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Inside this issue

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Mid-Year Update to OIG Work Plan Targets Laboratory Testing

Each year, the U.S. Department of Health and Human Services' Office of Inspector General's (OIG's) Work Plan highlights the projects and reviews it will pursue in the coming year. At the end of May, the OIG released an update adding new activities to that agenda. This latest updated added one item directly addressing clinical laboratories.

That new item "Annual analysis of Medicare clinical laboratory payments" indicates the OIG plans to focus on Medicare payments for lab tests, "including the top 25 clinical diagnostic laboratory tests by Medicare expenditures in 2014" because its prior reviews revealed Medicare pays more than other payers "for certain high-volume and high-expenditure laboratory tests." Citing the Protecting Access to Medicare Act of 2014 (PAMA), the OIG says it will annually review and "monitor Medicare expenditures and the new payment system for laboratory tests."

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The Art of Appeals: Don't Give Up Too quickly When a Payer Denies Your Claim

In the first part of this two-part series, we told you how to reduce the chances that payers would deny your claims. This month, you'll learn what you can do when, despite your best efforts, they refuse them anyway.

When claims come back denied, many people just sigh and write it off, or drop it in a desk drawer intending to deal with it later. "Don't do this," says Elizabeth Woodcock, president of the consulting firm Woodcock and Associates. "With a little effort you can get many refusals reversed, but payers do have timelines. You have to act promptly." Initial filing and appeals deadlines vary considerably from payer to payer, so be sure you know the deadlines of the payers you work with.

"The first round in the denials game is not that big a deal," explains Debbie Parrish, of Parrish Law Offices, a firm specializing in obtaining and protecting reimbursement for health care systems, physicians, and laboratories. "It's just computers talking to computers. The claim comes back denied and you resubmit." If the denial was due to incorrect coding, or some other mistake—such as inaccurate

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insurance information for the patient—you fix that and send it back through. But if the coding was accurate and the documentation supports the claim, you still have options. You can file an appeal. "The process varies from payer to payer, but if you feel they should have paid, with most private payers you can ask for a peer review, which means that other providers in the same specialty will review the claim," explains Tammie Olson of Management Resource Group, a firm offering financial management and support services for the health care community.

> ***"Lots of people don't know this, but there is a standard code set for denials. It used to be that each payer had a different coding system for denials, but HIPAA requires everyone to use the same code set now. It's called CARC (Claims Adjustment Reason Codes) and is published by Washington Publishing Company."***
>
> **—Elizabeth Woodcock, President, Woodcock and Associates**

At this stage, it is important to gather all your documentation to support your claim, including, if necessary, a written statement from the physician who ordered the tests. You want to make as strong a case as you can, because for private payers, this is the last level of appeal, your last chance to get the decision reversed. With Medicare, it gets a lot more complicated, and you have several more levels of appeal, but, Parrish warns, you won't be able to use any evidence later if you don't submit it at the first level of appeals. For Medicare that first level involves having the claim evaluated by different people than those who made the initial determination.

The Medicare Ladder

If you are appealing a Medicare claim, then at the second level of appeal your claim will be reviewed by a Qualified Independent Contractor. Sometimes, says Parrish, the QIC will deny a claim on a totally different basis than the original denial. In that case, you get to submit new support. Eventually in the Medicare appeals process (it has five stages), you'll get a hearing in federal district court, but your goal, says Parrish is to "win on paper."

Winning, of course, whether the claim is to Medicare or a private payer, on paper or in court, is a matter of having a good case and making it well. In order to do this, you have to understand exactly why your claim was refused in the first place. This is easier than it used to be. "Lots of people don't know this, but there is a standard code set for denials," says Woodcock. "It used to be that each payer had a different coding system for denials, but HIPAA requires everyone to use the same code set now. It's called CARC (Claims Adjustment Reason Codes) and is published by Washington Publishing Company. CARC codes are available online at http://www.wpc-edi.com/reference/." This will help when you're trying to figure out why your claim was returned and what you need to do to get it through next time.

