

# inSights

## INTO *The Changing World of Laboratory Medicine*

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# FROM THE CHAIR



Bradley J. Fedderly, MD, FAAP,  
Chair, COLA Board of Directors

This issue focuses on the rise of “retail medicine”, the newest, most rapidly growing healthcare delivery model. Enhanced by the development of digital technology, off-site testing, also known as Point of Care Testing (POCT), has allowed the decentralization of medical care; clinics can now operate in readily accessible retail locations, offering convenient hours and rapid service, even to walk-in patients. But technology alone is not the main reason for this rapid adoption; its acceptance and rapid growth reflect changes in demographics, societal norms and economic forces. Governmental and professional regulatory agencies are scrambling to catch up with these changes as well. Laboratories are at the nexus of all these changes, as 70% or more of medical decisions are based on the results of laboratory testing, and these off-site clinics rely heavily on their laboratories.

The first article, “The Rise of Retail Medicine,” chronicles these changes, defining this movement not only as a result of new technology, but as a result of cultural changes reflected by the rise of the Millennial generation, the increasing medical needs of an aging Baby Boomer generation; and the financial and regulatory effects of the Affordable Care Act. We also discuss how these clinics are evolving and expanding their services, and how the laboratory profession can assume more leadership. This discussion concludes with lists of the benefits and drawbacks of retail medicine.

The impact on our profession goes beyond adjusting to the decentralization of testing, to include concerns about maintaining the quality of patient care provided due to the increasing use of non-laboratory personnel in these retail settings. The second article, “Retail Medicine: Quality of Care Concerns” discusses four prime areas of concern for quality in the operation of retail medical clinics: the level of Provider Quality (since most clinics are not physician staffed, rather they are staffed primarily by nurse practitioners); the potential for Antibiotic Prescriptions Abuse; the effective promotion of Vaccinations; and for Continuity of Care: its effect on the Patient/Physician relationship.

Our Future Trends article focuses on the concerns about the increasing use of non-laboratory personnel for laboratory testing, and its impact, not only on the quality of care provided, but on the public’s perception of the laboratory profession. The increasing use and acceptance of non-laboratory personnel is related to the rise of POCT and/ Retail Clinics; the ongoing shortage of professionally trained laboratory staff; and the rapid development of digital technology allowing an expanding range of waived testing. Documented studies of the initiatives to perform laboratory testing taken by the nursing and pharmacy professions are presented, along with a discussion of whether addressing the lack of universal licensing would be the most effective response for our profession.

We complete this issue with our Feature article: “Shared Laboratories: Regulatory Requirements and Professional Considerations.” There are actually two types of shared laboratories:

1. When one or more providers at a single location share the expenses of operating a laboratory; with one CLIA certificate, staffed to meet all regulatory requirements including a designated laboratory director. All billing by participating physicians use this CLIA number. OR
2. Two separate and independent laboratory entities occupying the same physical space, but each at different times; each with their own CLIA certificate, and staff; maintaining their own records, quality control, proficiency testing, and billing. Each must be accredited or certified independently

Each type of shared lab is discussed with respect to operational considerations as well as how each is impacted by the Stark Law.

*Bradley J. Fedderly, MD*



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# The Rise of Retail Medicine

## Introduction

Retail clinics, which began operating in their present format in 2000, are medical clinics located in pharmacies, grocery stores, and “big box” stores, such as Target and Walmart. These clinics offer extended weekend and evening hours, walk-in availability, and short wait times. Many visits to retail clinics are in the evenings and weekends, when primary care offices are not available. The clinics treat a limited range of health conditions, such as minor infections and injuries, and provide vaccines and other preventive care. This care is usually delivered by a nurse practitioner or physician assistant. Prices are typically fixed and transparent.<sup>1</sup>

Key facilitators of retail (i.e. non-traditional) clinics are the development of easy to use rapid point of care testing, electronic data storage, telephone apps for mobile information exchange, accessible and visible locations, and appointments; and connections to other on-site services such as the pharmacy.

Ownership of these clinics is concentrated among relatively few retail organizations: CVS and Walgreens operate about two-thirds of all retail medical clinics; adding in clinics operated by Kroger, Walmart, Target, and RiteAid brings the total to 93 percent. Note that as of 2017, Target’s clinics are operated by CVS.<sup>2</sup>

## The Growing Utilization of Retail Clinics

The increasing acceptance, use and demand for retail medicine is driven by rapid advances in digital technology, evolving demographic and cultural expectations, and the effects of recent legislative action in healthcare delivery, most of which were underestimated just a few years ago.

However, a study by Dr. Ateev Mehrotra, associate professor of medicine at the University of Pittsburgh and health policy researcher at the nonprofit RAND Corporation<sup>3</sup> indicated that for the majority of patients “the main driver is convenience. You can walk into a retail health clinic without an appointment, and many clinics are open nights and weekends. In fact, nearly half of the visits in the study were on the weekends or other off-hours when doctors’ offices are typically closed.”

The other attraction of retail health clinics is price, Dr. Mehrotra and his colleagues found that it was “not the actual price, but the transparency of the cost.” Clinics offer a

menu of prices and services, which means there are fewer surprises when the bill arrives. And health insurance covers all—or a percentage of—the costs of services provided at these clinics, just as it does for care delivered at a doctor’s office.

In another study sponsored by the Rand Corporation<sup>4</sup>, the largest group of clinic users were younger adults, age 18–44, who accounted for 43 percent of patients. Nationally, this group made up only 23 percent of patients who visited primary care physicians. This study further showed that

1. Only about one-third of clinic users said that they had a primary care physician.
2. About 90 percent of visits to retail clinics were for preventive care and for ten simple acute conditions: upper respiratory infections, sinusitis, bronchitis, sore throat, immunizations, inner ear infections, swimmer’s ear, conjunctivitis, urinary tract infections, and blood tests. The same conditions accounted for 18 percent of visits to primary care physician offices and 12 percent of emergency department visits.
3. While the majority of clinics accepted commercial, Medicare and Medicaid coverage; and all accepted cash payment regardless of insurance status, only two-thirds of retail clinic visits were paid for with health insurance, compared with 90 percent of visits to primary care physicians.

