



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



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Editor's note

This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.



Special Supplement: COVID-19 News and American Rescue Plan Act Healthcare Provisions

In light of the daily volume of COVID-19 activity and news, we are continuing to provide [a supplement](#) to summarize COVID-19 news for the week (attached).

In addition, we are sharing our [summary of healthcare provisions in the American Rescue Plan Act](#), signed into law by President Biden last week.



Healthcare regulatory news

HHS [delayed](#) the drug rebate rule until 2023; [delayed](#) the Medicare Coverage of Innovative Technology rule until May 15; [delayed an insulin/epinephrine](#) discount rule until July 20; [delayed](#) a rule requiring regulation reviews every 10 years until 2022; and [plans to withdraw](#) a vaccine injury compensation rule... CMS withdrew Part D Payment Modernization Model [protected classes and downside risk](#) changes.

Increased ACA subsidies authorized by the *American Rescue Plan Act* [will be available](#) April 1... Biden Administration is considering [extending the ACA special enrollment period](#) past May.

HHS revoked [Arkansas](#) and [New Hampshire](#) Medicaid work requirements.

FDA [launched a dashboard](#) for [viewing adverse events](#) associated with vaccines/therapeutics authorized for emergency use, including for COVID-19.



Healthcare law and policy news

The Senate [confirmed Xavier Becerra \(50-49\)](#) as HHS Secretary.

MedPAC [recommended](#) Congress increase 2022 Medicare [acute-care and long-term care hospital reimbursement by 2%](#) and extend pandemic-related telehealth waivers for up to two years to [assess impacts](#).

The House voted to extend [the moratorium on Medicare sequestration](#) by nine months... Senate HELP Committee announced [a March 23 hearing on drug pricing](#).

Trinity Health [purchased a majority stake in Premier Health](#)... Doctor on Demand and Grand Rounds [will merge](#)... Humana is [consolidating its health services business](#) under CenterWell... Amazon will [offer its telehealth program](#) to other companies this summer... AHA urged the Justice Department to [investigate UnitedHealth Group's proposed acquisition](#) of Change Healthcare.

FTC will [more closely scrutinize](#) pharmaceutical mergers... Roche Holdings [will acquire GenMark Diagnostics](#) (\$1.8B)... Abbvie may [sell its \\$5B women's drugs portfolio](#) gained through its Allergan acquisition... Gilead and Merck will [collaborate on an experimental combination HIV treatment](#).

District courts [granted a preliminary injunction](#) halting [implementation](#) of the 340B dispute resolution rule and [dismissed claims](#) alleging [insulin price gouging](#) by Eli Lilly, Novo Nordisk, and Sanofi... The Sackler Family [agreed to pay \\$4.28B to settle](#) opioid-related lawsuits.

Private equity deal [volume increased 21% in 2020](#)... RAND [researchers found](#) that metropolitan areas [averaged 50 telemedicine visits/10,000](#)

[individuals](#) over the past year, compared to 31 visits/10,000 individuals in rural areas... 65 of the 100 largest hospitals [are noncompliant](#) with price transparency requirements... A study contends that [14% of ACA insurers inflate claims to avoid](#) paying MLR rebates.



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Center Insight Brief

Center for Healthcare Regulatory Insight



March 12, 2021

American Rescue Plan Act of 2021: Healthcare Related Provisions

The American Rescue Plan Act of 2021 (“Rescue Act”), a \$1.9 trillion COVID-19 relief package, was signed into law by President Joe Biden on March 11th. The Rescue Act is the second largest economic rescue package in US history, behind only the \$2.2 trillion CARES (Coronavirus Aid, Relief, and Economic Security) Act passed in March 2020 at the beginning of the pandemic. The Rescue Act extends unemployment assistance, directs stimulus payments to eligible Americans, expands the child tax credit, and provides funding to support states and local governments and schools in their response to the pandemic.