It may not seem like it's worth the time or expense to appeal denied claims, and only you can decide when it is and is not a good strategy for your lab. However, if you understand the process and have a routine for dealing with appeals, the money you make may well make up for the time spent going for it.

Takeaway: Denied claims are not a dead end. Understanding the appeal process and gathering all relevant documentation and information to support your claim can yield positive results. G2

Health Datapalooza Coincides with Release of Medicare Utilization and Payment Data

The U.S. Department of Health and Human Services' (HHS) annual Health Datapalooza was held May 31 to June 3, 2015 (Washington, D.C.), promoting new ways to use health care data to improve delivery of services. The conference, attended by data experts, entrepreneurs, technology developers and representatives of health care systems and communities has grown from a 45-person group who'd gathered 25 data sets five years ago to "more than 2,000 attendees, and thanks to leadership from HHS, local governments and state health departments … nearly 2,000 data sets available for them to explore and use in innovative ways," according to HHS Secretary Sylvia Mathews Burwell, in a statement on the HHS website. The data sets are accessible on HealthData.gov. Burwell solicited attendees' ideas on how to use data to better connect patients, physicians, and other providers and improve the health care system.

Health Datapalooza was accompanied by the release of a significant amount of data relating to Medicare services:

Physician and Hospital Medicare Payment Data Released. During Health Datapalooza, HHS' Centers for Medicare and Medicaid Services (CMS) announced its annual release of utilization and payment data (third year for hospitals and second year for physicians and other professionals). This year's data relates to 2013 health care services.

Innovators and entrepreneurs will now have access to CMS data including claims for research purposes.

"These data releases will give patients, researchers, and providers continued access to information to transform the health care delivery system," said acting CMS Administrator Andy Slavitt, in a press release announcing the data release. "It's important for consumers, their providers, researchers and other stakeholders to understand the delivery of care and spending under the Medicare program."

The physician/Part B data release shows payment and submitted charges for more than 950,000 providers, relating to $90 billion worth of Medicare payments. The information to be gained from the data allows comparison "by physician, specialty, location, types of medical services and procedures delivered," according to the CMS press release. For hospitals, the data compares hospital charges for services relating to the 100 most common reasons for hospitalization.

Access to Medicare Data for Researchers. Slavitt also announced that "innovators and entrepreneurs" will now have CMS data, including claims for research purposes. The data will not identify individual patients and research must be approved.

Data will be accessible through CMS Virtual Research Data Center (VRDC). Researchers can't remove the data from the system but they can "download aggregated, privacy-protected reports and results to their own personal workstation." Researchers can also request data quarterly, significantly increasing frequency from prior annual requests.

Part D Prescription Drug Data. While not directly relevant to laboratories, at the end of April, CMS also released data regarding prescriptions issued by physicians. That data release included information about prescribing patterns of over 1 million providers and related to over 3,000 drug products.

Takeaway: Transparency is not just a sound bite but a reality as the Centers for Medicare and Medicaid Services opens up access to payment and other health care information. G2

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Also of interest to laboratories is an item discussing electronic health records and coordination of care in Accountable Care Organizations (ACOs). The OIG says it will review ACO participants' use of electronic health records to share information while coordinating care and "identify best practices and possible challenges" as providers move toward interoperability. G2 Intelligence's report *Laboratory Services in Accountable Care Organizations* explains that achieving the "seamless" access to data of interoperability and "[t]o be able to collaborate and discuss diagnosis and treatment options, laboratories need to have easy access to clinical data stored in an EHR and clinicians need access to laboratory data stored in the LIS." The report cites interoperability as "one of the top two most significant challenges ACOs face in the deployment of HIT." G2 Intelligence surveys summarized in the report indicate ACO laboratories are taking action to improve data sharing and achieve interoperability.

The OIG will be checking up on how the Centers for Medicare and Medicaid Services oversees the reporting of this data and whether the data is displayed in public databases.

Finally, the OIG also plans to take a close look at the "number and nature of financial interests" reported under the Open Payments Program. The OIG will be checking up on how the Centers for Medicare and Medicaid Services oversees the reporting of this data and whether the data is displayed in public databases.