This data indicates millennials are the largest demographic group accessing these retail clinics, reflecting their economic situation, as well as the cultural preferences of this generation (convenient rapid access, less likely to have a particular primary physician, adept with mobile technology).

More recently, the percentage of users over 65 has also grown rapidly, possibly reflecting longer wait times to access traditional physician services. A recent study found that the Affordable Care Act has added pressure to a twofold problem that already exists in our country: a physician shortage and increasing wait times. The study’s conclusion notes that “an increase in the number of people with access to health insurance does not always guarantee access to a physician.”<sup>5</sup>

>> CONTINUED ON PAGE 4

As wait times to see a doctor lengthen, more and more people are turning to retail health clinics. The number of visits to such clinics quadrupled from 1.48 million in 2007 to 5.97 million in 2009, according to a study published in the journal *Health Affairs*, and topped 10 million in 2012. New research by Accenture forecasts that the number of retail health clinics will exceed 2,800 by 2017 with a capacity for 25 million patient visits in 2017, up from 16 million in 2014.

### **Retail Clinics Expand Laboratory Testing as They Expand Basic Primary Care Clinical Services<sup>6</sup>**

Clinical laboratory managers especially, should take note of the following development: in the early stages of the retail clinic movement, few of these rapid clinics were linked to hospitals or medical centers. Today, 1 in 10 has a hospital connection, according to Merchant Medicine News, an online newsletter for the clinic industry.

A *Managed Care Magazine* article, reported that Blue Cross & Blue Shield's plan now has traditional provider contracts with retail clinics, and the clinics are on the menu of provider options all members receive. The article further pointed out that some employers are offering employees incentives to use retail clinics by waiving copayments.

Retail clinics are positioning themselves to play a major role in the delivery of basic primary care services. Consumer and payer acceptance of the "convenience care" model has brought the concept to a tipping point in its potential to shift the ways that some basic primary care—including medical laboratory testing—services are delivered. Pathologists and clinical laboratory managers should expect to see, over time, a steady increase in the menu of diagnostic testing offered by retail clinics.

This is a positive development for clinical laboratories and pathologists, since convenient care clinics will need fast, accessible test services and will value the expertise of pathologists and laboratory scientists who can help interpret medical laboratory test results.

### **Retail Clinics Expand Laboratory Testing to add Chronic Disease Management to Basic Primary Care Services**

In late 2011, the largest retail clinic in the U.S. deployed hemoglobin A1c (HbA1c) testing analyzers in its 600 retail clinic sites in 24 states. This deal was announced between MinuteClinic, a division of CVS Caremark Corporation, and Axis-Shield plc of Dundee, Scotland. The agreement calls for

MinuteClinic to use Axis-Shield's Afinion analyzer in all 600 of its clinic locations across the nation. The system's HbA1c assay is CLIA-waived. The fully automated analyzer will allow MinuteClinic's providers to collect a patient specimen and get the results of the hemoglobin A1c tests in as little as three minutes.

Of course, the business strategy here is to add the clinical services necessary so that providers can serve patients with diabetes in these retail clinic settings. This represents a sizeable market.

The Axis-Shield Afinion desktop multi-assay analyzer enables immediate rapid testing, using a CLIA-waived test. The cartridge-based analyzer offers a range of other laboratory-quality tests as well on a single point-of-care system.

One notable aspect of the new agreement between MinuteClinics and Axis-Shield is that it demonstrates how the retail clinic industry is actively moving into chronic disease management. Naturally, an expanded menu of medical laboratory tests will be needed to support these additional clinical services.

This trend was affirmed by Sandra Ryan, R.N., MSN, CPNP, FAANP, who is the Chief Nurse Practitioner Officer for Walgreen's Take Care Health Systems. Ryan said that, expanding into chronic disease management is a new service strategy. "We're evolving our clinic offerings from episodic treatment to looking at how do we get more chronic disease management, how do we do more prevention, how do we do more screening?" she said to the ABC News reporter.

Ryan's comments echo analytical projections on future growth potential for retail clinics. According to a Deloitte report on the implications of retail clinics, this business model is capable of supporting additional revenue streams unrelated to its core operations. That means retail clinics will look to expand in areas beyond services around non-urgent primary care and prescription dispensing. This would include care management services and laboratory testing.

It shouldn't be too difficult for pathologists and clinical laboratory managers to connect the strategies of Walgreens and CVS when it comes to expanding the healthcare services they can provide to individuals who have diabetes. What becomes more interesting is how local medical laboratories can develop a menu of specialized laboratory testing

services that would add value to these retail pharmacies as they roll out expanded services to patients with diabetes and other chronic diseases.

Rapid clinic operators recognize that there are financial incentives to providing rapid medical laboratory testing. They also know there is even more money to be made by giving the patient immediate access to purchase the prescription drug(s) that would be indicated, based on the diagnostic test results performed by the clinician in the retail clinic.

## Summary

A quick review of the benefits and drawbacks of retail medical clinics is summarized below<sup>7</sup>:

### Pro

- Guaranteed appointment times
- Short consultations — most less than 15 minutes
- Convenient locations and hours
- Up-front pricing
- Lower prices than ER or urgent care
- Cash or insurance accepted
- Electronic health record available at all locations
- Some studies suggest clinics more likely to practice evidence-based medicine

### Con

- Short consultation may not leave much time to explain health history, details of current complaint
- May detract from the development of a “medical home” and relationship with primary care doctor
- Limited set of conditions treated — care for chronic conditions and major ailments not available
- May miss important follow-up care required for certain conditions, such as infections
- Some insurance companies waive co-pay at clinics — which could force some patients to choose clinics when they would prefer to see their primary care doctor
- Oversight of clinics varies from state to state
- Usually will not be treated by an M.D.

## Conclusion<sup>8</sup>

Retail clinics — often called “rapid clinics” — are growing at a phenomenal rate. Since the inception of this new care delivery model predictions that consumers would support rapid clinics located in certain retail settings have been more than substantiated; for that reason, pathologists and clinical laboratory managers should expect to see, over time, a steady increase in the menu of diagnostic testing offered by retail clinics.

