pennsylvania
DEPARTMENT OF HEALTH

May 28, 2014

Name of Laboratory Director
Or Current Lab Director
Name of Laboratory
Address
City, State Zip Code

RE: Revisions to the Pennsylvania Clinical Laboratory Act - Act 122-2013

Dear

As you are aware, the Pennsylvania Department of Health (Department), Bureau of Laboratories (Bureau) licenses (permits) clinical laboratories under the Pennsylvania Clinical Laboratory Act (Title 35 P.S. Ch. 21) (Lab Act). On December 18, 2013, Governor Corbett signed Act 122-2013 into law, resulting in significant changes to the Lab Act that may impact the operation of your clinical laboratory. These changes, which are summarized below, became effective on December 18, 2013. However, the Department will be phasing-in these changes to ensure an orderly transition to the Act 122 requirements.

Expanded Scope of the Lab Act

The scope of the Lab Act has been expanded to include both those clinical laboratories located in Pennsylvania (in-state clinical laboratories) and those clinical laboratories located outside of Pennsylvania (out-of-state clinical laboratories) that test specimens collected in Pennsylvania. Previously, out-of-state clinical laboratories could perform many tests on specimens collected in Pennsylvania without the need to obtain a permit under the Lab Act provided they were certified under the federal Clinical Laboratory Improvement Amendments (CLIA). Now, both in-state clinical laboratories and out-of-state clinical laboratories that test specimens collected in Pennsylvania are required to hold permits.

Out-of-state clinical laboratories that require licensure under Act 122 but do not currently hold a permit must submit a permit application to the Bureau. Applications are available in the Clinical Lab Licensure section of the Bureau's website (www.health.state.pa.us/labs). The deadline for out-of-state clinical laboratories not currently licensed by the Department to apply for a permit without penalty is August 15, 2014. The initial fee for a permit is $100. Permits will be valid through August 15, 2015.

Thereafter, annual renewal fees will be imposed as specified in the Department's regulations.

Prohibited Activities

The Lab Act now contains prohibitions against specific activities that might be used to induce a health care provider/practitioner to refer specimens to a particular clinical laboratory.

Under Act 122 it is generally unlawful for clinical laboratories to:

- Pay or receive a commission, bonus, kickback or rebate or engage in a split-fee arrangement in any form with a health care provider/practitioner.

- Lease or rent space, shelves or equipment or other services within a health care provider's/practitioner's office. This includes leasing or renting space for the purpose of establishing a specimen collection station.

- Directly or indirectly provide personnel to perform functions or duties within a health care provider's/practitioner's office for any purpose regardless of whether fair market value is offered or given.

- Permit the placement of paid or unpaid personnel to perform services (e.g., specimen collection, processing, packaging or handling or genetic counseling) in a health care provider's/practitioner's office.

Previously, the Department allowed laboratories licensed under the Lab Act to offer some specimen acceptance services in the offices of health care providers/practitioners. Out-of-state clinical laboratories not required to hold permits were not subject to any prohibitions related to specimen collection and acceptance. This practice is no longer allowed under Act 122. Therefore, laboratories must remove specimen collectors and/or other personnel from health care provider's/practitioner's offices by September 15, 2014 in order to avoid penalties.

Exceptions

Act 122 contains three (3) enumerated exceptions:

1) A health care provider/practitioner that owns and operates its own clinical laboratory may place its employees in the clinical laboratory.

2) A clinical laboratory licensed by the Department can refer specimens to another clinical laboratory licensed by the Department or to a CLIA-accredited or certified clinical laboratory.

3) Clinical laboratories are allowed to own or invest in a building in which space is leased or rented for adequate and fair consideration to health care providers/practitioners.

Fining Authority

The Department now has the authority to impose fines of up to $500 per day for violations of the Act or Department regulations, including violations relating to specimen collection, handling, and acceptance services.