Notably for the healthcare industry, the Rescue Act represents the biggest healthcare coverage expansion since the Affordable Care Act, enlarging employment-based, individual and small group, and Medicaid coverage. The Rescue Act also provides funding for testing and contact tracing, research and development of vaccines and therapeutics, the public health workforce, and mental and behavioral health services; ensures coverage of COVID-19 vaccines and treatments in Medicaid and CHIP; and eliminates the cap on Medicaid drug rebates. This issue brief summarizes major healthcare provisions in the Rescue Act, provides a section-by-section summary of all healthcare-related policy changes, and summarizes key non-healthcare provisions.



Key Healthcare Provisions

Coverage Expansion

- **COBRA Subsidies** Allows workers who are eligible for COBRA due to involuntary termination or reduction in hours to receive coverage under their employment-based health plan with a premium reduction of 100 percent, extending through September 30, 2021. (Sec. 9501)
- **Expanding Premium Assistance for Consumers**
 - Modifies affordability percentages used for 2021 and 2022 ACA premium tax credits by reducing the percentage of income an individual must contribute to premiums from 9.8 to 8.5 percent. (Sec. 9661)
 - Expands the availability of ACA premium tax credits for 2021 and 2022 to individuals whose income is above 400 percent of the federal poverty line (FPL). (Sec. 9661)
 - For tax year 2020, modifies the repayment obligations for taxpayers receiving excess premium tax credits so such payments are not subject to recapture. (Sec. 9662)
 - For individuals receiving unemployment compensation, provides advanced premium tax credits for 2021 as if the taxpayer’s income was no higher than 133 percent of FPL. (Sec. 9663)
- **Temporary Increase in FMAP For States that Choose to Expand Medicaid:** Provides an incentive for states to expand Medicaid by temporarily increasing the state’s base (non-expansion) FMAP by five percentage points for two years for states that newly expand Medicaid; expansion population remains at 90 percent FMAP. (Sec. 9814)
- **Coverage Under Medicaid For Pregnant and Postpartum Women:** Allows states, for five years, to extend Medicaid eligibility to women for 12 months postpartum. (Sec. 9812)

COVID-19 Funding

- **Funding for COVID–19 Vaccine Activities at CDC:** Provides \$7.5 billion in funding for the Centers for Disease Control and Prevention (CDC) to prepare, promote, administer, monitor, and track the coronavirus disease of 2019 (COVID-19) vaccines. (Sec. 2301)
- **Funding for Supply Chain for COVID–19 Vaccines, Therapeutics, and Medical Supplies:** Allocates \$5.2 billion to Health and Human Services (HHS) to support advanced research, development, manufacturing, production and purchase of vaccines, therapeutics, and ancillary medical products utilized for treatment and prevention of COVID-19, and any viral variant of SARS-CoV-2. (Sec. 2303)
- **Funding for COVID–19 Testing, Contact Tracing, and Mitigation Activities:** Provides \$46 billion to HHS to detect, diagnose, trace, and monitor COVID-19 infections, and for other activities necessary to mitigate the spread of COVID-19. (Sec. 2401)
- **Funding for Public Health Workforce:** Provides \$7.6 billion to HHS for establishing, expanding, and sustaining a public health workforce, and for State, local, and territorial health departments. (Sec. 2501)
- **Funding for Community Health Centers and Community Care:** Invests \$7.6 billion in Community Health Centers (CHCs), including at least \$20 million for Native Hawaiian Health Centers. (Sec. 2601)
- **COVID-19 Emergency Medical Supplies Enhancements:** Provides \$10 billion to support enhanced use of the Defense Production Act to the purchase, production, or distribution of medical supplies and equipment related to combating the 24 COVID–19 pandemic. (Sec. 3101)
- **Funding for Providers Relating To COVID-19:** Provides \$8.5 billion to rural providers through the Provider Relief Fund. (Sec. 9911)
- **Mandatory Coverage Of COVID–19 Vaccines and Administration and Treatment Under Medicaid and CHIP:** Requires Medicaid and CHIP coverage of COVID-19 vaccines and treatment without beneficiary cost sharing. (Sec. 9811 and Sec. 9821)

Drug Pricing

- **Sunset of Limit on Maximum Rebate Amount for Single Source Drugs and Innovator Multiple Source Drugs:** Eliminates the cap on Medicaid drug rebates, starting in calendar year 2024. (Sec. 9816)



Section-by-Section of Healthcare Provisions

The Rescue Act is organized by Titles corresponding to budget reconciliation instructions. The Senate Committees on Health, Education, Labor, and Pensions (HELP) and Finance are the major committees of jurisdiction on healthcare in the Senate and provided the majority of related provisions in the Rescue Act, however four other committees also included healthcare provisions under their jurisdiction: (1) Agriculture, Nutrition, and Forestry; (2) Banking, Housing, and Urban Affairs; (3) Veterans Affairs; and (4) Indian Affairs. Below is a summary of healthcare provisions from the six committees.