Retail clinic operators recognize that there is money to be made in providing medical laboratory tests. They also know there is even more money to be made by giving the patient immediate access to purchase the prescription drug(s) that would be indicated, based on the diagnostic test results performed by the clinician in the retail clinic.

If there is a message in all of this growth and market acceptance for retail clinics, it is that clinical laboratory managers and pathologists should understand that they are now an established care delivery model within the healthcare system. Thus, it may be productive for local clinical laboratories and hospital laboratory outreach programs to look for opportunities to provide medical laboratory testing support for the retail clinics in their area.

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# Retail Medicine Quality of Care Concerns

## Introduction

A frequent observation heard when talking about the state of American healthcare is that people use the emergency room for primary care. But that's not always about lack of insurance. It's about access. The emergency room is open when people can actually go. Emergency room use has gone up, not down, since the passage of the Affordable Care Act. More people have insurance, and now can afford care when they need it.

That care is also coming from retail clinics, usually found either in stand-alone storefronts or inside pharmacies. About 35 percent of retail visits for children are for pharyngitis — sore throats. Add in ear infections and upper respiratory infections, and you've accounted for more than three-quarters of visits for children. Parents bring their children to retail clinics to take care of quick, acute problems. Swap ear infections for immunizations, and you've got the main reasons adults use retail clinics, too.

Researchers for a study published in the American Journal of Medical Quality talked to patients who sought out care at retail clinics. Patients who had a primary care physician, but still went to a retail clinic, did so because their primary care doctors were not available in a timely manner. A quarter of them said that if the retail clinic weren't available, they'd go to the emergency room.

However, the growth of these clinics has also generated controversy. Provider groups, such as the American Medical Association, early on raised concerns about quality-of-care issues, including the potential overprescribing of antibiotics, lost opportunities for preventive care, and the disruption of existing patient-physician relationships.

## Do Retail Clinics Offer Comparable Quality of Care?

Critics of retail clinics are concerned that they may offer sub-standard care and that using a retail clinic disrupts patient-physician relationships. However, a series of studies conducted by RAND Health researchers, designed to provide a factual basis for assessing the quality provided by retail health clinics, provided evidence that suggests otherwise.<sup>3</sup> These studies were conducted between 2009 and 2016.

## Provider quality

RAND analysts evaluated claims data from enrollees in a large Minnesota health plan who received care for one of three common acute care conditions: otitis media (inflammation of the middle ear), pharyngitis (sore throat), or urinary tract infection. Based on 12 quality-of-care measures, retail clinics, physician offices, and urgent care centers had similar quality ratings; quality scores were lower for emergency departments.

Retail health clinics are often staffed by nurse practitioners instead of doctors. While that is not an issue for people who are visiting for routine vaccinations or an antibiotic prescription for an ear infection— does this staffing model provide quality care for chronic conditions? Research comparing nurse practitioners with doctors on several measures of care has been reassuring. In a study conducted by Dr. Ateey Mehrotra, Harvard Medical School's Department of Health Care Policy, also a health policy researcher at the nonprofit RAND Corporation<sup>4</sup> says "People who went to the nurse practitioner did just as well as those who went to a doctor." Patients who have conditions outside the clinics' scope of practice or who need ongoing care are routinely referred to a local physician.

In some aspects of care, retail health clinics may actually outperform physician's offices. "Whatever they do is guided by evidence-based protocols," says Regina Herzlinger, Nancy R. McPherson Professor of Business Administration at Harvard Business School, and author of Who Killed Health Care? Not only are nurse practitioners required to follow specific care guidelines, but they must also keep meticulous records on the care they've provided, she says. "They have a record of what they've done that's very detailed."<sup>5</sup>

## Prescriptions for Antibiotics

Acute respiratory infections, such as bronchitis and rhinosinusitis, are the most common reason that patients seek care in the United States and account for 60 percent of all retail clinic visits.<sup>6</sup> Physicians often overprescribe antibiotics for these conditions, and experts were concerned that overprescribing would be even more frequent in retail clinics due to potential conflicts of interest that could lead clinic providers to prescribe medications that would then be sold by the pharmacies in which clinics were housed.

>> CONTINUED ON PAGE 8

**RETAIL MEDICINE QUALITY OF CARE CONCERNS**

The research did not support this concern. Using data from the medical records of physician offices, retail clinics, and emergency departments, researchers found that the share of patients who were prescribed antibiotics was similar for retail clinics, physician offices, and emergency departments. In fact, care at retail clinics was more guideline-concordant. A one-year study published in the *American Journal of Medical Quality* showed that retail clinic practitioners adhered to clinical guidelines in 99.15 percent of patient visits by not prescribing unneeded antibiotics for patients who'd received a negative rapid strep test.<sup>7</sup> For such conditions as bronchitis, for which antibiotics are never indicated, retail clinics had a lower antibiotic prescribing rate than physician offices.

**Vaccinations**

Retail clinics have been viewed as a promising venue for administering vaccinations. A study examined how many vaccinations were delivered at the largest retail clinic chains from 2007 through 2009, what percentage of clinic visits included vaccinations, and which vaccinations were the most common. In the time period studied, vaccinations were administered in about 40 percent of visits; the most common vaccination was for influenza. Those receiving vaccinations were typically not “outside the medical system” but instead may have chosen to receive a vaccination at the retail clinic because it was more convenient than the doctor's office. Retail clinics could deliver more vaccinations if they counseled patients during acute care visits about the benefits of vaccinations.

**Continuity of care: Patient / Physician Relationships**

Some physician groups have expressed concerns that using retail clinics will disrupt existing patient-physician relationships. However, multiple studies have found that the majority of retail clinic patients report not having a primary care provider. Retail clinics seem to be serving a population that does not seek care in a doctor's office but might otherwise seek care in emergency departments. Retail clinics might reduce the likelihood that a patient will go to a primary care physician first for a new condition and decrease subsequent continuity of care. However, patients who visit retail clinics appear just as likely to receive preventive care or proper management of a chronic condition such as diabetes.