Please review the enclosed "Frequently Asked Questions" document. Additional questions may be addressed to Mary McCormick, Director, Division of Laboratory Improvement, at mamccormic@pa.gov and will be answered in future FAQ pages on the Bureau's website. You may also view the entire text of Act 122 at the following link:

http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=HTM&sessYr=2013&sessInd=0&billBody=S&billTyp=B&billNbr=1042&pn=1578

Sincerely,

/signed/

Julia A. Kiehlbauch, Ph.D., D(ABMM)
Director, Bureau of Laboratories

pennsylvania
DEPARTMENT OF HEALTH

FREQUENTLY ASKED QUESTIONS – VOLUME 1
Act 122-2013
MAY 28, 2014

Q1. **What is the definition of a "clinical laboratory"?**

A1. A "clinical laboratory" is any place, establishment or institution organized and operated primarily for the performance of all or any bacteriological, biochemical, microscopical, serological, or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.

Q2. **What is the definition of a "health care provider/practitioner"?**

A2. A "health care provider" is an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), the Commonwealth, or a political subdivision or instrumentality (including a municipal corporation or authority) thereof, that operates a health care facility.

A "health care practitioner" is an individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.

Q3. **Will my out-of-state clinical laboratory be subject to inspection by Pennsylvania?**

A3. Most likely not. For a clinical laboratory located outside of Pennsylvania, the Department may exempt or limit the inspection process provided the laboratory is certified or accredited under CLIA, as well as by its home state to the extent applicable. Any limitation or exemption would require the out-of-state clinical laboratory to show proof to the Department's satisfaction that it has been inspected pursuant to CLIA and/or under the laws of its home state. However, the Department has the authority at any time to visit, enter, examine and inspect the premises of an applicant for a clinical laboratory permit or a permit holder. The Department is reviewing the inspection process that would be used for out of state clinical laboratories.

Q4. **My facility/physician's office has a clinical laboratory employee from a separate company that accepts or oversees the collection of urine specimens for drug testing. Is it acceptable for this person from that laboratory to continue to accept urine specimens in my facility/physician's office?**

A4. No. The revisions to the Lab Act prohibit clinical laboratory employees from collecting, handling or accepting specimens obtained from within a health care provider's/practitioner's office. This prohibition now applies to acceptance and/or collection of urine specimens even though this practice was previously allowed under certain circumstances.

Q5. **I have a specimen collector employed by a clinical laboratory that rents space in my physician office. Is it acceptable for this person to continue to rent space and collect specimens?**

A5. No. The revisions to the Lab Act prohibit the placement of personnel in a health care provider's/practitioner's office or the renting or leasing of space by a clinical laboratory in a health care provider's/practitioner's office, regardless of whether fair market value has been given.

Q6. I am a physician who owns and operates a clinical laboratory. Is it acceptable for my employees to continue to collect specimens and send them to my clinical laboratory?

A6. Yes. If a health care provider or practitioner owns the clinical laboratory, it is acceptable for the clinical laboratory to place its own employees in the health care provider's/practitioner's office to collect specimens.

Q7. I am a physician who does not own or operate a clinical laboratory. Is it acceptable for my employees to continue to collect specimens and send them out to a clinical laboratory?

A7. Yes. Provided the laboratory holds a valid permit issued by the Pennsylvania Department of Health and federal law, as applicable.

Q8. If my clinical laboratory does not offer a certain test, is it acceptable for my clinical laboratory to refer a test to an out-of-state clinical laboratory?

A8. Yes. For specimens collected within Pennsylvania, it is acceptable for your clinical laboratory to refer a test to an out-of-state clinical laboratory provided the out of state clinical laboratory holds a permit issued by the Pennsylvania Department of Health or under CLIA and its home state. A deadline of August 15, 2014 applies to any out-of-state clinical laboratory that is now required to obtain a permit under Act 122. Permit applications submitted after August 15, 2014 may be subject to a penalty. An application form is available on the Bureau's web site at www.health.state.pa.us/labs under Clinical Laboratory Licensure. Permits are valid until August 15, 2015 and annually thereafter.

