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COVID-19 COVERAGE

STATE ACTIONS

California
2019 CA A.B. 1710 (NS), amended/substituted August 24, an act to amend Section 4052.8 of the Business and Professions Code, relating to pharmacy practice and vaccines.

District of Columbia
The Director of Department of Health Care Finance (DHCF hereby gives notice of the adoption of an amendment to Section 5003 (PCA Service Authorization Request and Submission) of Chapter 50 (Medicaid Reimbursements for Personal Care Aide Services) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR). See 2020 DC REG TEXT 520174 (NS).

1 This COVID-19 Coverage Snapshot was compiled by members of the publisher’s staff.
Florida
The emergency rule authorizes licensees to obtain all required continuing education hours by any means, live, virtual live, or online; and first year licensees to satisfy the required meeting attendance through either a live or online/livestreaming/webinar meeting for the ninety-day effective period of the emergency rule. See 2020 FL REG TEXT 563189 (NS).

Massachusetts
- Chapter 101 CMR 350.00 establishes the payment rates for MassHealth-covered home health services. See 2020 MA REG TEXT 552541 (NS).
- Chapter 101 CMR 204.00 governs the payment rates for services provided by resident care facilities to publicly aided and industrial accident residents. See 2020 MA REG TEXT 563280 (NS).
- Chapter 101 CMR 320.00 establishes the rates to be paid under the MassHealth program for clinical laboratory services. M.G.L. Chapter 118E, Section 13D requires the Executive Office of Health and Human Services to establish, by regulation, the rates paid by governmental units to providers of health care services. 101 CMR 320.00 is in accordance with this statutory requirement. See 2020 MA REG TEXT 563282 (NS).
- Chapter 101 CMR 345.00 establishes the maximum rates health care facilities may pay for services provided by temporary nursing agencies registered with the Department of Public Health (DPH). See 2020 MA REG TEXT 563283 (NS).
- Chapter 101 CMR 446.00 governs the payment rates paid by MassHealth and other governmental purchasers for certain COVID-19-related community health care services rendered to publicly-aided individuals by providers including: on-site and digital evaluation and management services rendered at isolation and recovery (I&R) sites by certain community health centers (CHCs); providers rendering remote patient monitoring services; durable medical equipment and supplies (DME) providers; ambulance and wheelchair van services providers; prescribed drug providers; and related provisions. See 2020 MA REG TEXT 563284 (NS).

New Jersey
- 2020 NJ S.B. 2436 (NS), amended/substituted August 27, authorizes pharmacists to order and cause to be administered test for coronavirus disease 2019 (COVID-19 or COVID-19 antibodies; requires health benefits and Medicaid coverage for tests.
- 2020 NJ S.B. 2788 (NS), amended/substituted August 25, provides supplemental payments to long-term care facility staff providing direct care services during COVID-19 pandemic.
- 2020 NJ S.B. 2848 (NS), introduced August 25, requires facilities offering COVID-19 tests to provide accurate timeframes for test results; requires DOH to update COVID-19 website with information regarding testing locations that provide COVID-19 test results within 48 hours.
- 2020 NJ A.B. 4479 (NS), amended/substituted August 24, provides supplemental payments to long-term care facility staff providing direct care services during COVID-19 pandemic.
• **2020 NJ A.B. 4481** (NS), amended/substituted August 24, establishes New Jersey Task Force on Long-Term Care Quality and Safety.

• **2020 NJ A.B. 4547** (NS), amended/substituted August 24, authorizes temporary rate adjustment for certain nursing facilities; appropriates $62.3 million.

• **2020 NJ A.B. 4559** (NS), introduced August 24, provides that certain civil immunities granted to for-profit healthcare facilities and healthcare systems during state of emergency and public health emergency would expire August 31, 2020.

**Rhode Island**

• The purpose of this rule is to establish fees for various COVID-19 testing methods provided by the State Health Laboratories. See **2020 RI REG TEXT 563175** (NS).

• The Department of Human Services will waive some requirements for access to benefits for applicants and recipients during COVID-19 crisis and the Declaration of Emergency. See **2020 RI REG TEXT 556357** (NS).

**Texas**

• The Executive Commissioner of the Health and Human Services Commission (HHSC or Commission) adopts on an emergency basis in Title 26, Texas Administrative Code, Chapter 553, Licensing Standards for Assisted Living Facilities, new s.553.2001, concerning an emergency rule in response to COVID-19 and requiring assisted living facility actions to mitigate and contain COVID-19. See **2020 TX REG TEXT 563114** (NS).

• The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 26, Texas Administrative Code, Chapter 553, Licensing Standards for Assisted Living Facilities, new s.553.2003, concerning an emergency rule in response to COVID-19 and permitting limited visitation in assisted living facilities. **2020 TX REG TEXT 563115** (NS).