Committee on Agriculture, Nutrition, and Forestry (Title I)

- **Emergency Rural Development Grants for Rural Health Care:** Provides \$500 million until Sept. 30, 2023 for needs-based grants to facilities that primarily serve rural areas, and that target and bolster certain aspects of the COVID-19 response efforts, including to increase vaccine distribution capacity, provide drugs or medical supplies to increase medical surge capacity, increase telehealth capabilities, construct temporary or permanent structures to provide healthcare services, and support staffing needs for vaccine administration and testing. (Sec. 1002)

Committee on Health, Education, Labor, and Pensions (Title II)

Public Health

- **Funding for COVID–19 Vaccine Activities at CDC:** Provides \$7.5 billion CDC funding to prepare, promote, administer, monitor, and track COVID-19 vaccines, including distribution and administration of vaccines and ancillary supplies, support for state, local, tribal, and territorial public health departments, community vaccination centers and mobile vaccination units, IT and data enhancements, facility enhancements, and public communications on when, where, and how to get a vaccine. (Sec. 2301)
- **Funding for Vaccine Confidence Activities:** Provides \$1 billion in funding for CDC to strengthen vaccine confidence, further information and education with respect to authorized or licensed vaccines and improve vaccination rates. (Sec. 2302)

- **Funding for Supply Chain for COVID-19 Vaccines, Therapeutics, and Medical Supplies:** Allocates \$5.2 billion to Health and Human Services (HHS) to support advanced research, development, manufacturing, production and purchase of vaccines, therapeutics, and ancillary medical products utilized for treatment and prevention of COVID-19, and any viral variant of SARS-CoV-2. (Sec. 2303)
- **Funding for COVID-19 Vaccine, Therapeutic, and Device Activities at the FDA:** Provides \$500 million for the Food and Drug Administration (FDA) to support the review, facilitate the development and post-marketing surveillance of COVID-19 vaccines and therapeutics, and address drug shortages, among other activities. (Sec. 2304).
- **Reduced Cost-Sharing:** For 2021, provides advanced premium tax credits as if the taxpayer's income was no higher than 133 percent of the federal poverty line (FPL) for individuals receiving unemployment. (Sec. 2305)

Testing

- **Funding for COVID-19 Testing, Contact Tracing, and Mitigation Activities:** Provides \$46 billion to HHS to detect, diagnose, trace, and monitor COVID-19 infections, and for other activities necessary to mitigate the spread of COVID-19. Specified activities include implementing a national strategy for testing, contact tracing, surveillance, and mitigation of COVID-19; guiding state and local public health departments in their work to implement the national strategy; support developing, manufacturing, procuring, distributing, and administering tests, personal protective equipment (PPE), and other supplies necessary for COVID-19 testing; establishing and expanding federal, state, or local testing and contact tracing capabilities, including investments in laboratory capacity, community-based testing sites, and mobile testing units; and sustaining our nation's public health workforce. (Sec. 2401)



- **Funding for SARS-Cov-2 Genomic Sequencing and Surveillance:** Provides \$1.75 billion for CDC to conduct, expand, and improve activities to sequence genomes, identify mutations, and survey the circulation and transmission of viruses including SARS-CoV-2. These dollars could also be used to provide genomic sequencing support to state, local, tribal, or territorial public health departments, expand the understanding of the COVID-19 variations, and build analytical capacity in health departments across the country. (Sec. 2402)
- **Funding for Global Health:** Provides \$500 million to allow CDC to establish, expand, and maintain data surveillance and analytics infrastructure and to modernize the U.S. disease warning system to forecast and track hotspots for COVID-19. (Sec. 2403)
- **Funding for Data Modernization and Forecasting Center:** Provides \$750 million to support CDC's efforts to combat COVID-19 globally, including those efforts relating to global health security, global disease detection and response, global health protection, global immunization, and global coordination on public health. (Sec. 2404)

