counts of accepting bribes from Biodiagnostic Laboratory Services (BLS) in exchange for lab test referrals. Over a seven-year period, BLS employees and business associates paid the doctor roughly $200,000 in monthly bribe payments disguised as rental, service agreements and consulting fees, for referrals generating $3 million worth of blood testing business for the lab.

Significance: This case is a reminder that penalties for paying and taking bribes for referrals are hardly limited to anti-kickback law sanctions. Charges in this case also included conspiracy, and Federal Travel Act violations, each carrying a maximum penalty of five years in prison and $250,000 fine, as well as count of wire fraud carrying a maximum prison sentence of 20 years. (For more on the BLS case, see Labs in Court, *GCA*, February 2017.)

Clinic Pays Physician to Sign Off on Patients Examined by Grad Student.

Case: The 47-year-old owner of a Houston clinic was sentenced to 33 months in prison and $560,000+ in restitution payments for fraudulently billing Medicare and Medicaid for over $1 million in diagnostic tests and other medical services.

Significance: The accusations include paying a physician to sign medical records for patients she didn't see and who were actually examined by an unlicensed foreign medical graduate and billing for the services using her Medicare provider number.

Hospital Fined $32K for Workplace Violence Hazards.

Case: OSHA fined a Pennsylvania mental health hospital $32,158 for a trio of safety violations, including failing to protect nurses, medical technicians and other employees against workplace violence risks [*BHC Northwest Psychiatric Hospital LLC, dba Brooke Glen Behavioral Hospital*, News Release, OSHA (Reg. 3)].

Significance: Although workplace violence risks within health care facilities are all too real, OSHA fines remain relatively rare. But three things worked against the hospital in this case, including the fact that:

- An employee actually complained to OSHA, triggering the inspection;
- Mental health and psychiatric hospitals are regarded as high risk settings for workplace violence; and
- Above all, the hospital had experienced a number of previous incidents in which employees suffered serious injuries after being bitten, punched, scratched, grabbed or hit with objects hurled by patients.

(For help managing workplace violence hazards at your lab, see *GCA*, Oct. 28, 2016.)

Dealing with the FDA: 12 Best Practices for Responding to a Form 483, *from page 1*

2. Make Sure Your CEO Has Hand in Response

Failure of upper management to exercise appropriate oversight is among the most common of 483 observations. Accordingly, it is highly advisable to show the FDA that your CEO had a hand in preparing the response—either by having the CEO sign the response letter or having the lab compliance manager sign the letter and cc'ing the CEO.

3. Strike the Right Tone

The tone of the 483 response may be as important as its substance. Although you need not agree with all of the observations, be careful not to come off as resistant, uncooperative or defensive. Specifically say that you take the matter seriously and that your lab is fully committed to quality, safety and compliance. Sample language:

> "[*Lab name*] takes very seriously the matters raised in the observations as well as its responsibilities to provide a quality and safe product to the public in accordance with FDA regulatory requirements."

Some labs go a step further by expressing appreciation to the FDA for its constructive feedback and suggestions. Others include praise for the investigator and his/her team. Having established the appropriate tone and attitude, you can state your points of disagreement.

The initial investigation should identify the root cause of each cited incident in which a mistake occurred. List root causes for the different incidents in the response letter.

4. Describe Immediate Response

The expectation and unwritten rule is that once a lab receives a 483, it should immediately open a new corrective and preventive action (CAPA) investigation to:

- Address the concerns raised;
- Identify causes; and
- Determine the necessary corrective actions.

Do not respond to the FDA until you complete the initial investigation so you can refer to the investigation and its findings in the response letter.

5. Address Each CAPA Cited

Many 483 observations cite specific CAPAs in which implementation breakdowns occurred. The expectation is that you will address each and every one of the cited CAPAs—even the ones that you have closed—in your investigation and response letter.

6. List Root Cause of Each Cited Mistake

The initial investigation should identify the root cause of each cited incident in which a mistake occurred. List root causes for the different incidents in the response letter.

7. List Corrective and Preventive Actions for Each Root Cause

Describe the actions you have taken or propose to take to correct the problem identified in the root cause and prevent it from happening again. Do not

simply tell the FDA that you are going to fix the problem; explain how. It may be appropriate to classify actions into two categories: i. immediate corrections; and ii. long-term solutions.

8. Describe Training and Other Implementation Actions

After you tell the FDA about your corrective and preventive actions, explain how you plan to implement them. Although details differ in each case, implementations typically include training personnel affected by changes made.