In the retail health clinic setting, the burden of continuity in record keeping often falls on the patient. Although clinics can send health records to a patient's primary care doctor, there's a good chance the two offices use incompatible electronic medical record systems, rendering the clinic's records unusable to the physician. “It's really up to the patient to make sure that the excellent records these retail medical clinics keep is embedded in their personal health record with their primary health care provider,” Professor Herzlinger says. Getting a printed copy of your record from the retail health clinic and bringing it to your doctor can help prevent any discontinuity of care.<sup>8</sup>

It's important to note, however, that retail clinics were conceived at a time when EHRs and evidence-based guidelines had become more common and the standard to aim for. It was relatively easy for new retail clinics to install EHRs and incorporate these guidelines from the outset.

Also, because these clinics generally are funded by “deep pocket” organizations, cost was not a barrier to implementation of this new technology. Most retail clinics are able to share both paper and electronic records with the patient's primary care provider.<sup>9</sup>

**Industry-wide Quality and Safety Standards**

In part because of initial opposition from the medical establishment, the Convenient Care Association (CCA), founded in October 2006, and now representing 90 percent of retail clinics, requires member clinics to follow established national guidelines and protocols. The CCA is committed to monitoring quality on an ongoing basis. The guidelines, known as Industry-wide Quality and Safety Standards, are used to assist providers with their decision making process and to ensure the highest level of patient care and satisfaction.<sup>10</sup>

**Conclusion**

It's understandable why physicians' groups might be opposed to retail clinics. Above and beyond the obvious economic loss when a patient goes elsewhere, many primary care physicians correctly point out that retail clinics often lack the knowledge and experience that come from continuity of care. For many years, experts have argued that medical homes are the optimal way to care for children, especially those with chronic conditions. Those are primary care doctors' offices that offer a comprehensive, patient-centered, team-based, coordinated approach.<sup>11</sup>

Retail clinics are pretty much the opposite. However, consumer friendly factors such as convenient location, after hours accessibility and transparent pricing, as well as reliant quality of care levels, often determine the decisions made at the time of need.

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# Shared Laboratories: *Regulatory Requirements and Professional Considerations*

## Introduction

The term “shared laboratories” can be defined through two separate concepts: one is where two or more sole practicing physicians or physician group practices, collectively pool resources to fund one laboratory operation. Under this arrangement, all billing for Medicare and Medicaid use the same CLIA number. The second is when two independent laboratories, each with their own identity and CLIA number, share the same physical location.

As a result of dual definitions for the same term, there have been instances of confusion among physicians about the legal requirements for operating shared laboratories.

Examples include<sup>1</sup>:

- Physicians, involved in shared laboratories, who have registered in a variety of ways with CMS for CLIA purposes.
- Physicians, involved in shared laboratories, who have registered separately, obtained their own CLIA numbers, and enrolled in proficiency testing (PT) multiple times for the same laboratory. and
- Physicians who have filed jointly, and requested that the shared laboratory be considered as a single site for CLIA certification purposes.

Fortunately, a few years ago, the Centers for Medicare and Medicaid Services (CMS) released guidelines to its regional offices and state survey offices to clarify these requirements. Each type of shared laboratory is defined below, including information on CLIA requirements, operating principles and limitations:

**Concept 1: Two or more independently practicing physicians share the costs of laboratory equipment and staff, with each physician billing separately for the tests they perform for their own patients.**

Current CMS policy requires these shared laboratories to obtain a single CLIA number. These laboratories must designate one physician as the laboratory director. The laboratory will be subject to a single biennial inspection, it will pay one compliance fee, and it will only be required to enroll in proficiency testing one time for all non-waived laboratory testing.

**In order to have this type of shared laboratory, these criteria must be met:**

1. The shared laboratory is located in a common area.

2. Two or more sole practicing physicians or group practices share the expenses necessary to operate the laboratory.
3. Laboratory testing in a shared laboratory is directed by one qualified individual who is responsible for the overall operation, quality assurance and administration of the laboratory.
4. Independent practices sharing the certificate can only perform the test complexity or category allowed under the shared laboratory CLIA certificate.

**In addition, an amended CMS – 116 Form must also be filed**

Directions for completing this form:

1. Obtain a new CMS-116 form on-line or from your state survey office.
2. In “Section VIII – Non-waived Testing” use the total non-waived test volume for all the physicians using the laboratory for their patients when calculating the “Annual Test Volume” for each specialty/subspecialty (do not count quality control tests and PT specimens). Also, check the boxes for all the specialties/ subspecialties performed by the physicians using the laboratory. In Section XII – Individuals Involved in Laboratory Testing include the total number of laboratory personnel involved in the laboratory.
3. Write the words “shared laboratory” in bold letters across the top of the CMS-116 form
4. Designate one physician as the laboratory director and use his/her CLIA number and federal tax identification number (if applicable) to complete “Section I - General Information” of the CMS-116 form. The designated laboratory director should sign the newly completed 116 form.
5. Attach a cover letter indicating the names and individual CLIA numbers of the additional physicians who are joining the shared laboratory arrangement.
6. In the cover letter, include the name and telephone number of the contact person in your office in case the state survey agency has questions.
7. Send the amended form and cover letter to your state survey agency.
8. Send a copy to your accreditation organization if you are accredited, or in the process of obtaining accreditation.
9. Retain a copy of the form and letter for your records.

Your laboratory will then receive a primary CLIA number for the shared laboratory to be used by all the physicians for billing Medicare and Medicaid. Your individual CLIA numbers will be terminated. It is important that you contact your PT program, and, if accredited, your accreditation organization to provide them with your primary CLIA number.

Shared laboratories which do not file an amended CMS-116 form will be asked to complete the form during their next biennial on-site inspection.

**Note:** Billing issues regarding multiple providers at a single location sharing one CLIA certificate must be addressed directly to the reimbursement entities, such as Medicare or insurance carriers. CLIA will only address issues regarding the laboratory's certification.