The OIG's *Fiscal Year 2015 Work Plan Mid-Year Update* is available on the OIG Website under Reports and Publications

Takeaway: Laboratories continue to attract scrutiny from the OIG and data continues to be a trending topic—both for the sake of transparency and compliance as well as for purposes of transforming health care delivery.

For further information or to obtain a copy of G2 Intelligence's report *Laboratory Services in Accountable Care Organizations*, please contact G2 customer service at 1-888-729-2315 or visit www.g2intelligence.com.

OIG Enforcement for First Half of Fiscal 2015 Expected to Yield $1.8 Billion in Recoveries

The U.S. Department of Health and Human Services Office of Inspector General (OIG) expects to recover more than $1.8 billion from its investigative and enforcement efforts during the first half of fiscal year 2015 (Oct. 2014 to March 2015), according to the OIG's semi-annual report to Congress.

That figure includes $544.7 million attributable to audits and $1.26 billion due from investigative efforts. The OIG excluded 1,735 individuals from participating in federal health care programs and reported 422 criminal actions and 320 civil actions relating to health care compliance issues. The Health Care Fraud Prevention and Enforcement Action Team (HEAT)'s Medicare Strike Force enforcement yielded $163 million, charges against 69 individuals or entities, and 124 criminal actions. Medicare and Medicaid investigations included fraud relating to laboratory testing, according to the report, as well as prescription drugs, home health agencies, and durable medical equipment. For example, the report described a case resulting in prison and $246,536 in restitution for

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G2 COMPLIANCE PERSPECTIVES

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Don't Overlook Varying State Requirements Applicable to Independent Clinical Labs

Through acquisition, merger, or organic growth, labs may find their operations expanding regionally or nationally. If your lab is operating facilities in multiple states or testing specimens collected or received from patients in multiple states, you must understand the distinct laws and rules in each applicable state. As these state law requirements may be different from those that apply in the state in which your lab facility is based, you may need to alter certain business practices and update the lab's compliance program and control protocols. All labs must also be cognizant of the ever changing legal landscape and monitor each applicable state for new or amended state laws and rules.

All labs must also be cognizant of the ever changing legal landscape and monitor each applicable state for new or amended state laws and rules.

The majority of states contract with CMS to administer the CLIA program for lab facilities operating in the state (independent, hospital, or physician-office lab). The states of New York and Washington have adopted laws that are equal to or more stringent than the CLIA regulations, and therefore, lab facilities operating in these states are termed CLIA-exempt.[1]

While many states follow or adopt the CLIA regulations for lab facility and personnel requirements by reference, multiple states impose additional requirements beyond the CLIA prerequisites to operate a lab facility or collection station within the state. Several of these states impose the same or similar state requirements upon out-of-state labs testing specimens collected or received from patients in the state. In addition, a lab that is "doing business" in a state, will be subject to the state business laws applicable to such commercial activities.

This article discusses in more detail several state law requirements that may apply to your lab operations. However, there are numerous other state law requirements that an independent clinical lab must understand and comply with that are not addressed in this article. For a list of state law requirements that may be applicable to your lab operations, see the box on page 9-10.

State License or Permit

A state license or permit may be required to operate a lab facility in the state or for an out-of-state lab to test specimens collected or received from patients in the state. Typically, a hospital or physician-office lab performing diagnostic tests for its patients is exempt from such state license or permit requirements, but may need to register with the designated state agency. Currently, 23 states (including Washington D.C. and Puerto Rico) impose licensure or permit requirements on independent labs physically located in the state, and 7 of those states (and Washington D.C.) impose state licensure or permit requirements on out-of-state labs testing specimens collected or received from patients in the state. Most of the remaining states only require a CLIA certified or accredited lab to register with the designated state agency. (See box on page 9-10 for a list of states with license or permit requirements).