Public Health Workforce

- **Funding for Public Health Workforce:** provides \$7.6 billion to HHS for efforts related to establishing, expanding, and sustaining a public health workforce, and to make awards to State, local, and territorial public health departments. These workforce positions would include contact tracers, social support specialists, community health workers, public health nurses, epidemiologists, lab personnel, disease intervention specialists, and communications personnel. Funds would also support necessary technology and supplies, such as PPE, for use by the public health workforce. (Sec. 2501)
- **Funding for Medical Reserve Corps:** Allocates \$100 million for the Medical Reserve Corps, which is a network of volunteers, including medical and public health professionals, who support emergency response efforts and community health activities. (Sec. 2502)

Public Health Investments

- **Funding for Community Health Centers and Community Care:** Invests \$7.6 billion in Community Health Centers (CHCs), including at least \$20 million for Native Hawaiian Health Centers. CHCs would be allowed to use these funds to carry out COVID-19 vaccine-related activities; conduct COVID-19 testing, contact tracing, surveillance, mitigation, and treatment; purchase COVID-19 equipment and supplies; support health care workforce; expand health care services and infrastructure; and conduct COVID-19 community outreach and education activities. (Sec. 2601)
- **Funding for National Health Service Corps and Nurse Corps:** Includes \$800 million for the National Health Service Corps and \$200 million for the Nurse Corps Loan Repayment Program, both supporting primary health care providers in high-need, low-resource areas across the country. (Sec. 2602 and 2603)
- **Funding for Teaching Health Centers that Operate Graduate Medical Education:** Provides \$331 million to expand the number of Teaching Health Centers (THC) Graduate Medical Education (GME) sites nationwide and increase the per resident allocation. (Sec. 2604)
- **Funding for Family Planning:** Provides \$50 million for the Title X Family Planning Program (Sec. 2605)

Mental Health and Substance Use Disorder

- **Funding for Block Grants for Community Mental Health Services and Block Grants for Prevention and Treatment of Substance Abuse:** Provides \$3.5 billion for the Substance Abuse Prevention and Treatment and Community Mental Health block grant programs administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). Both programs provide funding to all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and six Pacific jurisdictions. The Substance Abuse Prevention and Treatment block grant program also supports the Chippewa Tribal Nation. (Sec. 2701 and 2702)
- **Funding for Mental and Behavioral Health Training for Health Care Professionals, Paraprofessionals, and Public Safety Officers:** Provides \$80 million for mental and behavioral health training for health care professionals, paraprofessionals, and public safety officers. (Sec. 2703)

- **Funding for Education and Awareness Campaign Encouraging Healthy Work Conditions and Use of Mental and Behavioral Health Services by Health Care Professionals:** Provides \$20 million for a national evidence-based education and awareness campaign targeting health care professionals and first responders. (Sec. 2704)
- **Funding for Grants for Health Care Providers to Promote Mental and Behavioral Health Among Their Health Professional Workforce.** Provides \$40 million for grants for health care providers to promote mental and behavioral health among their health professional workforce. (Sec. 2705)
- **Funding for Community-Based Local Substance Use Disorder Services and Community-Based Funding for Local Behavioral Health Needs:** Provides \$80 million to develop new grant programs at SAMHSA to allow additional entities, such as community-based entities and behavioral health organizations, to receive grants to support mental health and substance use disorder services. (Sec. 2706 and 2707)
- **Funding for The National Child Traumatic Stress Network and Project AWARE:** Provides \$10 million for the National Childhood Traumatic Stress Network, an existing SAMHSA program that works to develop and promote effective community practices for children and adolescents exposed to a wide array of traumatic events. (Sec. 2708 and 2709)
- **Funding for Youth Suicide Prevention:** Provides \$50 million for existing SAMHSA grant programs that support youth mental health services and suicide prevention efforts. (Sec. 2710)
- **Funding for Behavioral Health Workforce Education and Training:** Provides \$100 million to the Behavioral Health Workforce Education and Training Program, which is administered by the Health Resources and Services Administration (HRSA), to expand access to behavioral health services through focused training for behavioral health paraprofessionals, such as peer support specialists. (Sec. 2711)
- **Funding for Pediatric Mental Health Care Access:** Provides 80 million through the Health Center Program to support pediatric access to mental health care. (Sec. 2712)
- **Funding for Certified Community Behavioral Health Clinics:** Provides 420 million for grants to Certified Community Behavioral Health Clinics. (Sec. 2713)