**One clarifying point:** physicians who perform testing in their own office in addition to utilizing the shared laboratory must also register their own laboratory for CLIA purposes. For example, if physicians perform waived testing in their own office in addition to utilizing the shared laboratory for more extensive laboratory work, they have to obtain a certificate of waiver.

**Concept 2: Two separate laboratory entities, each with their own identity and CLIA number at the same site.**

The following CMS requirements must be met in order for this type of shared laboratory to operate:

- The times (days and hours) of operation must be shown for each laboratory
- Two laboratories cannot operate concurrently to be considered a shared lab
- Each laboratory must have a unique name and directed by a different laboratory director.
- Each laboratory must maintain entirely separate records and demonstrate independent operation. (such as having separate policy and procedure manuals)
- Each of the laboratory's test reports must clearly identify the laboratory that performed the test.
- Each laboratory must develop policies to prevent proficiency testing sample sharing or information between the two labs.
- If applicable, each laboratory (CLIA number) should enroll in a separate proficiency testing program using different proficiency testing providers.



**Operational Considerations**

There should be detailed operating arrangements for each laboratory when sharing the same site. An example of such an arrangement is one where each laboratory operates on different days of the week, or different hours of the day. They cannot operate concurrently. Of course, all manner of arrangements are possible, tailored to the needs of each laboratory, by mutual agreement.

Operating in the same space does not preclude the need to maintain complete and separate records to the same degree as any other operating laboratory. This includes independent QC, Maintenance, Calibration, PT, QA and Personnel records. Each laboratory determines their own test menu, so some instruments may be shared, others may be used by only one of the laboratories. Separate personnel rosters must be maintained, even if some or all of the personnel are shared. Each laboratory must have all their required positions filled by qualified, competent personnel.

As stated before, proficiency testing must adhere to all CLIA requirements: i.e. absolutely no sharing of information. In fact, it is recommended that shared independent labs subscribe to different PT providers to preclude even accidental sharing of information.

If separate laboratories share the same instrumentation however, they may share routine periodic maintenance and repair as well as calibrations. However, daily maintenance must be performed by the laboratory utilizing the instrument(s) that day.

Each laboratory must have their own biennial inspections, meeting all CLIA requirements.

**>> CONTINUED ON PAGE 12**

## SHARED LABORATORIES: REGULATORY REQUIREMENTS AND PROFESSIONAL CONSIDERATIONS

### The Stark Law and Shared Laboratories<sup>5</sup>

#### Definition:

The Stark Law prohibits physicians from referring their patients to a laboratory with which they or an immediate family member has an ownership or compensation arrangement.

#### Frequently Asked Questions<sup>6</sup>:

##### Q Does the Federal Law Apply to All Laboratory Referrals?

**A** No. The federal prohibition on referrals applies to Medicare and Medicaid beneficiaries only, not patients covered by other third-party private insurance. However, it would be prudent to check with local or state medical or specialty society organizations regarding any possible state laws which prohibit referrals to laboratories in which you have an ownership.

##### Q Are Any Referrals Exempt from the Ban?

**A** Yes, *in-office ancillary testing*. In 1989 Congress provided a key exemption from the ban on referrals when it established the law—the ban does not apply to “in-office ancillary laboratory services.” This exemption was written into the law so that solo-practicing physicians and group practices could continue to provide convenient in-office testing to their patients.

##### Q What is the Definition of In-Office Ancillary Services?

**A** *In-office ancillary services are defined by the law as services which are personally performed by one of the following:*

- The referring physician; or
- A physician who is a member of the same group practice as the referring physician; or
- An individual who is directly supervised by the referring physician or, in the case of group practices, by another physician member of the same group practice. “Directly supervised” is defined as on-site and immediately available during testing.

*In addition, to qualify for the in-office ancillary exemption, the laboratory services must be provided in the same building as the referring physician, or in the case of group practices, in the same building as the practice or another building that is used by the group practice for providing ancillary services.*

*Finally, laboratory services billed to Medicare and Medicaid must be billed by the referring physician, the group practice of which the referring physician is a member or by an entity that is wholly owned by the physician or the physician's group practice.*

##### Q What About Shared Labs?

**A** Although the Department of Health and Human Services (HHS) does not establish a specific exemption for shared laboratories, the Agency does clarify that **certain shared laboratory arrangements could qualify for the general in-office ancillary exemption discussed above. To qualify for the in-office ancillary exemption each physician involved in the arrangement must comply with the location, direct supervision and billing criteria of the in-office ancillary exemption.**

HHS gives the following example of an arrangement that would qualify:

- Physicians A, B and C each have their own practices in the same building,
- Each physician “directly” supervises the laboratory staff during testing for his or her patients, and
- Each physician bills individually for the services provided.

HHS gives the following example of an arrangement which would **not** qualify:

- Ten individuals have their own practices on different floors and the laboratory they share is located in the basement where there is no physician practice; thus
- The physicians do not directly supervise the laboratory staff when testing is performed on their own patients; and
- The laboratory itself bills Medicare or Medicaid.

This arrangement is problematic on two counts:

1. According to HHS, the fact that the physicians involved in the shared laboratory arrangement are not on the same floor as the laboratory makes it difficult for the physicians to directly supervise laboratory staff.
2. The laboratory (rather than the individual physicians) bills Medicare and Medicaid.



## Conclusion

The decision about how you want to organize and manage your shared laboratory operation must take into account not only federal (CMS) technical requirements and regulations, but those of your local and state jurisdictions as well; the billing and reimbursement policies for Medicare/Medicaid, as well as those for private insurance carriers; and the logistics of being part of one shared laboratory operation under one CLIA number, or of operating your own independent laboratory, with your own CLIA number.

Physicians involved in shared laboratory arrangements should review the final Stark regulations to make sure they are in compliance with the law.

