

FREQUENTLY ASKED QUESTIONS – VOLUME 3

**Act 122-2013
JULY 31, 2014**

Q39. Is a clinical laboratory considered a health care provider under Pennsylvania’s Health Care Facilities Act or Pennsylvania’s Clinical Laboratory Act?

A39. No. Clinical laboratories are not licensed under the Health Care Facilities Act and as such, they are not considered health care providers under either Act. Clinical laboratories are permitted under the Clinical Laboratory Act as clinical laboratories.

Q40. What are the obligations of hospitals under Act 122?

A40. The Department has received numerous questions regarding hospitals since the enactment of Act 122, and as such, clarification is needed. This clarification is limited to facilities that are licensed as hospitals by the Department under Pennsylvania’s Health Care Facilities Act (HCFA), regardless of the classification these facilities have under Medicare or other laws. A hospital is licensed as a health care provider under the HCFA. As such, hospitals are subject to certain prohibitions under Act 122.

A hospital must either provide its own Department-permitted laboratory services or have a written agreement with a clinical laboratory that meets the requirements of state law under 28 Pa. Code § 125.1 and applicable federal law as set forth in the Social Security Act and implementing regulations at 42 CFR § 482.27. These requirements include possession of a Department-issued laboratory permit and certification under CLIA per 42 CFR Part 493. Provided the provision of laboratory services by the hospital or the agreement between the clinical laboratory and the hospital complies with these state and federal regulations, as well as applicable anti-kickback laws, the agreement entered into under 42 CFR § 482.27, and consistent with 28 Pa. Code § 125.1, meets the requirements of Act 122 allowing such clinical laboratories to provide phlebotomy and other laboratory services to hospital patients.

Q41. Regarding Q22 in Volume 1 of the Department’s Act 122 FAQ pages, does the Department’s answer apply only to anatomic pathology services or does it apply more broadly to laboratory services in general (all mark-up)?

A41. Q22 specifically dealt with anatomical pathology services. Therefore, the Department limited its answer to those services. However, the Department’s answer would also apply to other mark-up services. The Department does not regulate the medical profession or insurance billing practices. Therefore, although the Department would investigate this matter under its statutorily-defined authority, it would likely refer this matter to an appropriate agency for further investigation.

Q42. Does Act 122 permit a physicians’ practice to purchase the professional and/or technical component of a diagnostic test and then bill globally for the entire test?

A42. It depends. The Department would require that entities engaged in the purchasing of a diagnostic test comply with the “anti-markup rule” as issued by the Centers for Medicare & Medicaid Services (CMS). Generally, the anti-markup rule provision applies when a physician or other supplier orders a diagnostic test and bills for the technical component (TC) or professional component (PC) of the test that is performed or supervised by a physician or other supplier who does not “share a practice” with the billing physician or other supplier that ordered the test as defined by CMS under 42 CFR § 414.50. One possible exception to this prohibition is if the clinical laboratory testing is so inextricably linked to a procedure or is such an integral part of the procedure that the procedure cannot be

performed without the clinical laboratory testing taking place. This scenario was addressed in Volume 1 of the Department's Act 122 FAQ pages at Q16.

The Department does not regulate physicians under the Medical Practice Act or Osteopathic Practice Act. Therefore, the Department would investigate this matter under its statutorily-defined authority and likely refer this matter to the appropriate agency for further investigation.

Q43. We are working with a CLIA-certified clinical laboratory ("Laboratory A") that would like to invite physicians licensed in Pennsylvania to purchase equity interest in Laboratory A. Laboratory A is located outside of the Commonwealth and would obtain all appropriate Commonwealth permits prior to beginning its operations within the Commonwealth. Physician investors would be allowed, but not required, to refer commercial and self-pay patients to Laboratory A, and would be required to disclose their ownership interest in Laboratory A to all such patients before or at the time of making a referral to Laboratory A. Physicians would not refer patients to Laboratory A for whom the payor source for laboratory services is a state or federal governmental payor program such as Medicare, Medicaid or Tricare. If the source of payment is a governmental payor, a specimen will be processed by an alternative appropriately licensed clinical laboratory in which neither Laboratory A nor any of its physician owners have any equity or other financial interest. Distributions of profits, if any, are made to physician investors in proportion to their equity ownership in Laboratory A. The volume and value of referrals to Laboratory A made by a particular referring physician investor would be irrelevant to the allocation of profits and losses allocated to the physician investor. Is this type of an arrangement permitted under Act 122?

