DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
Services 7500 Security Boulevard
Baltimore, Maryland 21244-1850

DATE: June 19, 2020

TO: All Medicare Advantage Organizations (MAOs), Medicare-Medicaid Plans, and Programs of All-Inclusive Care for the Elderly (PACE) Organizations

SUBJECT: Diagnostic Testing of Nursing Home Residents and Patients for Coronavirus Disease 2019 (COVID-19)

On April 21, 2020, CMS issued guidance to MAOs, Part D sponsors, and Medicare-Medicaid Plans to inform them of the obligations and permissible flexibilities related to disasters and emergencies resulting from COVID-19. With respect to the coverage of testing and testing-related services for COVID-19, we explained that under Section 6003 of the Families First Coronavirus Response Act and Section 3713 of the CARES Act, with the exception of Medicare Advantage Medical Savings Account plans, MAOs must not charge cost sharing (including deductibles, copayments, and coinsurance) or apply prior authorization or other utilization management requirements for:

- clinical laboratory tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such tests;
- specified COVID-19 testing-related services (as described in section 1833(cc)(1)) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2); and
- COVID-19 vaccines and the administration of such vaccines, as described in section 1861(s)(10)(A).

We explained that the coverage of testing and the limit on cost sharing (including deductibles, copayments, and coinsurance) for COVID-19 testing and specified testing-related services applies to services furnished on or after March 18, 2020 and during the emergency period identified in section 1135(g)(1)(B) of the Act (that is, the public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, entitled "Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus," and any extensions thereof) ("applicable emergency period").

The Centers for Disease Control and Prevention (CDC) recently updated COVID-19 testing guidelines for nursing homes. The guidelines provide recommendations for diagnostic testing for residents and patients with symptoms consistent with COVID-19 as well as asymptomatic residents and patients. Under section 1862(a)(1)(A) of the Social Security Act and 42 C.F.R. § 410.32, Medicare has the authority to cover diagnostic tests. As noted in the MLN Matters Article SE20011, CMS has instructed the Medicare Administrative Contractors to make, starting on July 6, 2020, Medicare coverage determinations for laboratory tests to detect active SARS-CoV-2 infections in nursing home residents and patients that are consistent with the following

sections of CDC guidelines titled "Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents":

- Viral Testing of Residents for SARS-CoV-2
- Initial Viral Testing in Response to an Outbreak
- Recommended testing to determine resolution of infection with SARS-CoV-2
- Public health surveillance for SARS-CoV-2

These sections identify diagnostic and non-diagnostic testing situations for nursing home residents and patients.

In accordance with 42 C.F.R. 422.101(b), MAOs must comply with general coverage guidelines included in original Medicare manuals and instructions, including the following relevant sections of the CDC guidelines.

Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents

Viral Testing of Residents for SARS-CoV-2

- *Perform initial viral testing of each resident in a nursing home, as part of the recommended reopening process.*
    - *Initial viral testing of each resident in any nursing home (who are not known to have previously been diagnosed with COVID-19) is recommended as a diagnostic test because of the high likelihood of exposure during a pandemic, transmissibility of SARS-CoV-2, and the risk of complications among residents following infection. The results of viral testing, inform care decisions, infection control interventions, and placement decisions (e.g., cohorting decisions) relevant to that resident.*
- *At least daily, take the temperature of all residents and ask them about presence of COVID-19 symptoms; perform viral testing of any residents who have signs or symptoms of COVID-19.*
    - *Clinicians should use their judgment to determine if a resident has signs or symptoms consistent with COVID-19 and whether the resident should be tested. Viral testing in this setting is useful as a diagnostic test. Most people with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough). Some people may present with only mild symptoms or other symptoms as well.*
    - *Clinicians are encouraged to consider testing for other causes of respiratory illness, such as influenza, in addition to testing for SARS-CoV-2.*
    - *Facility leadership and local and state health departments should have a plan for performing contact tracing for close contacts of residents with SARS-CoV-2 infection*

Initial Viral Testing in Response to an Outbreak

- *Perform expanded viral testing of **all** residents in the nursing home if there is an outbreak in the facility (i.e., a new SARS-CoV-2 infection in any nursing home-onset SARS-CoV-2 infection in a resident). Given the risk of infection in this setting, this viral testing of residents would be considered a diagnostic test.*
    - *A single new case of SARS-CoV-2 infection in a nursing home-onset SARS-CoV-2 infection in a resident should be considered an outbreak. When one case is detected in a nursing home, there are often other residents who are infected with SARS-CoV-2 who can continue to spread the infection, even if they are asymptomatic. Performing viral testing of all residents as soon as there is a new confirmed case in the facility will identify infected individuals quickly to assist in their clinical management and allow rapid implementation of IPC interventions (e.g., isolation, cohorting, use of personal protective equipment) to prevent SARS-CoV-2 transmission. When undertaking facility-wide viral testing, facility leadership should expect to identify multiple asymptomatic and pre-symptomatic residents with SARS-CoV-2 infection and be prepared to cohort residents and mitigate potential staffing shortages. See Public Health Response to COVID-19 in Nursing Homes and Strategies to Mitigate Healthcare Personnel Staffing Shortages for more detail.*
    - *If viral testing capacity is limited, CDC suggests first directing testing to residents who are close contacts (e.g., on the same unit or floor of a new confirmed case).*
    - *See Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes for additional details.*

Recommended testing to determine resolution of infection with SARS-CoV-2

A test-based strategy, which requires serial tests, can be used as an alternative to a symptom-based or time-based strategy, to determine when a person with SARS-CoV-2 infection no longer requires isolation or work exclusion. This testing is diagnostic and could be considered in the following situations:

- *Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings*

Public health surveillance for SARS-CoV-2

Testing is a fundamental part of the United States SARS-CoV-2 Surveillance Plan, which uses multiple surveillance systems and epidemiology networks, in collaboration with state, local, and academic partners, to monitor the progression and impact of SARS-CoV-2 spread in the United States.

Viral tests are used in community, outpatient, and hospital-based surveillance systems to identify cases of SARS-CoV-2 infection. These data help identify areas of ongoing circulation (hot spots),

determine trends in disease by location, provide insight into the impact of the disease over time and by location, and inform disease forecasts.

Antibody tests are increasingly used to monitor disease burden by location and over time. Use of serologic assays in populations can help determine the proportion of a population previously infected with SARS-CoV-2. Thus, demographic and geographic patterns of serologic test results provide data that can be used in forecasts of disease spread that can support resource allocation decisions and planning by local, territorial and state officials.