Thomson Reuters Regulatory Intelligence

Health Policy Tracking Service

COVID-19 COVERAGE

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The COVID-19 pandemic has created unprecedented challenges for healthcare providers and health insurers. The following is a selection of federal and state actions as well as news and analysis articles from the Health Policy Tracking Service as published in its bi-weekly Snapshots. The selection includes Regulatory Intelligence and Reuters news coverage. More COVID-19 news and information can be found via the TRRI platform's search facility.

Additional COVID-19 resources are also available on the Thomson Reuters COVID-19 Resource Center. For a regularly updated list of U.S. state updates on insurance-sector regulatory changes related to the COVID-19 epidemic, please click on this link: http://go-ri.tr.com/fuaD4N.

IN THIS OVERVIEW

COVID-19 COVERAGE

COVID-19 LEGISLATIVE AND REGULATORY ACTIONS

STATE ACTIONS

Colorado

- On March 18, 2020 the Families First Coronavirus Response Act became law (FFCRA) (H.R. 6201). This bill increased the Federal Medical Assistance Percentage (FMAP) by 6.2%. The FMAP determines the percentage of funds that CDHS is required to pay to the federal government and that CDHS is able to pay to the counties in Colorado. Typically, counties are paid approximately 50% of the retained child support dollars they collect from parents with child support obligations. See 2020 CO REG TEXT 559974 (NS).
- The purpose of this emergency regulation is to require carriers offering health benefit plans to reimburse providers for provision of telehealth services using non-public facing audio or video communication products during the COVID-19 nationwide public health emergency. See 2020 CO REG TEXT 564785 (NS).
- The rule change will amend 10 CCR 2505-3 sections 110, 140, 310 and 320 based on the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the Families First

[1] This COVID-19 Coverage Snapshot was compiled by members of the publisher's staff.

Coronavirus Response Act (FFCRA) and the Affordable Care Act (ACA), which includes the Maintenance of Effort (MOE) provision. All policy revisions will align with federal regulations for the state to be in compliance during this Coronavirus (COVID-19) Public Health Emergency. See 2020 CO REG TEXT 564788 (NS).

Illinois
This Part is intended to help protect insured individuals' access during an epidemic or public health emergency to timely, affordable health care services by requiring temporary accommodations or exceptions to the terms of the health benefits arrangement that insures them or their employers. The COVID-19 epidemic is causing significant economic impact, including loss of income, wages, and working hours, for Illinois residents and employers. See 2020 IL REG TEXT 553557 (NS).

Michigan
- 2019 MI S.B. 1113 (NS), introduced September 15, to require long-term care facilities to follow certain testing and procedural requirements in response to COVID-19; to require the reporting of certain data; to prescribe civil sanctions; to provide for the powers and duties of certain state officers and entities; to require the promulgation of rules; and to repeal acts and parts of acts.
- 2019 MI H.B. 6234 (NS), introduced September 16, to provide for Medicaid expansion during health emergencies.

Minnesota
- 2019 MN S.F. 6 (NS), introduced September 11, distance learning broadband access grant program creation; telemedicine equipment grant program establishment and appropriation.
- 2019 MN H.F. 12 (NS), introduced September 11, COVID-19; distance learning equipment funding program established, telemedicine equipment grant program established, reports required, and money appropriated.
- 2019 MN S.F. 14 (NS), introduced September 11, long-term care facilities infectious disease control, consumer protections, rights enforcement, retaliation private cause of action, termination prohibition, and clients transfer provisions modifications; long-term care COVID-19 task force; appropriation.
- 2019 MN H.F. 18 (NS), introduced September 11, COVID-19; electronic monitoring requirements modified, long-term care setting infection control requirements modified, hospice and assisted living bill of rights modified, assisted living service termination during peacetime emergency prohibited, SARS-CoV-2 infection control plant in long-term care setting establishment required, Long-Term Care COVID-19 Task Force established, and money appropriated.

New Jersey
- 2020 NJ S.B. 2884 (NS), introduced September 14, requires availability of certain laboratory testing for coronavirus disease 2019.
- 2020 NJ S.B. 2890 (NS), introduced September 14, allows establishments offering services or treatments by licensees of New Jersey Board of Dentistry to charge patients additional fee to cover cost of certain personal protective equipment during coronavirus 2019 pandemic.
- 2020 NJ S.B. 2897 (NS), introduced September 14, "Sally's Law"; establishes testing and visitation requirements and employment restrictions for long-term care facilities in response to outbreaks of infectious disease.
- 2020 NJ A.B. 4476 (NS), adopted September 16, establishes certain requirements concerning State's preparedness and response to infectious disease outbreaks, including coronavirus disease 2019 (COVID-19) pandemic.