Q9. My clinical laboratory does not hold a permit from the Pennsylvania Department of Health. Is it acceptable for my clinical laboratory to test specimens collected within the Commonwealth of Pennsylvania?

A9. No. Under Act 122, any person or clinical laboratory, either in-state or out-of-state, that tests specimens in the Commonwealth or collected within the Commonwealth must be licensed by the Department. A deadline of August 15, 2014 applies to any out-of-state clinical laboratory that is now required to obtain a permit under Act 122. Permit applications submitted after August 15, 2014 may be subject to a penalty. An application form is available on the Bureau's web site at www.health.state.pa.us/labs under Clinical Laboratory Licensure. Permits are valid until August 15, 2015 and annually thereafter.

Q10. I own or operate an out of state clinical laboratory. Am I permitted to pay physicians to send specimens collected within Pennsylvania to my laboratory for testing?

A10. No. Under Act 122, it is unlawful for any person or clinical laboratory, regardless of location, to pay or receive a commission, bonus, kickback or rebate or engage in a split-fee arrangement in any form with a health care provider or health care practitioner, either directly or indirectly, for patients or to have their specimens referred to any clinical laboratory operating within this Commonwealth or any clinical laboratory testing a specimen accepted or collected within this Commonwealth.

Q11. **I operate a nursing home or other type of in-patient facility. Does Act 122 differentiate or otherwise provide exceptions for specimen collection services at in-patient facilities versus outpatient facilities like a physician's office?**

A11. No. Under Act 122, it is irrelevant if your facility is considered "in-patient" or "outpatient." If your facility fits the definition of a "health care provider" or "health care practitioner" as defined in Act 122, then your facility is subject to the prohibitions in Act 122.

Q12. **I operate a nursing home. Is it permissible for qualified personnel of the nursing home to draw specimens from patients and place those specimens in an onsite collection box for a clinical laboratory to pick up for testing provided the clinical laboratory is licensed by the Department?**

A12. Yes. Provided that there is no type of commission, bonus, kickback, rebate or split-fee arrangement between the health care provider/practitioner and the clinical laboratory or an arrangement where the clinical laboratory leases or rents space from the health care provider/practitioner to place a collection box or operate a collection station.

Q13. **Is it permissible for a nursing home, rural hospital or critical access hospital to procure the services of an independent contractor to perform specimen collection?**

A13. Yes. Provided there is no direct financial reimbursement by the clinical laboratory receiving the specimens, including a kickback, split-fee arrangement, or other prohibited activity under Act 122.

Q14. **I operate a nursing home. Is it permissible for qualified personnel of the nursing home to draw specimens from patients and ship them to a clinical laboratory for testing?**

A14. Yes. Provided that there is no type of commission, bonus, kickback, rebate or split-fee arrangement between the health care provider/practitioner and the clinical laboratory and the clinical laboratory is licensed by the Department.

Q15. **I operate a nursing home. Is it permissible for a clinical laboratory to process specimens at the nursing home?**

A15. No. It is a violation of Act 122 for a clinical laboratory to come onsite to the office of a health care provider/practitioner to process specimens.

Q16. **I operate a health care practitioner's office that performs specialized outpatient procedures that require clinical laboratory personnel to be onsite for frequent testing during the specialized outpatient procedures. Is it permissible to have a clinical laboratory onsite to perform those services if the clinical laboratory receives reimbursement directly from the patient or from an insurance company?**

A16. Yes. If clinical laboratory testing is so inextricably linked to a procedure, or the clinical laboratory testing is an integral part of the procedure, whereby the procedure cannot be performed without clinical laboratory testing taking place during the procedure, the clinical laboratory testing is considered part of the surgical procedure and thus the Department does not consider this a violation of Act 122, provided that the clinical laboratory does not give or

receive any type of commission, bonus, kickback, rebate or split-arrangement with a health care provider/practitioner. Note, this does not mean that any clinical laboratory testing done for a surgical procedure is permitted under Act 122. The clinical laboratory testing must be such that it is part of, and cannot be separated from, the overall surgical procedure. Further, as clinical laboratory testing is taking place within the Commonwealth or from a specimen obtained from within the Commonwealth, that clinical laboratory will need a permit to operate from the Department.