A43. Probably not. Act 122 prohibits a clinical laboratory from paying or receiving any type of prohibited transaction with a health care provider/practitioner, either directly or indirectly, for patients or their specimens referred to any clinical laboratory operating within this Commonwealth or testing a specimen accepted or collected in this Commonwealth. An exception to Act 122 allows a health care provider's/practitioner's office to wholly own a clinical laboratory and not be in violation of Act 122, but that exception does not apply in this situation wherein health care practitioners that are not a part of the same office or practice group choose to purchase equity interests in a clinical laboratory.

For purposes of Act 122, it is irrelevant that this type of arrangement would exclude state or federal governmental payor programs and only utilize commercial payors and self-pay patients. The Department shares similar concerns as published by the Office of Inspector General of the U.S. Department of Health and Human Services in its Special Fraud Alert dated June 25, 2014 entitled, "Special Fraud Alert: Laboratory Payments to Referring Physicians." The Department's concerns regarding this type of arrangement are not resolved when those arrangements apply only to specimens collected from non-federal or state health care program patients. Arrangements that exclude state or federal health care program beneficiaries or business from otherwise questionable arrangements implicate Act 122 and may violate it by disguising remuneration for state or federal health care program business through the payment of amounts purportedly related to non-federal or state health care program business. Because physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency, arrangements that carve out state or federal health care program business may nevertheless be intended to influence physicians' referrals of state or federal health care program business to the offering laboratories.

Under this scenario, while physicians are not distributed profits based upon the number of referrals but instead based upon their equity ownership in Laboratory A, these physicians will make more money if more business is diverted to Laboratory A, regardless of the amount of

equity ownership in Laboratory A. For every specimen that is sent to Laboratory A for processing, each physician stands to make more profit in relation to the equity ownership he or she has in Laboratory A. Therefore, the Department would view this type of arrangement as suspect.

Q44. May a health care practitioner charge a processing and handling fee to a clinical laboratory for the service of preparing a specimen and packaging the specimen for shipment to the clinical laboratory?

A44. It depends. "Specimen processing arrangements," as described here, are arrangements under which clinical laboratories pay physicians, either directly or indirectly, to collect, process, and package patients' specimens. Specimen processing arrangements typically involve payments from clinical laboratories to physicians for certain specified duties, which may include collecting blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, or packaging the specimens so that they are not damaged in transport. As with the previous question, the Department shares similar concerns with the Office of Inspector General. Act 122 is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of Act 122 occurs depends on the circumstances surrounding the transaction. Act 122 prohibits the payment of such amounts if even one purpose of the payment is to induce or reward referrals of clinical laboratory business. The probability that a payment is for an illegitimate purpose is increased, however, if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare.

While the Department will look closely at specimen processing arrangements, Act 122 does not prohibit these fees outright provided there is no inducement for services and clinical laboratories and health care practitioners follow guidelines for permissible charges allowed under federal law, including CMS' Clinical Laboratory Fee Schedule, the Medicare Claims Processing Manual and the Special Fraud Alert published by the Office of Inspector General referred to in the previous answer.

Q45. A physicians' group hires a pathologist who is not an employee of the physicians' group. The pathologist reads biopsy slides in the physicians' office but the physicians' office handles all of the billing. Does Act 122 allow this?

A45. It depends. The role of pathologists in a health care practitioners' office was addressed in Volume 1 of the Department's Act 122 FAQ pages at Q17 and Q27. If the pathologist is part of the health care practitioners' group, then Act 122 is not implicated because Act 122 does not dictate the structure of a health care practitioners' office. However, if the pathologist is affiliated with a clinical laboratory and is placed in the offices of a health care practitioners' group, then Act 122 is implicated and this arrangement would most likely be prohibited.

Q46. Is it permissible under Act 122 for a sponsor to run Institutional Review Board (IRB) approved clinical studies/samples whereby the sponsor pays the clinician's office on a per patient basis to collect patient informed consent data, complete the required case report forms, and perform other associated activities as required by the IRB approved protocol?

A46. Yes. Under federal regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with federal regulations, an IRB has the authority to approve, require modifications in research to secure approval, or to disapprove research.

