

Federal Distribution of Point-of-Care COVID-19 Testing Instruments for Nursing Homes Begins This Week

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The U.S. Department of Health and Human Services (HHS) announced on July 14, 2020 that it is distributing rapid point-of-care diagnostic test instruments and tests to all 15,400 nursing homes throughout the country to encourage recurrent testing of staff and residents. See HHS July 14 press release [here](#). Distribution of the instruments and testing supplies will begin this week, starting with 2,000 nursing homes identified at greatest risk due to community spread.

HHS described access to rapid point-of-care testing in nursing homes as necessary to further protect the Nation's most vulnerable patients. During a press briefing in Baton Rouge, Louisiana on July 14, the Administrator for the Centers for Medicare and Medicaid Services (CMS), Seema Verma, described the elderly in nursing homes as the most vulnerable of the Nation's citizens. Administrator Verma recognized that the restriction of visitors and activities because of COVID-19 has made this pandemic a very difficult time for the residents. [Click here](#) to see the press briefing transcript.

CMS COVID-19 data for the week ending 7/5/20 showed there have been 133,351 confirmed cases with 37,213 deaths in nursing homes. Increased rapid testing is seen as a means to augment current testing in nursing homes, in order to support efforts to respond to and prevent the spread of COVID-19.

Each nursing home will receive one diagnostic test instrument and associated tests. Nursing homes will need to purchase additional tests from manufacturers once the tests provided by HHS are exhausted. The testing instruments distributed will include BD Veritor system and Quidel Sofia and Sofia 2 systems. All the instruments use antigen tests which quickly detect fragments of proteins found on or within the COVID-19 virus. The testing is performed using nasal cavity swabs, and results can be provided in minutes.

Of note are reports that CMS will not distribute the test instruments and tests to nursing homes that do not have a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. See HHS July 14 press release referring to authorizations needed for use and LeadingAge July 16, 2020 article [here](#). Read more [here](#) on CMS guidance for applying for a CLIA Certificate of waiver.

CMS' guidelines for reopening nursing homes, released in May, cited the need for access to adequate testing as a key factor in gauging when and how to relax restrictions that have been implemented both voluntarily and by states on nursing home services and visitation activities. See CMS Reopening Recommendations. CMS recommends all nursing home residents receive a single baseline test, followed by weekly testing until all residents test negative.

Similarly, CMS recommends all nursing home staff receive a single baseline test, followed by weekly testing. In the July 14 press conference, HHS Assistant Secretary of Health, Admiral Brett Giroir, M.D., stated that in order to protect nursing home residents, staff should be tested once a week "to make sure that they don't bring, unintentionally, maybe even without symptoms, the virus into the nursing home." See press briefing transcript [here](#). Admiral Giroir added this testing would mean four to five million tests per month. Ongoing concerns about lengthy turnaround times for test results and the expensive nature of testing led to the upcoming distribution of the rapid, "20-tests-per-hour" instrument and tests.

In addition to residents and staff, HHS mentioned in its July 14 press release that the diagnostic test instrument and associated tests being distributed to nursing homes could be used to test visitors, if appropriate. See HHS July 14 press release. Relaxing restrictions on visitation also relies heavily on access to COVID-19 testing. In the last or third phase for reopening, CMS recommends nursing homes that allow visitation will have adequate access to testing and have had no new COVID-19 cases for 28 days. See CMS May Reopening Recommendations.

Overall, Admiral Giroir described the HHS initiative to distribute the testing instruments to the Nation's nursing homes as historic, and an effort that will "save thousands of lives." The distribution is expected to start this week with the 2,000 nursing homes identified as most at risk, followed by the additional 13,400 homes in the following weeks.

If you have any questions or would like more information, please contact Alice Harris or your regular Nexsen Pruet attorney.