

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.

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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 5-6.

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

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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 5-6 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 procedures (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 5-6 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 deductibles 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

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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))