- 2020 NJ A.B. 4547 (NS), adopted September 16, authorizes temporary rate adjustment for certain nursing facilities; appropriates $62.3 million.
- 2020 NJ A.B. 4657 (NS), introduced September 17, "Sally's Law"; establishes testing and visitation requirements and employment restrictions for long-term care facilities in response to outbreaks of infectious disease.

New York

To require confirmatory COVID-19 and influenza testing in several settings to improve case statistics and contact tracing. See 2020 NY REG TEXT 564988 (NS).

Ohio

2020 OH H.B. 606 (NS), approved September 14, to make temporary changes related to qualified civil immunity for health care and emergency services provided during a government-declared disaster or emergency and for exposure to or transmission or contraction of certain coronaviruses.

Oregon

- Due to the Coronavirus (COVID-19) state of emergency, the Oregon Department of Human Services, Office of Developmental Disabilities Services (ODDS) needs to immediately amend OAR 411-375-0070 to allow ODDS to immediately inactivate or terminate the provider number for an independent provider who knowingly engages in activities that may result in exposure of an individual to COVID-19. ODDS needs to proceed by filing a temporary rule change to provide immediate protection to individuals receiving services during the COVID-19 state of emergency. See 2020 OR REG TEXT 558864 (NS).
- Due to the COVID-19 state of emergency, the Department was asked by the COVID-19 Hospital Task Force to develop a plan to increase access to ventilator assisted services in nursing facilities. The Department is amending OAR chapter 411, division 70 to attempt to increase access to ventilator services, within the state, by working with nursing facilities on a rate that would be sustainable. Effective July 1, 2020, the nursing facility rate increased due to the legislatively approved budget. See 2020 OR REG TEXT 559468 (NS).
- Due to the Coronavirus (COVID-19) state of emergency, the Oregon Department of Human Services, Office of Developmental Disabilities Services (ODDS) has been granted temporary permission from the Centers for Medicare and Medicaid Services to allow developmental disabilities service providers to deliver attendant care while an individual is hospitalized under certain circumstances. See 2020 OR REG TEXT 564842 (NS).
- Explicitly making reportable all human cases of COVID-19, including hospitalization of any individual with COVID-19, whether or not the case was previously reported, deaths of any individual due to COVID-19, whether or not the case was previously reported, and all human cases of MIS-C will allow the Oregon Health Authority to track future cases and assess risk factors. Furthermore, licensed laboratories shall report all test results indicative of and specific for COVID-19 within 24 hours (including weekends and holidays) and all negative test results for COVID-19 within one local public health district. See 2020 OR REG TEXT 560738 (NS).

Pennsylvania

- 2019 PA H.B. 2779 (NS), amended/substituted September 16, providing for retaining health care innovations during the COVID-19 pandemic and imposing duties on the Joint State Government Commission.
- 2019 PA H.B. 2867 (NS), introduced September 15, providing for long-term infectious disease control.

Washington

- The department is extending the amendment of the rules listed below to ensure assisted living facilities are not significantly impeded during the hiring process due to an administrator's inability to obtain a certificate of completion of a recognized administrator training as referenced in WAC 388-78A-2521. This will help to increase the number of long-term care administrators necessary to provide essential services to some of Washington's most vulnerable adults during the outbreak of COVID-19. See 2020 WA REG TEXT 554942 (NS).
- The department is extending the amendment of the rules listed below to ensure nursing homes are not significantly impeded from admitting and caring for residents during the COVID-19 outbreak. These amendments will continue to align state nursing home rules with federal rules that were suspended or amended to help facilitate care during the COVID-19 pandemic. See 2020 WA REG TEXT 554950 (NS).