• The Executive Commissioner of the Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 40, Texas Administrative Code, Chapter 19, Nursing Facility Requirements for Licensure and Medicaid Certification, new s.19.2802, concerning an emergency rule in response to COVID-19 and requiring nursing facility actions to mitigate and contain COVID-19. See **2020 TX REG TEXT 563116** (NS).

• The Executive Commissioner of the Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 40, Texas Administrative Code, Chapter 19, Nursing Facility Requirements for Licensure and Medicaid Certification, new s.19.2803, concerning an emergency rule in response to COVID-19 describing requirements for limited outdoor visitation in a facility during Phase 1. See **2020 TX REG TEXT 563117** (NS).

**Virginia**

• **2020 VA H.B. 5041** (NS), engross August 27, provides for voluntary electronic monitoring of patient's or resident's rooms at nursing homes, certified nursing facilities, and assisted living facilities. The bill requires the Boards of Health and Social Services to adopt regulations governing voluntary electronic monitoring of patient's or resident's rooms and provides that no patient shall be denied admission to or discharged from a nursing home, certified nursing facility, or assisted living facility solely because the patient or resident implements electronic monitoring or refuses to consent to electronic monitoring in any room in which he resides.

• **2020 VA S.B. 5042** (NS), amended/substituted August 27, requires each nursing home, certified nursing facility, and hospice facility to allow each patient to receive visits, either virtually or in person, at least once per week from family or anyone designated by the patient. If such visits are conducted virtually, each such facility shall provide access to equipment and staff support that (i) allows each patient the ability to schedule and
receive no less than one virtual visit per week and (ii) provides both visual and sound technology.

- **2020 VA H.B. 5122 (NS)**, introduced August 24, directs the Department of Health to convene a work group, which may be a work group previously convened for a related purpose, to (i) evaluate the methods by which vaccines and other medications necessary to treat or prevent the spread of COVID-19 are made available to the public, (ii) identify and develop a plan to implement specific actions necessary to ensure such vaccines and other medications are equitably distributed in the Commonwealth.

### FEDERAL ADMINISTRATIVE ACTIONS

**HHS Releases $2.5 billion in Relief, 1.5 million N95 Masks to Nursing Homes**

The U.S. Department of Health and Human Services (HHS) has distributed nearly $2.5 billion of a planned $5 billion to nursing homes to support increased testing, staffing, and personal protective equipment (PPE) needs, the agency announced. The funding allocation was made through the Health Resources and Services Administration (HRSA) as a targeted distribution from the $175 billion Provider Relief program funded through the bipartisan CARES Act and the Paycheck Protection Program and Health Care Enhancement Act.

The distribution of almost $2.5 billion in additional funding to over 15,000 nursing homes nationwide supplements the $4.9 billion that was previously distributed to skilled nursing facilities, the agency said. HHS plans on distributing another $2 billion to nursing homes later this fall based on certain performance indicators (to be provided in the future).

On August 25, 2020, the Department of Health and Human Services (HHS) announced that 1.5 million N95 respirators from the national stockpile would be shipped to nursing homes reporting supply shortages the following Friday. The masks will be given to over 3,300 nursing homes that reported shortages in supplies through the National Healthcare Safety Network. HHS noted the respirators are meant to supplement existing supplies for personal protective equipment, and each facility will receive a seven-day supply meant to support an entire shift before being discarded.

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REGULATORY INTELLIGENCE AND REUTERS NEWS

FDA Authorizes Use of Blood Plasma to Treat Coronavirus
(Reuters) - The U.S. Food & Drug Administration (FDA) on Sunday said it authorized the use of blood plasma from patients who have recovered from COVID-19 as a treatment for the disease, a day after President Donald Trump blamed the agency for impeding the rollout of coronavirus vaccines and therapeutics for political reasons.4

The announcement from the FDA of a so-called “emergency use authorization” also comes on the eve of the Republican National Convention, where Trump will be nominated to lead his party for four more years.

A day before the FDA’s announcement, Trump tagged the agency’s Commissioner Stephen Hahn in a tweet and said, “The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics.” “Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives!”

Trump has announced a news briefing for 5:30 pm ET (2130 GMT) on Sunday. He is likely to make an announcement on this topic.

The FDA, which appeared to rush with an announcement on Sunday, said early evidence suggests blood plasma can decrease mortality and improve the health of patients when administered in the first three days of their hospitalization.

It was not immediately clear what the immediate impact of this decision would be.

“It appeared that the product is safe and we’re comfortable with that and we continue to see no concerning safety signals,” said Peter Marks, director of the Food and Drug Administration’s Center for Biologics Evaluation and Research said on a conference call with reporters.

The agency also said it determined this was a safe approach in an analysis of 20,000 patients who received this treatment. So far, 70,000 patients have been treated using blood plasma, the FDA said.

