



## Department of Health

ANDREW M. CUOMO  
Governor

HOWARD A. ZUCKER, M.D., J.D.  
Commissioner

SALLY DRESLIN, M.S., R.N.  
Executive Deputy Commissioner

October 4, 2018

Dear Administrator:

It has recently come to the attention of the New York State Department of Health (Department) that certain laboratory service providers with long-standing relationships with nursing homes are notifying these facilities they will be discontinuing testing services in the near future. Please be assured that the Department is working with both the laboratory and nursing home industry stakeholders to develop potential longer-term solutions. However, in light of these recent events, we are sending this letter to remind nursing home operators and administrators of the requirements of federal regulation with respect to the provision of laboratory services to nursing home residents, and suggest actions to help ensure compliance with these requirements.

Nursing Homes are required under federal conditions of participation to maintain access to lab services. Federal regulations (42 CFR 483.50) require that nursing homes "must provide or obtain laboratory services to meet the needs of its residents" and that they are "responsible for the quality and timeliness of the services." Regulations further prescribe that, if a facility "does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory." To summarize, there are two acceptable approaches: 1) the nursing home may provide such services itself on site; or, 2) the nursing home may enter into a contractual agreement to obtain such services from a laboratory service provider.

Upon conferring with experts, the Department has been informed that one of the reasons that lab providers are discontinuing services to nursing homes is the impact of a relatively recent change in federal reimbursement policy. The "Protecting Access to Medicare Act of 2014" (PAMA) significantly revises the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). PAMA establishes that the Medicare payment amount for a test on the CLFS generally will be equal to the weighted median of the private payor rates determined for the test, based on the data that was collected during a data collection period and reported to CMS. In effect, PAMA created a market-based pricing system for lab tests where Medicare payment for a test equals the weighted median of private payor rates. The statute also provides for a phase-in of payment rate reductions for the first six years of the revised payment system. The law took effect in 2014.

The federal government selected "applicable labs" to report payment rates and volumes from private payors and, when interpreting PAMA, did not include data from all segments of the laboratory market and did not include data from the local laboratories that service nursing homes. This resulted in significant reimbursement reductions to those laboratories that, due to the gradual phase in, have only recently begun to have the broader impacts we are observing. New York is committed to engaging in advocacy at the federal level to address this issue to ensure that PAMA does not negatively impact the ability of nursing homes to be able to obtain laboratory services for their residents. We are hopeful that, with advocacy by New York and other states, the federal government will reconsider the impact of their actions.

However, at this time, the Department is encouraging nursing homes to consider utilizing emerging lab testing alternatives to ensure access for nursing home residents. The Department has already brought together key industry stakeholders to facilitate discussion on the subject. That discussion resulted in the following recommendations for all nursing home administrators:

1. All nursing homes who use an outside laboratory provider should immediately evaluate their laboratory needs and its contract with its current lab service provider. Emphasis in their evaluations should be placed on understanding the long-term plan of that service provider and whether the nursing home has evidence of their continued operations past the next six months.
2. All nursing homes should immediately, seek an alternative lab service provider who can serve as a backup in case of emergency or transitions within the market. This will ensure that they are at a lower risk of being without lab services should their primary lab provider cease to provide lab services.
3. Nursing Homes should consider the possibility of performing lab testing on-site by using point of care tests instead of sending testing to a contracted lab wherever possible. This will help to meet the federal conditions of participation for maintaining access to lab services while also providing nursing homes with an opportunity to grow the skill sets of its employees and reduce turnaround time for test results providing an opportunity to diagnose and treat residents in a timely manner.
4. Nursing Homes should consider discussing laboratory testing options with local hospitals that have in-house labs.
5. Nursing homes should also consider the alternative of training staff to perform phlebotomy services on-site or contracting with a mobile phlebotomy service. Specimens could then be forwarded to the labs by courier. This may provide an opportunity for more labs willing to provide services to nursing homes.

In addition, the Department conducted a webinar for nursing homes on Thursday, October 4th that provided important information regarding Clinical Laboratory Improvement Amendment (CLIA) waived tests, as well information regarding the ability of nursing homes to provide phlebotomy services. If you would like copies of the meeting materials please email Angela Whyland at [Angela.Whyland@health.ny.gov](mailto:Angela.Whyland@health.ny.gov).

We hope this information assists nursing homes in taking the necessary steps to ensure that laboratory services are provided to their residents. We urge all nursing homes to follow the Department's recommendations. Should you have any further questions or concerns, please contact Shelly Glock, Director of the Division of Nursing Homes and Intermediate Care Facilities, at (518) 408-1267. Questions regarding lab services or testing, as well as phlebotomy should be directed to [clepltd@health.ny.gov](mailto:clepltd@health.ny.gov).

Sincerely,



Bradley Hutton, M.P.H.  
Deputy Commissioner  
Office of Public Health



Daniel B. Sheppard  
Deputy Commissioner  
Office of Primary Care and  
Health Systems Management