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## RESOURCES:

1. CLIA FACTS #10: How To Properly Register Your Shared Laboratory With CMS. [http://prolabconsulting.com/pdf/CLIA\\_Facts\\_10.pdf](http://prolabconsulting.com/pdf/CLIA_Facts_10.pdf)
2. IDPH (Illinois Department of Public Health) Frequently Asked Questions: Health Care Regulation / CLIA <http://www.dph.illinois.gov/topics-services/health-care-regulation/clia/faq>
3. CLIA FACTS #10: How To Properly Register Your Shared Laboratory With CMS. [http://prolabconsulting.com/pdf/CLIA\\_Facts\\_10.pdf](http://prolabconsulting.com/pdf/CLIA_Facts_10.pdf)
4. Lab Situations. Tennessee Government / TN Department of Health. <http://tn.gov/health/article/clia-lab-situations>
5. The Stark Law. Information on penalties, legal practices, latest news and advice. <http://starklaw.org/default.htm>
6. COLA Fast Facts 3. FINAL STARK 1 REGULATIONS. <https://www.cola.org/fast-facts/ff03.pdf>

# The Increasing Acceptance of Non-laboratory Personnel for Laboratory Testing:

## *An Important Challenge To the Laboratory*

### Profession

For many years, the majority of laboratory testing was performed in a central laboratory. This was necessary due to the complexity of the testing. With computer chip technology, testing has emerged from the laboratory to the patient's bedside, the pharmacy, the physician's office, the retail mall, the patient's home and other non-laboratory sites. This is point-of-care testing (POCT), and is defined as testing at the point where patient care is given, wherever that is located. With this move outside the laboratory walls some problems occur that were not problems within the laboratory. This often begins with the use of non-laboratory personnel. Many times there is a limited understanding by personnel of requirements for documentation, adherence to written procedures<sup>3</sup>, and results interpretation. Personnel training and competency requirements are often misunderstood by managers of these sites as well, even with waived testing.

Citing concern that the lack of oversight in an increasingly large number of waived laboratories could contribute to errors and patient harm, the accreditation organization, COLA, has added nine criteria specifically for waived testing; the accreditation manual has updated the requirements to include competency testing for staff performing testing at all levels of complexity.<sup>2</sup>

Several parallel trends are now converging that raise these concerns about the use of non-professional personnel to a higher level: that of ensuring quality patient care at these alternative testing sites. This has led to more intense internal review, and more intense strategic thinking, about how to respond and move forward.

- Trending issues impacting the laboratory profession....
- The continued decentralization of laboratory testing, including the rapid growth of retail medicine and the accompanied growth of POCT
- The continued technological revolution in computerized, mobile and remote testing, contributing to the continued growth in the number of tests and variety of instruments that are categorized as "waived";
- The development of personalized medicine, including the management of chronic diseases as part of a continuum of care, creating both the pathways and the incentives for other healthcare professionals to

also operate within this continuum.

- The intention of other healthcare professions to extend their involvement in the patient care continuum to include on-site laboratory testing. These professions include Nursing and Pharmacy.
- Changes in interpretation of federal regulations - recognizing nursing degrees as biological science degrees to meet the educational qualifications for non-waived testing.
- The shortage of trained and qualified laboratory professionals to meet the staffing needs of our growing patient loads, due to both the increased number of insured people through the Affordable Care Act and demographic changes including an aging population.
- The growing argument that the lack of professional licensing for laboratory technologists in all but 12 states, constitutes an important factor in the ability of other (licensed) healthcare professionals to expand into this field.

These developments have reignited decades-long arguments about dealing with these challenges to our profession. There is palpable concern that our profession is under siege. The calls for licensing by all states continues to grow louder, but there is also pushback by those who feel that professional certification already provides the needed level of recognition and requirements.

### Key Issues

#### Maintaining Quality Standards

#### Increased Use of Non-laboratory Personnel<sup>3</sup>

The majority of point of care testing (POCT) is performed by non-laboratory clinical personnel with minimal laboratory knowledge, such as nurses or medical assistants. These operators are focused on direct patient care, are subject to the pressures of a fast-paced work environment, and do not necessarily understand why they must be responsible for POCT. They are often unfamiliar with routine laboratory procedures regarding the importance of proper patient preparation, sample collection, calibration, instrument maintenance, and quality control. One of the concerns of laboratory professionals is that POCT equipment will not be used and maintained properly, or will not include appropriate quality control and quality assessment procedures. Non-compliance with standard operating procedures can be a contributory factor in POCT errors. With

the diversity of education and experience levels and high turnover rate of staff who perform the tests, quality issues can occur.

#### **Training & Competency Assessments<sup>4</sup>**

Both CLIA and CAP report confusion between training requirements and ongoing competency assessments. Interestingly, 20 percent of CAP deficiencies involving POCT are related to competency testing. For CLIA and accrediting agencies (CAP and COLA), initial training is required prior to POC device operation, followed by documented competency assessments at specific intervals. Details of specific requirements vary between agencies and between waived and non-waived testing. For waived testing, CAP and COLA require annual competency testing for all operators, whereas CLIA only requires annual competency assessments for personnel performing non-waived testing.

#### **Nurses Can Now Perform High Complexity Testing: CMS<sup>5</sup>**

In recent years there has been quite a strong lobby from nursing to recognize a nursing degree as a biological science degree, having the requisite credit hours of biology, chemistry etc.

Now CMS has weighed in definitively by saying that, yes, a nursing degree is a science degree making nurses qualified to meet the educational qualification for high complexity testing personnel. The CMS guidance to its CLIA inspectors directs them to accept a bachelor's degree in nursing as a biological science degree qualifying the holder to perform even high complexity testing, and that an associates in nursing qualifies the holder to perform moderate complexity testing. This implies meeting the qualifications to manage laboratory testing as well. This came after lobbying from nurses who wanted to perform and supervise laboratory testing.