An IRB-approved study or research project is governed under federal law. The focus of an IRB-approved study or research project revolves around human subjects. As such, payment from a sponsor, such as a clinical laboratory, to a health care provider/practitioner in this

case is for patient data to further the study or research project as opposed to an inducement for the referral of business. Provided the clinical laboratory has an IRB-approved study or research project that follows the guidelines set forth by the IRB, and there is no inducement for the referral of future business, the Department has no authority to supplant the IRB process under Act 122.

Q47. I own a clinical laboratory located at a different location from my medical practice. Does Act 122 allow my clinical laboratory to utilize the services of another clinical laboratory?

A47. Yes. Provided that the receiving clinical laboratory is serving as a reference laboratory due to the sending laboratory's inability to perform certain laboratory tests. Whether the receiving clinical laboratory is located in-state or out-of-state will dictate what type of permit or certification the receiving clinical laboratory must have. Referral scenarios are addressed further in Q48 through Q51.

Q48. Are there any exceptions that apply in referral scenarios?

A48. Yes. If the federal government maintains and operates a clinical laboratory, that clinical laboratory is not subject to the referral requirements of Act 122. Q49 through Q51 address scenarios in which the sending or receiving clinical laboratories are not maintained and operated by the federal government.

Q49. Is it acceptable for a clinical laboratory that possesses a Department-issued clinical laboratory permit to refer specimens originating in the Commonwealth to another in-state clinical laboratory if the receiving in-state clinical laboratory does not possess a Department-issued clinical laboratory permit?

A49. No. All clinical laboratories located within the Commonwealth must possess a Department-issued clinical laboratory permit. Therefore, an in-state clinical laboratory that possesses a Department-issued clinical laboratory permit cannot refer specimens to another in-state clinical laboratory that does not possess a Department-issued clinical laboratory permit.

Q50. Is it acceptable for a clinical laboratory that possesses a Department-issued clinical laboratory permit to refer specimens originating in the Commonwealth to an out-of-state clinical laboratory if that out-of-state clinical laboratory does not possess a Department-issued clinical laboratory permit?

A50. Yes. Act 122 provides an exception that allows a Department-permitted clinical laboratory to refer a specimen to an out-of-state clinical laboratory that does not hold a Department-issued clinical laboratory permit if the sending laboratory is unable to perform a needed test. The receiving laboratory must possess a CLIA certificate unless it is located in one of the states that CMS has designated as exempt from CLIA certification. The receiving laboratory must possess all applicable permits required by the laws of its home state. As addressed in Volume 2 of the Department's Act 122 FAQ pages at Q37, this exception is only applicable when the receiving laboratory is able to perform a test which the sending laboratory is not able to perform. The exception does not apply when specimens are sent to consulting or confirmatory laboratories that verify a result obtained by the sending laboratory.

Q51. Is it acceptable for a CLIA-certified clinical laboratory that does not have a Department-issued clinical laboratory permit to refer specimens originating in the Commonwealth to either another CLIA-certified clinical laboratory that does not have a Department-issued clinical laboratory permit or to a clinical laboratory that does possess a Department-issued clinical laboratory permit?

- A51. No. Act 122 requires the sending clinical laboratory to possess a Department-issued clinical laboratory permit. A clinical laboratory that possesses a CLIA certificate, but does not possess a Department-issued clinical laboratory permit, may receive specimens originating in the Commonwealth if those specimens are referred from a laboratory that possesses a Department-issued clinical laboratory permit and the receiving CLIA-certified clinical laboratory is located out-of-state. The answer to Q48 describes the circumstances under which a clinical laboratory that possesses a Department-issued clinical laboratory permit may refer specimens to a clinical laboratory that does not possess a Department-issued clinical laboratory permit. Whenever a clinical laboratory that possesses a Department-issued clinical laboratory permit refers specimens to a clinical laboratory that does not possess a Department-issued clinical laboratory permit, the receiving laboratory may not refer those specimens to any other laboratory.
- Q52. Does Act 122 apply to Federal Qualified Health Centers (FQHC), Federal Qualified Health Center Look-Alikes (FQHC Look-Alikes) or Rural Health Clinics (RHC)?**
- A52. No. Act 122 does not apply to FQHCs, FQHC Look-Alikes or RHCs as they are governed under federal law and are not licensed as health care facilities under the Pennsylvania Health Care Facilities Act. Therefore, these facilities are not considered health care providers under Act 122.