The requirement to obtain a state license or permit is generally limited to labs performing moderate to high complexity testing (waived and provider performed microscopy proce-

The state licensing laws typically address common issues such as applications, training requirements, fees, renewal, cancellation, and exceptions.

dures (PPMP) testing generally require only registration and approval). The lab may only perform the specialty or subspecialty procedures authorized under its state license or permit. It is important to note that any change in ownership, the lab director, or the physical location of the lab facility may automatically void or revoke the existing state license or permit unless prior notice and approval by the state agency.

The state licensing laws typically address common issues such as applications, training requirements, fees, renewal, cancellation, and exceptions. In some states, the lab may be subject to performance standards, on-site inspections and/or proficiency testing conducted by the state agency to assess compliance with state requirements, including specimen collection, handling, transporting, identification, examination and storing and quality control, recording, test reporting, and even advertisements.

Failure to comply with these requirements may result in civil or criminal penalties, depending on the state, enforced against the individuals performing tests and owning, operating, or maintaining a testing facility without a proper license or permit. While some states may issue a temporary permit, the lab is not otherwise authorized to begin testing specimens during the period of time the application is under review.

There are also nuances to this issue for certain specific operations:

Reference Laboratory: There are several states that require an out-of-state lab to obtain a state licensure or permit if acting as a reference lab to an in-state licensed lab. In fact, in several states, the referring laboratory could have its state license revoked if it refers a specimen for examination to a lab which is not properly licensed by the state agency. Whereas certain states only require that the out-of-state, reference lab is approved by the state agency and comply with state requirements for specimen collection, identification, examination, quality control, and test reporting. Of course, there are usually exemptions to such rules; for example, Pennsylvania state law does not require an out-of-state reference lab to be issued a state permit in order to receive and test a specimen from an in-state lab, if the referring lab is unable to perform a "needed test."[2]

Collection or Draw Station: Depending on the state, there are three types of state requirements that may impact the operation of a collection station (synonymous with draw station, patient service center, or outpatient center) by an independent lab within the state.

First, several states require a collection station to be operated by a state licensed lab or to be licensed by the state agency. The Florida statute is representative of this type of state requirement: "[i]f person represents or maintains an office or specimen collection station or other facility for the representation of any lab in-state or out-of-state which makes examinations in connection with the diagnosis and control of diseases." In some states, to collect or receive specimens for analysis by a lab not licensed by the state agency is a limited or prohibited act.

Second, a few states require an in-state or out-of-state lab to register a collection station with the state agency and comply with state requirements for specimen collection, identification, shipping, and recording.

Third, several states limit or prohibit the location of a collection station or the placement of a phlebotomist in a physician's office. For example, in New York, a lab is prohibited from locating a collection station "within or sharing space in any part of the practice, administrative, office or waiting area of any health services purveyor that refers specimens to the clinical laboratory."[3]

A majority of the states restrict out-of-state physicians from diagnosing or treating patients in the state without a state license to practice medicine.

Lab Personnel

CLIA regulations require individuals performing moderate to high complexity or PPMP testing to possess a current license issued by the state in which the lab facility is located (if such licensing is required), in addition to meeting the level of personnel skill and training required by the CLIA program.[4] However, only a minor percentage of states have state licensure requirements for certain lab personnel. Typically, the states have opted to regulate the lab personnel and require minimum qualifications and experience standards. (See box on page 9-10 for a list of states with specific personnel requirements).

Depending on the state, the term "lab personnel" may include lab directors, supervisors, assistants, scientists, technologists, technicians and phlebotomists. In some states only the laboratory director must obtain a state license, while in others the lab director and other specified lab personnel must obtain a state license or certificate of qualification. The components of the laws vary by state, but typically the state agency will examine the credentials of lab personnel by requesting documentation of certification, education, training, or professional competency and require the lab to maintain current records of the same. Generally, lab directors and scientists are able to perform any test in their specialty or subspecialty areas, and technicians are limited to performing tests that do not require independent judgment and must work under supervision.