Q17. **Is it acceptable for a pathologist affiliated with an outside clinical laboratory to provide contract work at an ordering physician's office when the pathologist is not an employee or member of the ordering physician's practice group so long as the pathologist is paid at fair market value or less?**

A17. Most likely not. Act 122 prohibits a person or clinical laboratory from the placement of paid or unpaid personnel to perform services, including but not limited to specimen collection, processing the specimen or packaging or handling services or genetic counseling in a health care provider's or health care practitioner's office regardless of whether fair market value is offered or given. If the pathologist performs any of the aforementioned services in a health care provider's/practitioner's office, then those services would be a violation of Act 122 unless the pathologist is considered an integral part of the surgical team such as described in the previous answer regarding specialized outpatient procedures.

Q18. **An insurance company does not separate reimbursements between a health care provider/practitioner and a clinical laboratory. Instead, the health care provider/practitioner receives the reimbursement and then pays the clinical laboratory. Is this permissible under Act 122?**

A18. Yes. Provided the insurance company clearly delineates the amount of reimbursement for each entity. If instead the insurance company provides one lump sum and the health care provider/practitioner and the clinical laboratory determine how to split the reimbursement, that scenario may be considered a split-fee arrangement.

Q19. **Is it possible to obtain an exception from the requirements of Act 122 from the Department if a clinical laboratory does not have the processes in place to accept insurance reimbursements and thus must rely on payment from the health care provider/practitioner?**

A19. No. The Department does not have the authority to grants exceptions to Act 122. However, the answer to the previous question would still apply in this scenario.

Q20. **Act 122 contains an exception that allows clinical laboratories to own or invest in a building in which space is leased or rented for adequate and fair consideration to health care providers or health care practitioners. Is it permissible under Act 122 for health care providers/practitioners that own or invest in a building to lease or rent space for adequate and fair consideration to other health care providers/practitioners?**

A20. Yes. Act 122 amends the Clinical Laboratory Act and thus regulates the actions of clinical laboratories in relation to each other and with health care providers/practitioners. Therefore, Act 122 does not prohibit health care providers/practitioners from leasing or renting space in

buildings to other health care providers/practitioners for adequate and fair consideration, though other laws may govern those transactions.

Q21. **Regarding the previous question, does Act 122 allow health care providers/practitioners to lease or rent space to clinical laboratories?**

A21. Yes. If the health care provider/practitioner owns the clinical laboratory, Act 122 does not prohibit this arrangement.

If the health care provider/practitioner does not own the clinical laboratory, this arrangement is still permitted under certain conditions as the prohibitions in Act 122 apply to clinical laboratories that lease or rent space within a health care provider's/practitioner's office. Health care providers/practitioners may lease or rent space to clinical laboratories provided that the clinical laboratory is separate and independent from the health care provider/practitioner and there is no type of commission, bonus, kickback, rebate or split-fee arrangement between the health care provider/practitioner and the clinical laboratory. In essence, the health care provider/practitioner and the clinical laboratory cannot be engaging in a "sham" lease or rental agreement where the lease or rental payments from the clinical laboratory to the health care provider/practitioner act as payment for the referral of patients for specimen collection purposes.