**The Veterans Administration (VA) has already followed through: In a recent letter to its members ASCLS said the following regarding the VA decision:**

*"The Department of Veterans Affairs (VA) has published Proposed Rule that would expand the authority of Advanced Practice Registered Nurses (APRNs) beyond ordering and interpreting lab tests, as they can now, to supervising and performing laboratory testing. If adopted, an APRN could supervise and direct a clinical laboratory.*

#### **Pharmacists Interested in Point of Care Testing<sup>6</sup>**

##### **Statement from the American Pharmacists Association (APhA):**

"The pharmacy profession is at a crossroads. Efforts to expand the patient care activities of pharmacists to include areas of primary, preventive, and chronic care, while at the

same time improving access, quality, and cost effectiveness of such care, have aligned with the profession's pursuit of recognition as health care providers under federal and state law. One such area of expanding patient care activities is the involvement of pharmacists and student pharmacists in POCT programs.

POCT programs can also contribute to the successful monitoring and management of various chronic diseases, thus helping address the increasing burden of chronic disease. With more than 60,000 community pharmacies in the United States, and an estimated 4,000 weekly patient visits per pharmacy, pharmacists undoubtedly have the access necessary to make a positive effect on the health and well-being of patients in various areas of patient care."

#### **Summary of Key Concepts**

- The pharmacy profession is working diligently to develop a sound, structured plan that will provide medication therapy management, chronic condition management, and other health and wellness services within contemporary health care. As health care continues to shift toward primary and preventive care, performing POCT may become a standard area of practice for all pharmacists.
- Pharmacists are permitted under federal law to perform POCT by using tests that have been waived by the Clinical Laboratory Improvement Amendments (CLIA).
- Further education and training are needed to support pharmacist and student pharmacist participation in POCT programs.

#### **Challenges to be overcome for Pharmacist Involvement with POCT**

- Pharmacists' lack of familiarity with POCT program processes
- Pharmacists' lack of physical assessment and specimen collection skills
- Low level of acceptance of pharmacists' by other health care providers
- Administrative burden of meeting state regulations, federal requirements, and other third-party demands
- Feasibility of incorporating POCT programs into the pharmacy workflow
- Financial considerations regarding testing equipment, supplies, and documentation programs
- Relatively limited financial incentives to provide such testing

**>> CONTINUED ON PAGE 16**

**Challenges For the Medical Laboratory Profession****Increased calls for state licensure to mitigate drops in funding as demand for laboratory professionals rises:**

Medical Laboratory Education programs are essential for ensuring that qualified individuals graduate each year to keep up with the demand. As the baby boomers retire, the demand will continue to increase.

Some states require licensure to promote the profession and solidify the need for implementation of new MLS or MLT programs. Licensure provides a means to gather information about the number of laboratory professionals in the state and where the need for educational programs is most profound.

Funding is always an issue for educational programs. Recently, the MLS program at the University of Texas Southwestern was closed due to the lack of funding. Licensure bills can be written so that funds will be generated for Medical Laboratory Education. Programs in jeopardy including those in rural or underserved areas would be able to apply for funds that could save the educational programs that train individuals in these areas. Licensure not only ensures minimum educational standards, but has the potential to increase revenue for states to fund access to continuing education or give assistance to struggling education programs.

**A growing shortage of healthcare professionals leads to laxer hiring requirements**

Nationally, there are approximately 2,600 MLS and 2,300 MLT students graduating each year, creating a total of 4,900 new personnel to fill over 9,100 job openings – resulting in a 46 percent vacancy rate.

In recent years, state legislation and appropriations to improve recruitment and retention of health professions students has targeted nursing and licensed health professions. Students of clinical laboratory science cannot benefit from these programs, as they prepare for an unlicensed profession. Also, because of the absence of licensure, states have never been able to accurately determine the number of laboratory personnel, therefore unable to even plan on addressing any personnel shortages.

Proponents of licensure state that this is the most historically proven type of occupational regulation. Licensure refers to the right bestowed by a governmental

agency or entity to engage in a legally defined occupational scope of practice. Licensure can address the maintenance of a licensee's skill through continuing education and/or competency requirements. It can also "provide a universal benchmark for entry-level personnel."<sup>8</sup>

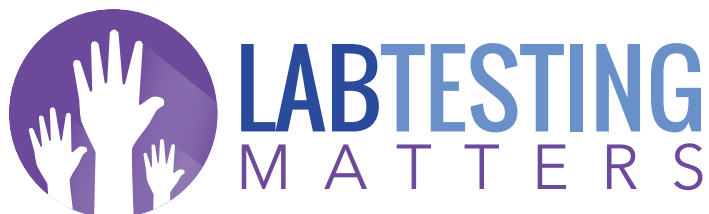
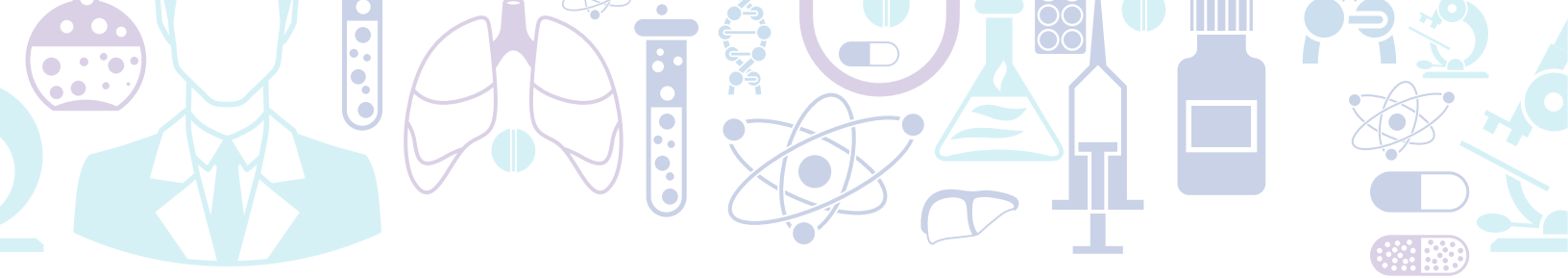
The opposition to licensing claims that licensure will increase costs for labs, make it harder to hire out-of-state personnel, and increase the shortage.