Typically, the state requirements related to lab personnel do not apply to pathologists (or pathologist assistants) duly licensed and registered to practice medicine in the state and certified or eligible for certification by the American Board of Pathology. However, it is important to note that there may be state licensure issues to address if an out-of-state pathologist examines a specimen and renders a primary diagnosis of a patient who is located in another state. The question is whether the pathologist is engaged in the practice of medicine and must be licensed by the originating state. A majority of the states restrict out-of-state physicians from diagnosing or treating patients in the state without a state license to practice medicine. For example, South Carolina has opined that an out-of-state pathologist would need to be licensed under its state law; however, a "pathologist who merely reports a numerical value, such as a prothrombin time, would not have to be licensed by the State."[5]

Finally, the American Society for Clinical Pathology has taken the position that the CLIA lab personnel standards are insufficient for "the complexity of new test requirements, especially for genetic and molecular testing…" and "[s]tate licensure laws can and should provide higher standards."[6] As such, the industry may experience new and more stringent state regulation of lab personnel related to training and qualification requirements.

Waiver of Copayment and Deductible

A major issue in the lab industry is the waiver of cost-sharing amounts owed by patients under their private health benefits plan (i.e., deductible and coinsurance) (also referred to

as "out-of-pocket costs"). There are currently only a handful of states with statutes, regulations, or guidance that expressly limit or prohibit the waiver of the cost-sharing amount owed by the patient.[7] Furthermore, unlike the federal Anti-Kickback Statute, most state anti-kickback laws only prohibit the offer, payment, solicitation or receipt of remuneration to a referring provider—not to a patient—and thus do not encompass such waivers.

A major issue in the lab industry is the waiver of cost-sharing amounts owed by patients under their private health benefits plan.

As a result, commercial insurers have initiated civil actions against providers, including labs, alleging the practice of waiving deductibles and coinsurance violates certain state insurance fraud and unfair competition laws.[8] The majority of the state insurance fraud laws throughout the country prohibit the "knowing submission of false or misleading information" concerning "any fact or matter material to the claim." The argument, in summary, is that if the provider had no intention of collecting the deductible or coinsurance, in whole or part, from the patient upon submission of the claim, then billing the full service charge is a false claim or at least a fraudulent misrepresentation of the provider's actual charges.

The complexity inherent in a state regulated insurance industry, however, is that each individual state may promulgate, interpret and enforce seemingly similar state laws in a divergent manner. For example, the term "material" is not always clearly defined under most state insurance fraud laws or consistently interpreted by the state agency overseeing the enforcement of the law.[9] Nonetheless, a common premise is that advance notice to the insurer of the intent to waive or not pursue the patient for the deductible or coinsurance may offer a stronger defense against a civil action for violation of state law or common law.[10] Nevertheless, the notice and disclosure may result in a denial of the claim and, if the insurer does not accept, a provider risks displaying the requisite intent.

Another common cause of action alleged is tortious interference of contract between the insurer and enrollee related to the contractual obligation of the enrollee to pay a defined cost-sharing amount for the health service.[11] In fact, certain health plans have started to withhold or deny payment to out-of-network providers, including labs, unless and until the provider submits proof that the patient has paid the full amount of his or her cost-sharing obligation in accordance with the plan policy. The argument, in summary, is that the terms and conditions of the plan policy do not obligate the insurer to make payment for health care services unless and until the plan enrollee has incurred any expenses and met his or her cost-sharing obligations. Depending on the applicable state law, this may violate prompt payment laws and be grounds for a breach of contract action against the insurer. However, this practice is relatively recent and this author is not aware of any case law addressing the legality of the practice.

Moreover, the implementation of the Marketplace under the Affordable Care Act ("ACA") is reflective of a recent trend in the health insurance industry to market lower premiums (or the face-value) by deferring costs on the backend through a higher deductible and coinsurance. In the end, the negative result of this trend is that patients will not be able to cover the high out-of-pocket costs, and the providers will need to address how to deal with the increased collection activities and loss of revenue due to unpaid patient services.

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ENDNOTES

[1] The state of Oregon discontinued its CLIA exemption in January 2000.

[2] Pennsylvania (35 P.S. §2163.1).