Patients who benefited the most from this treatment are those under 80 years old and who were not on a respirator, the agency said. Such patients had a 35 percent better survival rate a month after receiving the treatment.

FDA Director Stephen Hahn said Trump had not spoken to him or the agency and did not play a role in its decision to make the announcement on Sunday.

CMS Announces New COVID-19 Testing and Reporting Requirements
(Regulatory Intelligence) - The U.S. Centers for Medicare & Medicaid Services (CMS) announced new requirements for nursing homes to test staff for COVID-19 and offer testing to residents. Laboratories and nursing homes conducting their own tests will be required to report results under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).5


5 Melissa D. Berry, U.S. Medicare agency announces new COVID-19 testing and reporting requirements, Thomson Reuters Regulatory Intelligence (August 26, 2020) at: http://go-ri.tr.com/KSMpDV.
The new rules also require hospitals to report COVID-19 cases and related data to the U.S. Department of Health and Human Services (HHS).

The requirements are intended to improve surveillance of the coronavirus and keep nursing home residents safe. The reporting requirements will also help federal and state efforts to identify the spread of the virus and appropriately allocate resources in response.

“These new rules represent a dramatic acceleration of our efforts to track and control the spread of COVID-19,” said CMS Administrator Seema Verma in a news release. “Reporting of test results and other data are vitally important tools for controlling the spread of the virus and give providers on the front lines what they need to fight it.”

NURSING HOME TESTING
The new rule on home staff testing makes mandatory for any provider participant in the Medicare and Medicaid programs what had previously been a recommendation. CMS will make recommendations for the frequency of staff testing based on the rate of community spread. CMS will announce the frequency of testing through separate guidance.

Nursing homes are now required to offer COVID-19 testing to residents when there is an outbreak or when residents show symptoms.

CMS is directing nursing home surveyors to inspect nursing homes for compliance with the new testing requirements. Failure to comply could result in civil money penalties in excess of $400 per day.

CMS recently said it had imposed more than $15 million in civil money penalties to more than 3,400 nursing homes for noncompliance with infection control requirements and failure to report COVID-19 data.

HOSPITAL REPORTING REQUIREMENTS
The emergency regulations also require hospitals including rural "critical-access" hospitals to report key COVID-19 data every day. The reporting includes the number of confirmed or suspected COVID-19 patients, ICU beds occupied and the availability of essential supplies and equipment.

Although hospitals are voluntarily reporting the information now, the new rules make the reporting a requirement of participation in the Medicare and Medicaid programs.

LABORATORY REPORTING REQUIREMENTS
The new rule also implements a CARES Act requirement that laboratories report COVID-19 tests daily to the HHS Secretary. The requirement applies to all laboratories conducting COVID-19 testing, including hospital labs, nursing home and other facilities conducting testing.

Additionally, CMS now will impose a fine of $1,000 for the first day and $500 for each subsequent day a lab fails to report data. Labs will have a one-time, three-week grace period to being reporting required test data.

PHYSICIAN AND PHARMACIST ORDERS FOR TESTS
Under its previous policy, CMS covered repeated COVID-19 testing for Medicare beneficiaries without a physician or other practitioner order during the public health
emergency. Under the new policy, a Medicare beneficiary may receive one COVID-19 test without an order but will require an order for any subsequent tests.

This rule change will help ensure beneficiaries receive medical attention, if they need multiple tests, and also prevent fraudulent billing for unnecessary tests.

**Abbott Wins U.S. Authorization for $5 Rapid COVID-19 Antigen Test**

(Reuters) - Abbott Laboratories said on Wednesday it won U.S. marketing authorization for a COVID-19 portable antigen test that can deliver results within 15 minutes and will sell for $5.6

The portable test is about the size of a credit card, requires no additional equipment to operate, and can be conducted using a less invasive nasal swab than traditional lab tests, Abbott executives said on a call with reporters.

Abbott expects to ship tens of millions of tests in September, ramping to 50 million tests a month from the beginning of October.

The test, BinaxNOW COVID-19 Ag Card, could be used to check that people participating in larger gatherings, such as those returning to schools or workplaces, do not have COVID-19 and could help aid the reopening of the U.S., the executives said.

Abbott created a downloadable app that people who have taken the test could present before entering venues to show that they are COVID-19 free, they said.

Antigen tests are cheaper and faster than molecular diagnostic tests but somewhat more likely to fail to identify positive cases of the virus than lab-based diagnostic tests.

The U.S. Food and Drug Administration granted the approval under its emergency use authorization program. Becton Dickinson and Co. and Quidel Corp. already market antigen tests.

The United States now has more cases of the coronavirus than any other country at more than 5 million, and hospitals and labs have struggled to meet the demand to test thousands of people.

Since March, the company has got U.S. authorizations for five other coronavirus tests, including one called the ID Now that can deliver results within minutes and is used at the White House.

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