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.

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**COVID-19 COVERAGE**

**COVID-19 LEGISLATIVE AND REGULATORY ACTIONS**

**FEDERAL ACTIONS**

**Moratorium on Medicare Sequestration Cuts Extended Until End of Year**
On April 14, President Biden signed legislation extending the moratorium on Medicare sequestration, after the U.S. House of Representatives passed the Medicare Sequester Relief Act, which extended mandated 2% Medicare cuts to healthcare providers until the end of 2021. The Partnership for Home Healthcare said the extension will give providers additional breathing room as they continue to battle fallout from the COVID-19 pandemic and adapt to the new Patient Driven Grouping Model (PDGM) payment system.

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1 This COVID-19 Coverage Snapshot was compiled by members of the publisher’s staff.
“While the COVID-19 crisis has underscored the value of care delivery in the home, providers continue to struggle with the impacts of the 4.3% PDGM payment cut that took effect in 2020 and again in 2021,” Joanne Cunningham, executive director of the Partnership, said. “The sequestration moratorium provided by Congress has been incredibly valuable to the home health sector due to the challenges of providing care during the (public health emergency), coupled with the PDGM payment cuts this year and last. The continued relief will help stabilize the delivery of home care to Medicare’s most vulnerable seniors.”

In March of 2020, Congress temporarily halted the 2% Medicare cuts until the end of last year as part of the Coronavirus Aid Relief and Economic Security (CARES) Act. It extended them again until March 31. A few days before the cuts were to take effect again, the Senate voted overwhelmingly to extend them further.

Sequestration was part of the Budget Control Act of 2011. The cut is imposed on the 80% allowed charge that healthcare providers received directly from Medicare.²

**Biden Jobs Plan Includes $400 Billion for HCBS**

The second installment of the Biden administration’s $2.3 trillion recovery plan, called the American Jobs Plan, contains $400 billion to revamp and reinvest in Medicaid home- and community-based services over the next 8 years.³

Biden’s strategy is to provide more solutions to help the overburdened healthcare systems serve the country’s aging and other special needs populations through increased funding. Across 41 states, nearly 820,000 people are currently on HCBS waiting lists with an average wait of 39 months. Expanding access will also help alleviate the 53 million family members providing care to vulnerable seniors and people with disabilities.

Aside from more funding, the plan aims to bolster the “care infrastructure” (i.e. low-wage workers providing care, who are often women, immigrants and people of color). Increasing pay and benefits for workers seeks to help recruit more caregivers as demand for HCBS increases.

Thus far, the plan lacks specific provisions in the bill, which, as a whole, will likely face a lengthy political battle due its hefty price tag. However, the plan has been met with industry praise, including the American Association of Family Physicians, the National Association for Home Care & Hospice and others, which could aid in the plan’s passage.

**STATE ACTIONS**

**Arkansas**

- **2021 AR S.B. 332** (NS), engrossed April 19, to establish the Public Health Readiness Act; to improve the ability of medical facilities to respond in a pandemic; to require manufacturers of electronic equipment used by medical facilities to make available documents, parts and service tools; to require disclosure of information in certain

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circumstances that is otherwise prohibited to be disclosed; to provide for civil action by
certain persons and for other purposes.

- **2021 AR S.B. 603** (NS), adopted April 19, to clarify the law concerning a healthcare
insurer's contracting with a temporary hospital facility and to regulate healthcare
contracts to require good-faith cooperation.

**Colorado**

- **2021 CO S.B. 214** (NS), engrossed April 19, concerning state payments to licensed hospice
facilities for residential care provided to certain persons enrolled in the Medical Assistance
program, and, in connection therewith, making an appropriations.

**Connecticut**

- **2021 CT H.B. 6636** (NS), amended/substituted April 19, to expand access to care under the
Medicaid program by using enhanced federal matching funds provided to states during the
COVID-19 pandemic to increase Medicaid provider rates.

**New Jersey**

- **2020 NJ S.B. 3625** (NS), introduced April 19, authorizes certain forms of testing for

**New York**

- To waive cost-sharing for in-network telehealth services. See [2021 NY REG TEXT 581809](#)
(NS).
- To waive cost-sharing for in-network visits and laboratory tests necessary to diagnose
the novel coronavirus (COVID-19). See [2021 NY REG TEXT 581810](#) (NS).
- To require immediate coverage, without cost-sharing, for COVID-19 immunizations and
the administration thereof. See [2021 NY REG TEXT 581811](#) (NS).

**Washington**

- **2021 WA H.B. 1127** (NS), enrolled April 21, relating to protecting the privacy and security of
COVID-19 health data collected by entities other than public health agencies, health care
providers, and health care facilities; amending RCW 42.56.360; adding a new chapter to
Title 70 RCW; providing an expiration date; and declaring an emergency.

**FEDERAL ADMINISTRATIVE ACTIONS**

**FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19
Vaccine Use Following Thorough Safety Review**

Following a thorough safety review, including two meetings of the CDC’s Advisory
Committee on Immunization Practices, the U.S. Food and Drug Administration and the U.S.
Centers for Disease Control and Prevention have determined that the recommended pause
regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should
be lifted and use of the vaccine should resume, the agencies [announced](#) on April 23.