Q22. **Does a markup of anatomical pathology services by an ordering physician, who performs no component of the service, on a discounted laboratory technical, professional, or discounted global service client that is billed to the ordering physician, constitute a fee-split, rebate, or kickback?**

A22. Possibly. However, the Department does not regulate the medical profession or insurance billing practices. Therefore, while the Department would investigate this activity pursuant to its statutorily-defined authority, the Department would likely refer this matter to the Department of State for possible violations committed by the ordering physician.

Q23. **Is it permissible for a non-licensed facility that performs histological processing of specimens (i.e. technical component) to engage in any form of specimen soliciting, collecting, processing, handling, or receiving?**

A23. It depends. Section 13.1 of the Clinical Laboratory Act, as amended by Act 122, prohibits a person or clinical laboratory from soliciting, collecting, processing, handling, or receiving, among other prohibitions, unless that person or clinical laboratory possesses a permit from the Department.

However, the Department is still required to have jurisdiction over a facility in order to enforce the provisions of Act 122 on that facility. If the specimen is tested or collected within the Commonwealth, then under Act 122 the non-licensed facility is required to obtain a permit from the Department to perform any component of specimen testing. In that case, the facility would not be able to engage in any of the services listed in the question unless one of the statutorily provided exceptions applies. If the specimen is not tested or collected within the Commonwealth, then the non-licensed facility is not subject to the prohibitions under Act 122 and does not require licensure from the Department.

Q24. **Is it permissible for physicians who are part of a medical practice (either as an employee or independent contractor) to lease space from the practice for their separate clinical laboratory?**

Q24. Yes. Health care providers/practitioners may lease or rent space to clinical laboratories provided that the clinical laboratory is separate and independent from the health care provider/practitioner and there is no type of commission, bonus, kickback, or split-fee arrangement between the health care provider/practitioner and the clinical laboratory.

Q25. **Regarding the question above, what if the medical practice and the clinical laboratory have a shared waiting room or entrance?**

A25. The Department's concern is whether the medical practice and the clinical laboratory are engaging in prohibited arrangements under Act 122, such as kickbacks or split-fee arrangements. The fact that the two entities share a waiting room or entrance does not make this arrangement illegal under Act 122. Common entrances or shared waiting rooms are not by themselves prohibited under Act 122.

Q26. **Is it permissible for a drug treatment or rehabilitation center to use independent contractors to procure specimens from patients under Act 122?**

Q26. Yes. Due to privacy concerns surrounding drug treatment centers and patients, these facilities may use independent contractors to procure samples from patients provided there is no type of direct payment to the independent contractor, kickback, split-fee arrangement, or other prohibited activity under Act 122 by the clinical laboratory receiving the specimens.

Q27. **Is it permissible for a health care practitioner's office to have a pathologist as part of its practice?**

A27. Yes. Act 122 does not dictate the structure of a health care practitioner's office. Further, since the pathologist is part of the practice group, that pathologist does not fall under the prohibitions for specimen collection under Act 122.

Q28. **A critical access hospital serves an Amish population. This hospital supplies kits to the Amish for purposes of specimen collection. The hospital then sends the kits, containing the collected specimens, to an independent clinical laboratory where the specimens are processed. Is this permissible under Act 122?**

A28. Yes. As long as the clinical laboratory holds a valid permit issued by the Pennsylvania Department of Health and federal law, as applicable, there is no violation of the Clinical Laboratory Act.

pennsylvania
DEPARTMENT OF HEALTH

FREQUENTLY ASKED QUESTIONS – VOLUME 2
Act 122-2013
June 23, 2014

Q29. **Your initial letter indicates that the fee for a clinical laboratory permit is $100. However, section 4 of the Lab Act, 35 P.S. § 2154, states that the fee for a clinical laboratory permit is $25. What is the correct fee?**

A29. $100. Section 4 of the Clinical Laboratory Act, 35 P.S. § 2154, was superseded by a section contained in Act 48-1981. Act 48 increased the fee that the Department could assess clinical laboratories for an initial permit from $25 to $100. The portion of Act 48 that is applicable to clinical laboratories is codified in the Administrative Code, as opposed to the Lab Act, at 71 P.S. § 240.9A.