REGULATORY INTELLIGENCE AND REUTERS NEWS

Pressure Mounts on Trump Administration to Hike Aid to State Medicaid Programs
(Regulatory Intelligence) - Pressure is building on the federal government to increase its monetary assistance to state Medicaid programs after the COVID-19 pandemic has led to a large spike in Medicaid enrollment with more people signing up for health coverage and states suspending annual eligibility checks during the public health emergency.[2]

Over half of the 38 states reporting monthly enrollment having grown by more than 7 percent from February to May, according to a study from Families USA. Eight states reporting August enrollment clocked an 11 percent growth in average enrollment since February, the healthcare-focused consumer advocacy organization said.

"Based on these trends and the continued loss of job-based coverage reflected in weekly new unemployment claims, it is clear that many states are likely to see even more growth in Medicaid enrollment in the coming months, putting significant financial pressure on state Medicaid programs," the nonpartisan organization said.

In addition, some states like Missouri, Oklahoma and Utah recently voted to allow Medicaid expansion in the coming year and are likely to face fiscal strain from the added coverage as well.

In comparison, last year, Medicaid enrollment averaged a decrease of 0.69 percent among all states between February and August. No state had clocked an increase higher than 2.1 percent during the period, excluding Virginia and Utah, which implemented Medicaid expansion programs.

Healthcare experts and consumer advocates have urged the administration of President Donald Trump to increase the percentage of its monetary assistance to state Medicaid programs in order to allow them to expand coverage to as many people as possible during the pandemic.

Congress authorized a temporary increase in the Federal Medical Assistance Percentage -- the rate used for calculating the federal government's share of state Medicaid spending, by 6.2 percent as part of the Families First Coronavirus Response Act in March. But this

[2] Antonita Madonna, Pressure mounts on Trump administration to hike aid to state Medicaid programs, Thomson Reuters Regulatory Intelligence (September 14, 2020) at: http://go-ri.tr.com/HsFxbj.

increase has been decried as inadequate. The FMAP figure is currently set at a minimum of 50 percent but its actual contribution varies from state to state with some states receiving more than others.

Without increased federal aid, states will have to absorb the additional costs of the Medicaid enrollment growth. The financial pressure comes at a time when state revenues have been hurt by widespread business closures and reduced economic activity as a result of the COVID-19 outbreak.

The state of New York, for instance, was facing a $6.1 billion state budget deficit prior to the pandemic largely as a result of its Medicaid program. and Governor Andrew Cuomo had been making plans to cut costs by imposing restrictions on benefits and funding cuts to healthcare providers. The state is now staring at a projected $14 billion shortfall in 2021. The Trump administration has not yet made public any plans to increase federal assistance to state Medicaid programs.

U.S. Plans to Distribute COVID-19 Vaccine Immediately After Regulators Authorize It

(Reuters) - The U.S. government on Wednesday said it will start distributing a COVID-19 vaccine within one day of regulatory authorization as it plans for the possibility that a limited number of vaccine doses may be available at the end of the year.[3]

Officials from the Department of Health and Human Services and the Department of Defense on Wednesday held a call with reporters and then released documents on the distribution plans that it is sending to the states and local public health officials.

"Our goal at Operation Warp Speed, is that 24 hours after (regulatory authorization) is issued, we have vaccine moving to administration sites," one of the officials said.

The federal government will allocate vaccines for each state based on the critical populations recommended first for vaccination by the U.S. Centers for Disease Control and Prevention.

The guidelines suggest that the government is likely to broadly follow guidelines generated by an independent expert panel tapped by U.S. health officials to lay out which Americans to prioritize while vaccine supplies are limited.

The document, called the COVID-19 Vaccination Program Interim Playbook, said limited COVID-19 vaccine doses may be available by early November 2020 if one is authorized by then, but that supply may increase substantially in 2021.

Officials also said they were working to make sure there was no cost to patients for the vaccine.

ON-SITE VACCINATIONS

Pharmacies and hospitals are the primary vaccination points, and the CDC document said the agency is working directly with pharmacies to develop on-site vaccination in long-term care facilities.

[3] Michael Erman, Caroline Humer and Mrinalika Roy, U.S. plans to distribute COVID-19 vaccine immediately after regulators authorize it, Reuters (September 16, 2020) at: https://www.reuters.com/article/us-health-coronavirus-usa-vaccine/u-s-plans-to-distribute-covid-19-vaccine-immediately-after-regulators-authorize-it-idUSKBN2672CU.

During a press call, officials said they were also looking to reach other groups of people in close contact, such as those that work in meatpacking plants or are in homeless shelters.

Officials said they were working with states on how to track vaccination through state immunization databases and pharmacy records.