9. Specify Implementation Dates or Timetables

List the date of implementation for corrective and preventive actions you have completed and a rough deadline or timetable for actions still in the pipeline.

10. Describe Verification Efforts

The FDA requires you to verify the effectiveness of your corrective and preventive actions. Be sure to describe your verification efforts in the response letter.

11. Provide Documentation

Failure to provide adequate detail about corrective and preventive actions can lead to Warning Letters. So include copies of modified protocols, forms, procedures and policies with your response. It may also be advisable to include documentation of verification activities.

12. Provide Regular Implementation Updates

If your proposed corrective and preventive actions plan is expected to take two months or longer to implement, give the FDA regular monthly progress reports on the status of each measure until all actions are implemented.

Takeaway: To avoid escalation into Warning Letters, labs must respond to FDA Form 483s in writing within 15 days. The response must be appropriately toned, thorough, specific, supported by documentation and be signed by or cc'd to the lab CEO. It is equally important to follow up and implement the corrective actions your response letter describes and keep the FDA apprised of progress in implementation.

FDA Enforcement Glossary

483 (FDA Form 483) is issued by the inspector at the end of the inspection to notify lab management of the conditions observed that may violate the Food Drug and Cosmetic Act.

Response Letter: After receiving a Form 483, labs are expected to respond and set out a corrective action plan for each observation (or make a request for clarification) in writing within 15 days.

Observations are listed on the 483 in order of significance and describe the objectionable conditions or practices the FDA inspector saw during the inspection.

Citations, which are listed on the 483, are references to the part(s) of the Code of Federal Regulations violated by the objectionable conditions or practices noted in the observation.

Warning Letters are escalated enforcement actions issued after FDA officials review the 483 observations to indicate that a serious violation may exist. The lab must then reply or request an extension in writing within 15 days or other deadline specified.

SPOT THE COMPLIANCE MISTAKE(S)

Customized Test Panels & Medical Necessity

SITUATION

As a convenience to clients, Nonexistent Laboratories (NL) offers medical groups the option of designing their own customized test panels. NL requires the medical director of the group to sign off in advance to verify that every test in the panel is medically necessary. NL devises a special requisition form for the group listing each of its panels (but not its component tests). Individual physicians can order the test using the group's NPI. At the bottom of the requisition, NL lists the following statement:

"In ordering the listed panels, the physician agrees that each test in the panel is medically necessary, reasonable and appropriate for purposes of evaluating, diagnosing and treating a patient's medical condition."

QUESTION

Can you spot the four things NL did wrong?

ANSWER

Physicians often welcome and sometimes even request the convenience of being able to order tests in panels. But while panels may make clients happy, they also raise medical necessity red flags. NL recognized and attempted to address those concerns. But it didn't do so effectively. Here's a rundown of the mistakes.

Mistake 1: Relying on Medical Director Verification

Having a central authority, like the medical director of a practice group, isn't adequate to establish medical necessity, experts say. Every physician in the group that orders a customized test panel should verify medical necessity individually.

Mistake 2: Letting Physicians Order Panel Using Group NPI

Mistake 2 is another variation on the theme of relying on a central medical director rather than individual ordering physicians for medical necessity verification.

Mistake 3: Not Listing Component Tests

Failure to list the panel's component tests on the requisition removes the physician's option to order the tests individually and forces them to order the panel.

Mistake 4: Relying on Medical Necessity Statement

A blanket statement on the requisition purporting to make the act of ordering a panel an indication that each test it contains is medically necessary isn't enough—especially when those individual tests aren't listed. "It's not the recitation of the sentence that's important, it's the reason why it's medically necessary," according to Jane Pine Wood, now Chief Legal and Compliance Officer at BioReference Labs, who addressed the issue of medical necessity in detail in "Compliance Perspectives: Focus Medical Necessity Efforts on Three Core Elements," *GCA*, Febuary 2016, pages 6-8.

Takeaway: What You SHOULD Do

If you offer customized test panels, conduct an audit to ensure that the records include the three core elements of medical necessity documentation that Wood emphasized:

1. Documented Test Order

- A signed requisition;
- An electronic signature via e-mail; or
- Signed documentation in the patient's chart.

What if you *don't* have one of those three things? *Answer:* Wood advised getting a signed attestation from the ordering physician documenting the test order.

2. Documented Need for Test

The next core element is documentation in the medical record that each test in the panel is medically necessary.

3. Documented Use of Test Results

The third core element is documentation that the ordering physician actually reviewed and/or used the test results in the patient's treatment. Absence of such documentation is bound to raise red flags with payers about whether the panel and its component tests were medically necessary.