Q30. **What are the obligations of nursing facilities under ACT 122?**

A30. The Department has received numerous questions regarding long-term care nursing home facilities (nursing facilities) since the release of the Volume 1 FAQ pages, and as such, clarification is needed. This clarification is limited to nursing facilities. A nursing facility is licensed as a health care provider under the Health Care Facilities Act (HCFA). As such, nursing facilities are subject to certain prohibitions under Act 122.

A nursing home patient is considered a resident of the nursing facility, regardless of whether the patient is ambulatory or non-ambulatory. Because of the specialized needs of nursing facility residents, a nursing facility must either provide its own Department-licensed laboratory services or have a written agreement with a clinical laboratory licensed by the Department that meets the requirements of state law and applicable federal law as set forth in the Social Security Act and implementing regulations at 42 CFR § 483.75(j). These federal requirements have been incorporated into the Department's nursing facility licensure regulations at 28 Pa. Code § 201.2(10). Provided the provision of laboratory services by the nursing facility or the agreement between the clinical laboratory and the nursing facility complies with these state and federal regulations, as well as applicable anti-kickback laws, the agreement entered into under 42 CFR § 483.75(j), as incorporated at 28 Pa. Code § 201.2(10), meets the requirements of Act 122 permitting such clinical laboratories to provide phlebotomy and other laboratory services to the residents of nursing facilities.

Q31. **Does Act 122 allow a clinical laboratory to establish laboratory draw sites adjacent to an urgent care center? In this scenario, "adjacent to an urgent care center" means that they are next to one another but have separate and distinct entranceways/entry doors. Similarly, if the laboratory draw site and the urgent care center share a common entranceway and/or a common vestibule, is this permitted? In this latter scenario, once the individual enters through the common entranceway, there would be an inner entranceway/door off of the vestibule, separate from the entranceway/door to the urgent care center. In both scenarios, the laboratory draw site would have its own registration area, waiting area, and rest room.**

A31. The Department answered a similar question in Volume 1 of its FAQ pages at Q25. The Department's concern is whether the urgent care center and the clinical laboratory are engaging in prohibited arrangements under Act 122, such as kickbacks or split-fee arrangements. The fact that the two entities share a waiting room or entrance does not make this arrangement illegal under Act 122. Common entrances or shared waiting rooms are not by themselves prohibited under Act 122 and the Department is not going to require

businesses to restructure their buildings so that each business entity has its own separate entrance.

Q32. **An insurance company's policy is to provide a lump sum payment to the health care provider/practitioner. As such, the insurance company does not delineate how much of the payment is for the health care provider/practitioner and how much of the payment is for the clinical laboratory. The health care provider/practitioner then must pay the clinical laboratory. Is this permissible under Act 122?**

A32. Possibly. As stated previously in the answer to Q22 of Volume 1 of the Department's Act 122 FAQ pages, the Department does not regulate insurance billing practices. The Department would encourage the health care provider/practitioner and clinical laboratory to work with insurance companies and discuss the ramification of Act 122 to see if the insurance companies would be able to delineate payments. If an insurance company provides for one lump sum payment without any delineation between the health care provider/practitioner and the clinical laboratory, then it is up to the health care provider/practitioner and the clinical laboratory to have their own agreements that clearly delineate how payments are to be distributed. If the Department receives a complaint regarding lump sum payments, the Department will investigate the specific agreement in place between the health care provider/practitioner and the clinical laboratory to ensure that there are set distributions of payments as opposed to arbitrary payment structures that would indicate that the health care provider/practitioner and the clinical laboratory are engaging in a prohibited split-fee arrangement.