The pause was recommended after reports of six cases of a rare and severe type of blood
clot in individuals following administration of the Janssen COVID-19 Vaccine. During the
pause, medical and scientific teams at the FDA and CDC examined available data to assess
the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in
the brain), and other sites in the body (including but not limited to the large blood vessels
of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood
platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers
and clinicians to ensure they were made aware of the potential for these adverse events and
could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

The two agencies have determined the following:
- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine’s known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.

Health care providers administering the vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

CDC’s independent Advisory Committee on Immunization Practices met today to discuss the latest data on TTS, hearing from the vaccine manufacturer Janssen and the COVID-19 Vaccine Safety Technical (VaST) Subgroup, as well as a risk benefit analysis. ACIP is committed to be vigilant and responsive to additional information that could impact the risk benefit analysis of any of these vaccines. Vaccine safety monitoring will continue and any new information about TTS will be brought to ACIP as needed.

“Safety is our top priority. This pause was an example of our extensive safety monitoring working as they were designed to work—identifying even these small number of cases. We’ve lifted the pause based on the FDA and CDC’s review of all available data and in consultation with medical experts and based on recommendations from the CDC’s Advisory Committee on Immunization Practices. We have concluded that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks in individuals 18 years of age and older. We are confident that this vaccine continues to meet our standards for safety, effectiveness and quality. We recommend people with questions about which vaccine is right for them have those discussions with their health care provider,” said Janet Woodcock, M.D., Acting FDA Commissioner.

“Above all else, health and safety are at the forefront of our decisions,” said CDC Director Dr. Rochelle P. Walensky. “Our vaccine safety systems are working. We identified exceptionally rare events – out of millions of doses of the Janssen COVID-19 administered – and we paused to examine them more carefully. As we always do, we will continue to watch all signals closely as more Americans are vaccinated. I continue to be encouraged by the growing body of real-world evidence that the authorized COVID-19 vaccines are safe and effective, and they protect people from disease, hospitalization, and death. I urge anyone with questions about the COVID-19 vaccines to speak with their healthcare provider or local public health department.”
REGULATORY INTELLIGENCE AND REUTERS NEWS

**J&J COVID-19 Vaccine Manufacturing Halted at U.S. Plant that had Contamination Issue**

(Reuters) - Production of Johnson & Johnson's COVID-19 vaccine at a U.S. manufacturing plant was halted by the U.S. Food and Drug Administration while the agency investigates an error that led to millions of doses being ruined last month.4

Emergent BioSolutions Inc, the company that owns and runs the Baltimore plant that had been making the J&J vaccine, said in a regulatory filing that the FDA requested a pause on April 16 in production of new drug substance for the shot pending completion of the inspection.

Johnson & Johnson said it would work with Emergent and the FDA to address any findings at the end of the inspection.

J&J was put in charge of manufacturing at the plant in early April by the U.S. government after it disclosed the error in which ingredients from AstraZeneca's shot also being produced at the plant at that time contaminated a batch of the J&J vaccine.

The request to pause manufacturing is the latest setback to J&J's vaccine, which has been paused for use by U.S. regulators as they review reports of rare but serious brain blood clots in people who took the one-dose shot.

The Baltimore plant had been seeking authorization from the FDA for the J&J vaccine when the error occurred. J&J has authorization to make doses in the Netherlands and finish them in the U.S. plant of Catalent Inc.

"At this time, it is premature to speculate on any potential impact this could have on the timing of our vaccine deliveries," J&J said. The company has previously said it would deliver 100 million doses of its vaccine to the United States during the first half of 2021 and has so far delivered about 18 million.

J&J said in a statement it was focused on securing emergency use authorization for the Emergent plant.

Emergent said on Monday in a regulatory filing that the FDA started its review on April 12. The company said it would quarantine existing material manufactured at the Baltimore facility until the review is complete.

"We acknowledge that there are improvements we must make to meet the high standards we have set for ourselves and to restore confidence in our quality systems and manufacturing processes," Emergent said in an emailed statement.

In March, J&J said it had found a problem with a batch of the drug substance for its COVID-19 vaccine being produced by Emergent.

J&J did not say how many vaccine doses the spoiled batch would have produced, but the New York Times, without citing a source, reported that about 15 million doses were ruined.

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U.S. Administers 225.6 million Doses of COVID-19 Vaccines - CDC
(Reuters) - The United States had administered 225,640,460 doses of COVID-19 vaccines in the country as of Saturday morning and distributed 290,685,655 doses, the U.S. Centers for Disease Control and Prevention said.\(^5\)

That is an increase from the 222,322,230 vaccine doses the CDC said had been administered by April 23 out of 286,095,185 doses delivered.

The agency said 138,644,724 people had received at least one dose while 93,078,040 people had been fully vaccinated as of Saturday.

The CDC tally includes two-dose vaccines from Moderna and Pfizer/BioNTech, and Johnson & Johnson's one-shot vaccine as of 6 a.m. ET Saturday.

The United States can immediately resume use of Johnson & Johnson's COVID-19 vaccine, top health regulators said on Friday, ending a 10-day pause to investigate its link to extremely rare but potentially deadly blood clots.

A total of 7,789,075 vaccine doses have been administered in long-term care facilities, the agency said.

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