[3] New York (10 N.Y.C.R.R. § 34-2.6).

[4] 42 C.F.R. §493.1363(a) ; 42 C.F.R. §493.1423(a); 42 C.F.R. §493.1489(a).

[5] Medical Practice Act §40-47-32.

[6] American Society for Clinical Pathology, State Licensure of Laboratory Personnel, Policy Number 05-02 (2010).

[7] Colorado (Colo. Rev. Stat. Ann §18-13-119); Florida (Fla. Stat. §817.234(7)); New York (10 NYCRR 34.2.12); North Dakota (N.D.A.C. § 26.1-02.1-01(3)(a)(3)); Texas (Tex. Ins. Code. Ann. §1204.055).

[8] See, e.g., New York (*People v. Brigham*, 261 A.D.2d 43 (3d Dep't 1999); *Aetna Health Inc. v. Rak*, No. 2011-652819 (N.Y. Sup. Ct. October 14, 2011)); New Jersey (*Garcia v. Health Net of N.J., Inc.*, 2009 N.J. Super. Lexis 2858 (App. Div. Nov. 17, 2009) (cert. denied, *Garcia v. Health Net of N.J., Inc.*, 201 N.J. 442 (N.J. 2010); *Aetna Health Inc., et al. v. Abdelghani, et al.*, No. L-5047-10 (N.J. Super. L. January 11, 2011)); Texas (*Aetna Health Inc., et al. v. Sofola et al.*, No. 2011-73949 (Tex. Dist. Ct. Dec. 7, 2011)).

[9] Florida (Fla. Stat. Ann. § 817.234 (7)(a)) (Florida insurance fraud statute defines a material omission as "if a provider has agreed with the insured or intends to waive deduct¬ibles or copayments, or does not for any other reason intend to collect the total amount of such charge."); Oregon (Or. Rev. Stat. Ann. § 165.692) (Oregon criminal code makes it a crime when a person "knowingly conceals from or fails to disclose to a health care payor the occurrence of any event or the existence of any information . . . to obtain or retain a health care payment in an amount greater than that to which the person is or was entitled."); Texas (Tex. Penal Code Ann. §§ 35.02(a)(2); 35.015) (Texas penal code includes an insurance fraud provision which defines a false statement as material "if the statement could have affected the eligibility for coverage or amount of the payment on a claim for payment under an insurance policy.").

[10] See, e.g., New Jersey Dental Assoc., 191 N.J. Super 426 (1983) (*aff'd Feiler v. New Jersey Dental Assoc.*, 199 N.J. Super. 363, 366 (App. Div. 1984); *Garcia v. Health Net of N.J., Inc.*, 2009 N.J. Super. Lexis 28580, at *6. See also *Aetna Health, Inc. v. Carabasi Chiropractic Ctr., Inc.*, 2006 WL 66460, at *3 (App. Div. 2006) (unpublished).

[11] See, e.g., *Kennedy v. Conn. Gen. Life Ins. Co.*, 924 F.2d 698 (7th Cir. 1991).

Specific Issues Affected by State Requirements for Independent Laboratories

By Charles C. Dunham IV, Associate, Epstein Becker Green

As explained in this month's Compliance Perspectives, state laws impose various requirements on independent laboratories that operate in more than one state or test specimens collected from patients in other states. Here are some additional notes and facts regarding those state requirements:

State authority:

The general public policy behind state regulation of labs is to protect the health and safety of the residents of the state; however, the state authority ("police power") to regulate an out-of-state lab has been the topic of legal discussion and litigation. This author is not aware of any cases that have ruled on the specific issue of whether a state has such power to regulate an out-of-state lab, despite challenges by labs regarding the constitutionality of such state laws.[1] However, case precedent involving similar issues relating to the practice of medicine suggest that regulation of an out-of-state individual or entity is indeed permitted.[2] In fact, in New York, state courts have opined that lab testing is a professional activity, rather than a mercantile business, which regulation of the professions is left to the state.[3]

Specific Issues Affected by State Requirements for Independent Laboratories:

- State License or Permit
- Personnel License or Qualifications
- Collection or Draw Station License or Permit
- Authorized Persons and Direct Access Testing
- Patient Consent and Notification
- Specimen Collection and Handling
- In-Office Phlebotomist Prohibition
- Test Report Content and Record Retention
- Patient Privacy and Records Access
- Disease and Incident Reports
- Direct Billing and Anti-Markup Rules
- Assignment of Benefits Enforcement
- Medicaid Enrollment and Lowest Price Rules
- Anti-Kickback and Self-Referral Prohibitions
- Insurance Fraud and False Claims Laws
- Waiver of Copayment and Deductible Prohibitions

[1] See *Center for Disease Detention, LLC v. Rullan*, 288 F.Supp.2d 136 (D.P.R. 2003)

[2] See *Smith v. Laboratory Corporation of America*, 2010 WL 5464770 (W.D. Wash., December 30, 2010)

[3] *Lefkowitz v. Biochemical Procedures, Inc.*, 327 N.Y.S.2d 804, 807 (N.Y. County 1971)

State licensure requirements for facilities:
There are currently 23 states with state licensure or permit requirements for an independent lab facility physically located within the state: Alabama, Arizona, California, Connecticut, Florida, Georgia, Hawaii, Illinois, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington and Wyoming. Washington D.C. and Puerto Rico also have licensure requirements.[4] Of those listed above, only 7 states and Washington D.C. currently impose state licensure or permit requirement upon an out-of-state lab testing specimens collected or received from patients in the state: Arizona, California, Maryland, Nevada, New Jersey, New York, and Pennsylvania. Most of the remaining states require only that the CLIA certified or accredited lab register with the designated state agency for approval.

State licensure requirements for lab personnel:
There are currently 16 states which require certain lab personnel to obtain a state license or certificate of qualification: Alabama, California, Florida, Georgia, Hawaii, Kentucky, Louisiana, Maine, Michigan, Montana, Nevada, New York, North Dakota, Oregon, Rhode Island, and West Virginia. New York even requires a lab director of an out-of-state lab to obtain a certificate of qualification if the lab is testing specimens collected or received from a patient in the State.

[4] Puerto Rico (24 L.P.R.A. § 91); Washington D.C. (DC ST § 44-202(a))

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health care fraud involving an allergy testing laboratory that was alleged to have billed Medicare, Medicaid, TRICARE and private payers for blood sample allergy testing not actually performed. The OIG also reported another example regarding a chief financial officer of a medical center prosecuted for allegedly falsely attesting to electronic health records usage and meaningful use, to meet incentive requirements of the Electronic Health Records Incentive programs.

The OIG's efforts also uncovered inefficiencies in Medicare policies and practices that could "invite exploitation or hinder consistent payment determinations" and potentially improper payments. For example, the OIG noted hospice care to assisted living residents reached $2.1 billion in 2012 potentially indicating that hospices may be targeting beneficiaries in assisted living facilities because they yielded higher Medicare payments than other settings.

Takeaway: Fraud enforcement continues to be successful in gaining big recoveries and continues to include laboratory services as a productive target.

G2 Compliance Corner

Closely Scrutinize Arrangements with Physicians

Pay close attention to the arrangements your laboratory makes with physicians, because the government will too. The U.S. Department of Health and Human Services Office of Inspector General (OIG) recently issued another Fraud Alert targeting payments to physicians. In a June 9, 2015 Fraud Alert, the OIG focused on medical directorships and similar compensation arrangements with physicians, noting recent settlement with 12 physicians with regard to "questionable medical directorship and office staff arrangements." Typically, the arrangements at issue with medical directorships are those between hospitals and health systems and physicians that refer to the hospital. Note that in June last year, the OIG also issued a Fraud Alert, which directly addressed laboratories and payments to physicians. Additionally, the Biodiagnostic Laboratory Services case, which we have reported on multiple times, has involved criminal charges and even prison sentences for physicians who the government alleged had consulting and services arrangements with the laboratory. The government alleged payments under those arrangements were really kickbacks for referrals—which is the same risk this fraud alert highlights.

"Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business," said the OIG in this latest Fraud Alert. The OIG cautioned physicians to "carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering them" and ensure they exchange fair market value compensation for bona fide services that the physician really does provide.

Factors and circumstances that the OIG found concerning in prior arrangements include:

- compensation that "took into account the physicians' volume or value of referrals,"
- compensation greater than fair market value,
- physicians failing to provide services as described in the agreement, and
- physician office staff salaries paid by affiliated entities (relieving the physician of that financial cost and thus benefitting the physician).

To avoid such compliance problems, the OIG suggested consulting its compliance program documents and other guidance available on the OIG's website. Laboratory compliance officers should ensure any arrangement that yields some payment or other benefit to a physician receives appropriate scrutiny to avoid any potential kickback risks.

News at a Glance

U.S. Supreme Court Upholds Nationwide Individual Insurance Subsidies. The United States Supreme Court issued its ruling in *King v. Burwell*, maintaining income-based subsidies that allow millions of Americans to purchase individual health insurance policies from the federal healthcare.gov insurance exchange. In a 6-3 decision, authored by U.S. Chief Justice John G. Roberts, Jr., the Court deferred to the legislative intent of Congress when it drafted and passed the Affordable Care Act more than five years ago. The case centered around one sentence in the law suggesting that subsidies should only be offered through health insurance exchanges established by individual states. Declaring that sentence ambiguous, the Court said it must look to the "broader structure of the Act" to interpret its meaning. In doing so, the Court found interpreting the language to exclude subsidies for individuals enrolling in the federal exchange would "destabilize" state insurance markets and "likely create the very 'death spirals' that Congress designed the Act to avoid." Roughly two-thirds of states rely on the federal exchange for individual health insurance policies. A study released last year by the Urban Institute concluded that an adverse ruling in *King v. Burwell* would have eliminated subsidies worth $28.8 billion to 9.3 million people, likely causing many to give up their coverage.

Health Diagnostic Laboratory Files for Bankruptcy Protection. Health Diagnostic Laboratory filed for bankruptcy protection earlier this month. The Virginia-based HDL entered into the Chapter 11 filing on June 7 in the Eastern Virginia district of U.S. Bankruptcy Court. Last June 25, the U.S. Department of Health and Human Services' Office of the Inspector General issued a fraud warning regarding the payments by laboratories to physicians to process samples, warning those payments could constitute an illegal kickback. Less than three months later, the *Wall Street Journal* published a front-page story highlighting the fraud alert and putting HDL in the spotlight. In April of this year, the company entered into a $47 million settlement with the U.S. Department of Justice regarding how it would process samples. "The confluence of these events and associated media coverage, as well as certain payer issues and changes in billing practices in certain states that affected the fees earned by HDL from each sample test, caused significant disruption to the Company's business and negatively impacted HDL's recent financial performance," the company said in its bankruptcy filing.

Sequenom Loses Patent Dispute on Appeal. The Federal Circuit appeals court upheld a trial court decision that Sequenom's Patent No. 6,258,540 (referred to as the '540 Patent) relating to cell-free fetal DNA (cffDNA) didn't assert claims that were patent eligible and was thus invalid. The decision addresses claims by Sequenom that Ariosa Diagnostics, Inc., Natera Inc., and DNA Diagnostics Center, Inc. had infringed that patent. The court agreed with Ariosa that the patent claims addressed a natural phenomenon that wasn't patentable subject matter. Relying on Supreme Court decisions regarding patentable subject matter in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics*, the appeals court explained the '540 Patent "focused on the use of a natural phenomenon in combination with well-understood, routine, and conventional activity"—that is, routine methods applied in using the cffDNA found in maternal plasma and serum.

Quoting the *Myriad* decision, the court concluded that "'groundbreaking, innovative or even brilliant discovery'" and significant contributions to the medical field aren't automatically patentable. (*Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Fed. Cir., No. 2014-1139, No. 2014-1144, 6/12/15). G2

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