Q33. **Is a drug & alcohol (D&A) facility considered a "health care provider" or a "health care facility" for purposes of Act 122?**

A33. No, unless it is located within a health facility per the definition of "health care facility." Act 122 refers to section 103 of the Pennsylvania Health Care Facilities Act (HCFA) for the definition of a "health care provider." Section 103 defines a health care provider as a particular entity (see Q2 of Volume 1 of the Department's Act 122 FAQ pages for a complete definition) that operates a "health care facility." However, the definition for health care facility provided for in section 103 pertained specifically to Chapter 7 (Certificate of Need) of the HCFA. This Certificate of Need program has now expired and is not currently applicable. Therefore, that definition is not applicable to Act 122. Instead, the Department must use the definition of health care facility as contained in Chapter 8 of the HCFA. That definition does not include D&A facilities.

Q34. **What is the definition of a "health care facility"?**

A34. A health care facility includes, but is not limited to, a general, chronic disease or other type of hospital, a home health care agency, a home care agency, a hospice, a long-term care nursing facility, cancer treatment centers using radiation therapy on an ambulatory basis, an ambulatory surgical facility, a birth center regardless of whether such health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government.

The term health care facility shall not include an office used primarily for the private practice of a health care practitioner, nor a program which renders treatment or care for drug or alcohol abuse or dependence unless located within a health facility, nor a facility providing treatment solely on the basis of prayer or spiritual means. The term health care facility shall not apply to a facility which is conducted by a religious organization for the purpose of providing health care services exclusively to clergymen or other persons in a religious profession who are members of a religious denomination.

Q35. **Medicaid's current payment regulation states that diagnostic laboratory services used to detect a patient's use of drugs are included in the clinic visit fee as part of the services provided in Narcotic Treatment Programs, including Methadone Maintenance Programs. Does Act 122 affect payments made by Medicaid?**

A35. As stated in the answer to Q33, Act 122 does not cover a D&A facility's interactions with a clinical laboratory. Therefore, Act 122 does not prohibit fees for diagnostic laboratory services from being included in the clinic visit fee. Further, the Department does not regulate the Commonwealth's Medicaid program. As such, issues surrounding the applicability of the Medicaid program will likely be referred to another agency.

Q36. **May D&A facilities contract with clinical laboratories to draw patient specimens?**

A36. To clarify the Department's answer to Q26 of Volume 1 of the Department's Act 122 FAQ pages, a D&A facility's interactions with a clinical laboratory generally are not covered under Act 122. What may be covered, depending on the circumstances, are D&A facility's interactions with a health care provider or health care practitioner. In those circumstances, the Department will likely refer the matter to the appropriate government entity.

Regarding the answer to Q26, a D&A facility may use an independent contractor at its facility to procure patient samples. However, the D&A facility must remain aware of other laws that may prohibit this arrangement, such as the federal Anti-Kickback and Stark laws.

Q37. **Is an out-of-state clinical laboratory required to be permitted by the Department if it serves as a consulting or confirmatory laboratory for testing performed by a licensed and/or permitted clinical laboratory?**

A37. Yes. Provided the specimen was collected within the Commonwealth, an out-of-state clinical laboratory is required to be permitted by the Department. Act 122 does not provide an exception to the licensure requirements for consulting or confirmatory testing laboratories. However, Act 122 provides certain exceptions to clinical laboratories that are referred specimens by another clinical laboratory when the originating clinical laboratory is unable to conduct a test on a specimen and therefore must refer the specimen for testing to another clinical laboratory. In a consulting or confirmatory scenario, the original clinical laboratory is able to conduct the test, however, and the consulting or confirmatory clinical laboratory is conducting an additional test or otherwise confirming the results of the original clinical laboratory. Therefore, the consulting or confirmatory laboratory is subject to the Department's permitting requirements.

Q38. **Does Act 122 apply to personal care homes and assisted living residences?**

A38. No. Act 122 does not apply to personal care homes and assisted living residences because they are not defined as health care facilities under the Pennsylvania Health Care Facilities Act and are therefore not health care providers under Act 122.