

PADONA Journal

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NEW CHANGES TO CLINICAL LAB ACT MAY AFFECT NURSING HOMES¹

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On December 18, 2013, Governor Corbett signed Senate Bill 1042, which amended the Clinical Laboratory Act for the first time since the 1970s. The new law, known as Act 122 of 2013, prohibits clinical laboratories from leasing or renting space, shelves or equipment within a health care provider or practitioner's office. The law also prohibits the clinical laboratory from placing personnel, including employees or contractors, within a health care provider's office for any purpose, specifically including collecting or handling of specimens. In addition, the law prohibits a health care provider from permitting a clinical laboratory to place personnel within its office.

The full impact of this law on nursing homes has not yet been determined. The intent of the law appears to have been to prohibit kickbacks, rebates, and fee-splitting for lab services, as well as to stop labs from co-locating collection stations in the offices of unrelated providers. As written, however, the scope is potentially much broader. It is possible, for example, that the law could have the unintended consequences of prohibiting clinical labs from providing venipuncture services in a nursing home, even when those services are paid for at fair market value. Likewise, depending on how the terms "collected or handled" are ultimately interpreted, the law may make it difficult, if not impossible, for a clinical lab to transport blood samples drawn by nursing home personnel, even if the courier services are paid for by the nursing home at fair market value.

Although the law became effective when the Governor signed it on Decem-

ber 18, 2013, we understand that the Department of Health will not be enforcing the law until the Bureau of Laboratories issues written guidance to all clinical laboratories, anticipated to occur by February. The Department will also be publishing notices in the *Pennsylvania Bulletin* and on the Bureau of Laboratories' website, which will explain the new law and its effect on both in-state and out of state clinical laboratories. The notices will also explain the enumerated exceptions (such as when the lab and provider's office are wholly owned and operated by the same entity) in the law and give deadline dates for compliance. The compliance deadlines will govern when out of state laboratories need to obtain a license from the Department without penalty, as well as when clinical laboratory specimen collectors, handlers, and accepters must be removed from health care provider/practitioner offices without penalty.

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We have been in contact with the Department and are encouraged by the Department's willingness to provide assistance during this transition period.

Specifically, the Department is looking into some of the potential ways this law may affect long-standing relationships between labs and nursing homes. We have been told that once letters are sent to the licensed labs, the Department will identify a contact person within the Bureau of Laboratories to whom questions and concerns should be sent. We would encourage you to begin discussions with your clinical lab services provider about the potential impact of Act 122 on your operations, especially if your lab provides venipuncture or collection services to your facility.

The good news is that the Department wants to work with providers in the coming months to understand and comply with the law before imposing fines or taking additional information. The deadlines are meant to give clinical labs time to comply as well as allowing them to contact the Bureau for assistance and any questions that may arise. The Bureau's intent is to assist labs to comply with the law before levying fines (which is also part of the Act) or taking other actions against the labs.

¹*This article does not offer specific legal advice, nor does it create an attorney-client relationship. You should not reach any legal conclusions based on the information contained in this article without first seeking the advice of counsel.*

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³A copy of S.B. 1042 and its legislative history is available at <http://www.Legis.State.Pa.Us/cfdocs/billinfo/bill-info.cfm?sYear=2013&sInd=0&body=S&type=B&bn=1042>.