Exchange Grant Program

- **Establishing a Grant Program for Exchange Modernization:** Provides \$20 million for State-Based Marketplaces (SBMs) to modernize information technology systems. (Sec. 2801)

Committee on Banking, Housing, and Urban Affairs (Title III)

- **COVID-19 Emergency Medical Supplies Enhancements:** Provides \$10 billion to support enhanced use of the Defense Production Act for the purchase, production, or distribution of medical supplies and equipment related to combating the COVID-19 pandemic. (Sec. 3101)

Committee on Veterans Affairs (Title VIII)

- **Funding Availability for Medical Care and Health Services:** Provides \$13.4 billion for healthcare services and related support to eligible veterans under the Department of Veterans Affairs (VA) programs through Sept. 30, 2023. (Sec. 8002)

Committee on Finance (Title IX)

Support to Skilled Nursing Facilities in Response to COVID-19

- **Providing for Infection Control Support to Skilled Nursing Facilities through Contracts With Quality Improvement Organizations:** Provides \$200 million to HHS for infection control efforts through the development and dissemination of protocols related to COVID-19 prevention and mitigation in skilled nursing facilities (SNFs) and another \$250 million for states to establish and implement strike teams to assist SNFs with clinical care, infection control or staffing during the emergency period. (Sec. 9401)
- **Funding for Strike Teams for Resident and Employee Safety in Skilled Nursing Facilities:** Provides another \$250 million for states to establish and implement strike teams to assist SNFs with clinical care, infection control or staffing during the COVID-19 emergency period. (Sec. 9402)

Preserving Health Benefits for Workers

- **Preserving Health Benefits for Workers:** Allows workers who are eligible for COBRA due to involuntary termination or reduction in hours to receive coverage under their employment-based health plan with a premium reduction of 100 percent. Premium assistance will be available to workers beginning the first month following the date of enactment and will remain available through September 30, 2021. Provides for an extended election period to allow individuals who previously experienced a qualifying event to enroll in coverage. Requires employers to provide clear and understandable written notices to workers and establishes an expedited review process for workers who are denied premium assistance. Provides a payroll tax credit to allow employers and plans to be reimbursed for the full amount of COBRA premiums not paid by workers. (Sec. 9501)

Premium Tax Credit

- **Improving Affordability by Expanding Premium Assistance for Consumers:** Modifies the affordability percentages used for 36(B) premium tax credits for 2021 and 2022 to increase credits for individuals eligible for assistance under current law and provides 36(B) credits for taxpayers with income below 400 percent of the federal poverty line (FPL). (Sec. 9661)
- **Temporary Modification of Limitations on Reconciliation of Tax Credits for Coverage under a Qualified Health Plan with Advance Payments of Such Credit:** For tax year 2020, modifies the repayment obligations for taxpayers receiving excess premium tax credits under Section 36 (B) so such payments are not subject to recapture. (Sec. 9662)
- **Application of Premium Tax Credit in Case Of Individuals Receiving Unemployment Compensation During 2021:** For 2021, provides advanced premium tax credits as if the taxpayer's income was no higher than 133 percent of the federal poverty line (FPL) for individuals receiving unemployment compensation as defined in section 85(B) of the Internal Revenue Code. (Sec. 9663)