**Summary**

The development of personalized medicine and the concept of a continuum of healthcare throughout life is leading inexorably to the blurring of lines of demarcation among the various healthcare specialties. As a result, the particular nature of laboratory testing where some testing is regulated and some is not (absent federal requirements), the continuing decentralization of testing into retail settings as well as POCT beyond the office or hospital, has opened up the laboratory profession to opportunities seen by others, such as nurses and pharmacists, as extensions of their own patient care mandate. Our profession lacks the visibility, and public standing of other allied professions such as nursing, pharmacists or therapists. The lack of licensure in 38 of the 50 states is also cited as a major barrier to long-term professional survival.

**RESOURCES:**

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2. Laboratory Point-of-Care Testing: A Future Outlook POCT Progression & the Importance of Connectivity. Futrell, K. June 2015. Orchard White Paper. file:///C:/Users/irwinr/Downloads/2015-08-06%20Orchard%20white\_paper\_lab\_poc\_testing%20(2).pdf
3. Ibid.
4. Ibid.
5. CMS Says Nurses Can Perform High Complexity Testing. Advance Healthcare POV. . McDaniel, G. July 31, 2016. [http://community.advanceweb.com/blogs/mt\\_2/archive/2016/07/31/cms-says-nurses-can-perform-high-complexity-tests.aspx](http://community.advanceweb.com/blogs/mt_2/archive/2016/07/31/cms-says-nurses-can-perform-high-complexity-tests.aspx)
6. Point-of-Care Testing Background Paper Prepared for the 2015–2016 APhA Policy Committee. Gilbreath, M. <https://www.pharmacist.com/sites/default/files/files/POCT%20Policy%20Background%20Paper%20-%20FINAL.pdf>
7. Almost anyone can perform your medical laboratory tests – wait, what? Your barber, realtor, electrician and massage therapist are all licensed, but only 12 states in the US license medical laboratorians. ELSEVIER. Rohde, R., Falleur, D., Ellis, J. Posted March 2015. <https://www.elsevier.com/connect/almost-anyone-can-perform-your-medical-laboratory-tests-wait-what>
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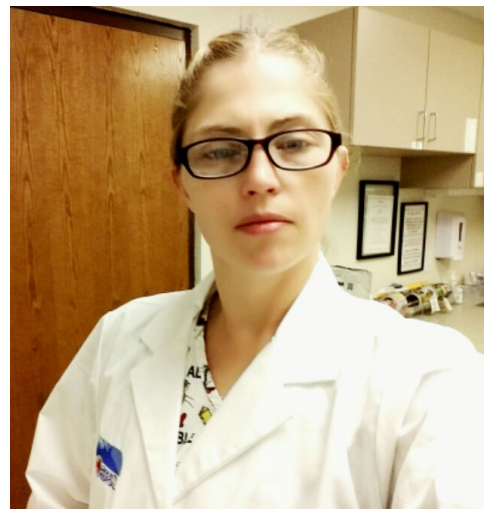


## Stories from the Front Lines: The Lab Test Indicated Something Was Very Wrong.

**Name:** Crystal Mead, PST (ASCP)<sup>CM</sup>

**Title:** Medical Lab Assistant, Morrill County Community Hospital

**Location:** Bridgeport, Nebraska



I was 20 years old and very green in my position as General Manager at the Village Twin movie theater, when I was invited to attend a managers' meeting in Colorado. I didn't know what to expect from this event. My City Manager (who I would be traveling with) and my District Manager (who would be conducting the meeting) both intimidated me so I was pretty nervous; and, if I was totally honest I was pretty under trained and irresponsible in my position. We arrived in the early evening and had a delicious steak dinner with other managers from around the tri state area. We talked theater talk and laughed for hours before retiring to our individual hotel rooms for a good night's sleep before the full day of meetings that would begin bright and early.

When I woke the next morning I felt an uneasiness in my stomach. It seemed I was even more nervous than I had realized. As the meeting commenced, the butterflies in my stomach shifted to a dull, annoying nausea. I decided I just needed something to eat, and a few hours later the caterers arrived and I was served a marvelous Asian chicken salad. I ate every last bite.

That's when things got bad.

As the afternoon portion of the meeting proceeded the feeling in my stomach became more and more painful. I felt pressure like I would literally explode. To make matters worse, I felt dizzy and clammy. I didn't catch a single word that was said at the meeting the rest of the day. I had become completely absorbed in my own suffering.

Finally the meeting concluded, and on the drive home I admitted to my boss that I wasn't feeling the best. Then I began to vomit. It didn't stop all the way home and all through the night. I decided it must be food poisoning. I considered going to the hospital but since I had no insurance I decided instead to suffer through alone in my home.

I didn't sleep at all, but by morning the immense pain had faded to a dull ache that radiated into my right hip. It caused me to walk with a limp but otherwise I felt okay. I took the day to rest but returned to work the following day. I thought I was out of the woods. The dull ache persisted, but other than keeping me up at night, it really didn't interfere with my day to day life. My appetite on the other hand was completely gone. When I did try to eat I became so nauseous that I finally quit eating all together.

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# GB365

Sponsored by COLA

## Join COLA in Giving Back, so the Lab Community can Move Forward.

COLA is proud to unveil **GB365**, a new website that encourages laboratory professionals to give back to the lab community and enrich the lives of future laboratory professionals, 365 days a year.

The foundation of GB365 is based on four core components:

### **Student Enrichment**

GB365 will excite students of all ages about the field of Laboratory Medicine through on-site presentations, STEM festivals, and school sponsored events. We encourage you to host your own event.

### **Student Mentoring Program**

COLA will connect students considering or currently pursuing a MLT or MLS degree with professionals in the industry that can help answer their questions.

### **Scholarships**

COLA through GB365 will offer \$500 scholarships to aid students currently pursuing a degree in the field of Medical Laboratory Science within an accredited program. It's an important investment in the future of our industry. We encourage you to support a future laboratorian via a scholarship donation.

### **Disaster Relief**

GB365 provides resources to laboratories nationwide that have been affected by a natural disasters, offering support and advice for safeguarding your lab before a natural disaster occurs and tips for getting your lab back on track.

**We invite you to visit GB365.** And join COLA in giving back to the Lab Community 365 days a year.



*Accreditation Education Innovation*