U.S. Plans for Hundreds of Millions of Cheap, Fast COVID-19 Tests

(Reuters) - U.S. manufacturers are sharply increasing production of cheap, fast - but less accurate - COVID-19 tests, aiming for 100 million per month by year end that will enable schools and workplaces to significantly expand testing.[4]

Manufacturing and government sources tell Reuters that more than half a dozen so-called antigen tests will likely be authorized by the end of October. U.S. regulators in recent months have authorized antigen tests from Abbott Laboratories, Becton Dickinson & Co, Quidel Corp and LumiraDX.

When planned production of the newly authorized tests are combined with previously approved diagnostics, overall monthly U.S. testing capacity will exceed 200 million per month by year end, these sources said.

Makers of the four recently-approved antigen tests have the capacity to make around 40 million per month, but expect to more than double that by year end, according to a Reuters analysis that includes proprietary figures shared by companies.

Unlike the $100 and up molecular diagnostics currently dominating U.S. testing that must be sent to a lab and often take several days for results, antigen tests can cost as little as $5. They can be performed anywhere and produce results in minutes.

That opens the possibility of regular screening at schools and businesses of even asymptomatic people, an important tool for containing future outbreaks, experts said.

"If we could get testing to a scale where everyone you want to test can be tested quickly and cheaply with a quick turnaround time (for results), then you could screen people" before they spread the virus, said Dwayne Breining, director of labs at Northwell Health, New York state's largest hospital system.

Lab-based molecular tests are too hard to make and deploy at that level, he said.

Antigen tests detect certain proteins that are part of the virus from samples taken via nasal or throat swabs, similar to rapid tests for strep throat in a doctor's office.

RELIABILITY CONCERNS

A lack of testing capacity and little federal coordination early in the pandemic hampered efforts to control spread of the virus that has infected more than 6 million people in the United States.

Still, regulators and health experts are concerned about antigen test reliability. They typically detect the virus around 80% to 90% of the time, below the more than 95% rate of

[4] Carl O'Donnell, U.S. plans for hundreds of millions of cheap, fast COVID-19 tests, Reuters (September 17, 2020) at: https://www.reuters.com/article/us-health-coronavirus-usa-testing/u-s-plans-for-hundreds-of-millions-of-cheap-fast-covid-19-tests-idUSKBN2681ME.

lab-based tests. False negative results raise the likelihood that sick people could unwittingly spread COVID-19.

There is also not enough data to be certain the new tests can detect the virus when infected people are in the early, pre-symptomatic stage, potentially limiting their usefulness.

The U.S. conducted around 25 million tests in August, including lab and antigen tests, according to data from the University of Oxford. Antigen test makers and their suppliers are gearing up for a huge boost.

Tony Lemmo, chief executive of BioDot Inc, which makes dispensers of chemicals used in the tests, says he has recently received orders that would translate into some 500 million tests in the coming months.

The United States could have capacity to conduct 3 million coronavirus tests per day this month, about half of them antigen tests. That could climb to as high as 135 million monthly tests in October, a top health official told a U.S. congressional panel on Wednesday.

European diagnostics companies Roche Holding AG and Quiagen NV have said they will apply for U.S. authorization for their antigen tests.

The National Institutes of Health is working with companies on new tests that will likely add as many as another 30 million tests per month to overall capacity this year, a U.S. official told Reuters. The agency has also provided grants to help testmakers boost manufacturing capacity, including $71 million to Quidel in July.

The U.S. official, who was not authorized to speak publicly, told Reuters that getting to 100 million tests a month by year end could potentially slip by a couple of months because of production challenges.

To ramp up, companies need to hire enough skilled workers and source the paper used in the tests, called nitrocellulose, the official said.

"There's just so much required to go from zero to millions of tests," said Quidel CEO Douglas Bryant, whose company is working with large U.S. universities on daily testing of student athletes.

College football teams in the Big Ten conference will use antigen testing after announcing on Wednesday they would go ahead with games beginning next month.

Nursing homes are using Becton Dickinson's antigen tests to screen residents and staff through a government program.

Even if testmakers succeed in scaling production, capacity will remain tight for some time, as schools, employers and others clamor for tests, executives and officials said.

Quidel has prioritized customer requests for its tests, Bryant said, with healthcare facilities and schools near the top, and industries like tourism further back in line.