Medicare

- **Floor on the Medicare Area Wage Index for Hospitals in All-Urban States:** Restores Medicare wage index floor to hospitals in an all-urban State (i.e., New Jersey, Rhode Island, and Delaware). (Sec. 9831)
- **Secretarial Authority to Temporarily Waive or Modify Application of Certain Medicare Requirements with Respect to Ambulance Services Furnished during Certain Emergency Period:** Ensures that ambulance providers get reimbursed at the same level when COVID-19 keeps them from moving a Medicare patient to an approved location. (Sec. 9832)

Provider Relief Fund

- **Funding for Providers Relating To COVID-19:** Provides \$8.5 billion to rural providers through the Provider Relief Fund. (Sec. 9911)

Committee on Indian Affairs (Title XI)

- **Indian Health Service:** Provides \$6.094 billion for tribal health programs. These dollars will support activities at the Indian Health Service, including \$2 billion for lost revenue; \$500 million for Purchased/Referred Care; \$140 million for information technologies, telehealth, and electronic health records infrastructure; \$84 million for urban Indian health programs; \$600 million for vaccine-related activities; \$1.5 billion for testing, tracing, and mitigating COVID-19; \$240 million for public health workforce; and \$420 million for mental and behavioral health prevention and treatment services among Indian tribes, tribal organizations, and urban Indian organizations. Also includes \$600 million to fund tribal health care facilities and infrastructure, and \$10 million for potable water delivery. (Sec. 11101)



Key Non-Healthcare Provisions

Unemployment Assistance

- **Extension of Pandemic Unemployment Assistance:** Extends the temporary federal unemployment benefits at \$300 per week through September 6 and makes the first \$10,200 of unemployment insurance benefits non-taxable for households with incomes of less than \$150,000. (Sec. 9011)

Taxes Changes

- **2021 Recovery Rebates to Individuals:** Provides a \$1,400 rebate payment to qualifying individuals with incomes up to \$75,000 and couples making \$150,000 with eligibility phasing out at \$80,000 and \$160,000, respectively. This would be in addition to the \$600 supplemental payments enacted in the December COVID relief bill, bringing total eligible individual payments up to \$2,000 per individual. (Sec. 9601)
- **Child Tax Credit Improvements for 2021:** Provides a \$3,000 temporary, fully refundable child tax credit for children between 6 and 17; \$3,600 for children under six. (Sec. 9611)
- **Refundability and Enhancement of Child and Dependent Care Tax Credit:** Expands the temporary, fully refundable Child and Dependent Care Credit from the current limitation of \$1,050 per child or dependent up to \$4,000 for one child and \$8,000 for two or more children or dependents. (Sec. 9631)

State and Local Funding

- **Coronavirus State and Local Fiscal Recovery Funds:** Provides \$195.3 billion for States and the District of Columbia; \$130.2 billion divided evenly between cities and counties; \$4.5 billion for territories; and \$20 billion for Tribal governments (Sec. 9901)

School Funding

- **Elementary and Secondary School Emergency Relief Fund:** Provides \$122.7 billion for the Elementary and Secondary School Emergency Relief Fund to remain available through Sept. 30, 2023. (Sec. 2001)

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 29.6 million confirmed COVID-19 cases in the US, with a [death toll over 535,000](#)... The country [averaged 55,000 new cases/day](#) over the last week, down 5% from the week before.

116 million COVID-19 [vaccine doses have been administered](#) in the US (2.5M/day over the last week)... 77.2 million Americans ([29.8% of Americans 18 and older](#)) have received at least one dose of a COVID-19 vaccine... A CDC study found that from mid-December to February, vaccination coverage (the proportion of residents who received at least one dose of COVID-19 vaccine) was [1.9 percentage points lower in the most socially vulnerable locations](#) across the country.

Executive and Administrative Action

The Biden Administration will [invest \\$12.25 billion to expand COVID-19 testing](#) in schools (\$10B) and to address disparities in testing and mitigation (\$2.25B)... the Administration will [also invest \\$150 million to increase access to COVID-19 monoclonal antibodies](#) in underserved communities across the country... The White House will unveil a [\\$1.5B public relations campaign](#) to boost vaccine confidence and uptake.

President Biden selected [Gene Sperling to oversee implementation](#) of the American Rescue Plan Act.

The Administration agreed [to send 4 million doses of AstraZeneca's COVID-19 vaccine](#) to Mexico (2.5M) and Canada (1.5M).

