

July 29, 2020

ADM Brett P. Giroir, M.D. Assistant Secretary for Health U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Admiral Giroir,

LeadingAge heard, with great interest, the HHS announcement of a new testing initiative for nursing homes. We appreciate your attention to the needs of older adults, their families, and their care workers. Testing is a key component in the fight against COVID-19. We certainly understand that, as with any new initiative of this magnitude, much is still unclear. Our more than 5,000 mission driven member organizations are looking to us for timely and accurate information and it is in that spirit that we write this letter. We hope to meet with you soon to discuss our questions and concerns.

Major concerns that our members have raised include:

- High rate of false negative results and need for retesting. Antigen testing is useful for rapid positive results with residents and staff who are symptomatic, allowing providers to take quick actions to treat and isolate individuals. We note, however, that these tests have a 20% false negative result; the manufacturers recommend that all individuals whose tests that come back negative must be retested using PCR testing. The FDA recommends this. Is that also the position of HHS? Understandably, our members are concerned about the time and expense of testing nearly everyone twice.
 - In addition, the need for retesting will lead to the same concerns our members have been experiencing: limited supply of tests and increasing turnaround times for results. Additionally, the costs of weekly staff PCR testing are approximately \$120-\$150 per staff member tested.
- Cost of ongoing testing and retesting. Our members are also concerned about the costs of ongoing antigen testing, including staff time to draw samples and run the machine. Our conservative weekly cost estimates for testing, staff time, and retesting negative results using PCR tests are: \$19,265 for those with 100 employees, \$28,428 for those with 150 employees, and \$37,590 for those with 200 employees. This estimate does not include the additional PPE needed to conduct tests. Testing, of course, is but one of the expenditures/lost revenues that Provider Relief Funds must support.

Number of Nursing Home Employees	100	150	200
Weekly cost of antigen testing i	\$2,500.00	\$3,750.00	\$5,000.00
Cost for staff time to administer antigen testing "	\$940.80	\$940.80	\$940.80
Staff pay for test processing ***	\$1,575.00	\$2,362.50	\$3,150.00
Antigen test cost	\$5,015.80	\$7,053.30	\$9,090.80
Cost of PCR retest (assuming 95% negative antigen tests, \$150 per test)	\$14,250.00	\$21,375.00	\$28,500.00
Potential weekly cost	\$19,265.80	\$28,428.30	\$37,590.80

- Many state and local health departments do not accept antigen testing results. Many, if not
 most state health departments do not recognize the results of antigen tests for COVID-19 due to
 the relatively high rate of false negatives. Therefore, it appears that providers in those states will
 need to use PCR tests rather than antigen tests in order to fulfill state and local health
 department reporting requirements.
- Slow speed of testing. More information about the speed and volume of testing would also be useful. It is our understanding that one test can be completed in 15 minutes. We also understand that a number of tests can be matured for 15 minutes outside of the machine and then batch tested. One laboratory expert very familiar with the Sofia machines with whom we spoke indicated that she would not recommend batches of more than five tests at a time as beyond that the likelihood of error rises significantly. Is that your position as well? Understandably, our members are trying to figure out how they would successfully test large numbers of staff at the start of each shift. Your guidance would be helpful. Or perhaps this specific testing strategy is only targeted to residents?
- Reporting to the NHSN. Can you confirm that the results of antigen tests can be used for
 reporting to the CDC's National Healthcare Safety Network, despite the FDA recommendation
 that those with negative test results be retested and the fact that many state and local health
 departments do not accept antigen testing results? How can we ensure that with a 20% rate of
 false negative results the NHSN data are correct?
- Coverage for testing. We would like to understand more about Medicare, Medicare Advantage, and private insurance coverage for antigen testing particularly repeat testing of asymptomatic individuals. This MLN Matters article states the types of testing covered, including surveillance testing, contrasted with Administrator Verma's comments during a press conference that surveillance testing is not covered by Medicare.
- Logistics of the rollout. It would be helpful to hear more about the logistics of the rollout. We have notified our members that they will need to have CLIA waivers. Will nursing homes be notified in advance of their shipments? Who will provide training for those running the tests?

We were pleased to hear initial plans last week. Could you spell out how many tests nursing homes will receive if classified as small, medium, etc.? Are you looking at current census or number of beds? Does the person doing the swabs need to have particular credentials? Are there particular storage protocols for the kits?

We strongly urge the Administration to establish a national testing program that will produce reliable, rapid results testing with at least 95 percent specificity.

We look forward to discussing these questions and concerns with you and identifying ways we can help address and allay our members' concerns and support use of the new machines. Again, we thank you for your focus on the critical need to make COVID testing available and, we hope, save the lives of older people.

Sincerely,

Katie Smith Sloan President and CEO

LeadingAge

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¹ Assumes a cost of \$25 per antigen test.

[&]quot;Cost for staffing the antigen staff assumes a full-time (40 hours per week) Licensed Practical Nurse (LPN) earning \$23.52 per hour, the median hourly rate for LPNs in nursing homes. Facilities with more staff may require additional staff time to administer tests. (Bureau of Labor Statistics, https://www.bls.gov/oes/current/naics4 623100.htm)

Staff pay for test processing assumes one hour per week per staff member of paid time while waiting for antigen test results, based on an hourly rate of \$15.75, the median hourly rate for workers in nursing homes. (Bureau of Labor Statistics, https://www.bls.gov/oes/current/naics4 623100.htm)