

## **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 Section 4 of the Clinical Laboratory Act, 35 P.S. § 2154, was superseded by a section contained in Act 48-1981.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 entrances/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.