CDC announced [\\$2.25 billion in grants to public health departments](#) to address COVID-19 disparities in underserved communities.

CDC [revised social distancing guidance for children in schools](#), permitting students to sit three, instead of six, feet apart if they are wearing masks... CDC released [updated guidance for how child care programs can operate safely during the pandemic](#).

Healthcare Regulatory News

CMS [increased Medicare reimbursement for administering the COVID-19 vaccine](#) from \$28 to \$40 for the administration of a single-dose vaccine and from \$45 to \$80 for the administration of two doses...

FDA updated emergency use authorizations for Eli Lilly and Regeneron monoclonal antibodies, requiring [close monitoring of their efficacy against emerging strains](#) of COVID-19.

FDA will permit some COVID-19 test developers to market their products for at-home, school, and business use [without first testing efficacy in asymptomatic individuals](#).

FDA [granted marketing authorization](#) to BioFire's COVID-19 diagnostic test through the De Novo premarket review pathway, the first COVID-19 test permitted for marketing beyond the public health emergency... FDA warned of [potential false positive results](#) with Roche's rapid COVID-19 & flu test.

OSHA has [delayed release of a COVID-19 workplace safety rule](#).

Healthcare Law, Business, and Policy News

49% of [Republican men responding to a NPR/PBS/Marist](#) survey do not plan to be vaccinated if a vaccine is available to them... Former President Donald Trump [encouraged Americans](#), including his supporters, to get the COVID-19 vaccine.

NIH Director Anthony Fauci, FDA CBER Director Peter Marks, and CDC Director Rochelle Walensky of the CDC testified before the House Energy and Commerce [Oversight and Investigations Subcommittee on COVID-19 vaccine rollout](#)... Dr. Fauci said the NIH is [aiming to develop inhaled and swallowed versions](#) of COVID-19 vaccines.

A [pre-print study](#) suggests that some people with “[long COVID](#)” [had their symptoms improve](#) after receiving a COVID-19 vaccine.

Walmart is partnering with Commons Project and Clear to launch a [digital health record that customers can use to demonstrate](#) that they have received a COVID-19 vaccine.

Surveillance, Testing, and Treatment

A CDC study found that partial vaccination (i.e., one dose of Pfizer-BioNTech's vaccine) of residents and staff in nursing homes was [63% effective in preventing](#) COVID-19 infection... BioNTech is [building a manufacturing alliance of 13 companies](#) to meet, or exceed, its goal of producing 2 billion doses of its COVID-19 vaccine developed with Pfizer.

Moderna began a clinical trial of its COVID-19 [vaccine in children aged 6 months to 11 years](#) and began testing [a potentially refrigerator-stable version](#) of the vaccine.

The World Health Organization (WHO) [listed Johnson & Johnson's COVID-19 vaccine](#) for emergency use in all countries and for COVAX rollout... Catalent will [expand its COVID-19 vaccine production in Europe](#) to increase doses of Johnson & Johnson's COVID-19 vaccine.... Johnson & Johnson is [working on multiple “next generation” COVID-19 vaccines](#) to address emerging virus strains.

After [several European countries suspended use](#) of the AstraZeneca-Oxford COVID-19 vaccine, the European Medicines Agency said that [the vaccine was “safe and effective”](#) but that it needed to further review evidence of a causal link between the vaccine and blood clots... WHO is [expected to issue its findings](#) on the blood clotting issues today... A [NEJM study found](#) that the AstraZeneca vaccine is only 10% effective against the South African strain of the virus... AstraZeneca warned the European Union that it [no longer expects to supply EU countries with around 100 million COVID-19 vaccine](#) doses that it pledged to import.

Medicago began [a phase 3 trial of its plant-derived COVID-19 vaccine candidate](#) in combination with an adjuvant supplied by GlaxoSmithKline.

HHS [stopped distribution of Eli Lilly's single-antibody therapy](#) in three states out of concerns about its efficacy against a variant of the virus that originated in California... AstraZeneca will supply the US [with up to 500,000 more doses of its COVID-19 monoclonal antibody](#) therapy, which has not yet been authorized for use.