# The American Rescue Plan Act of 2021: Implications for Healthcare and Life Sciences Companies

**March 12, 2021**

On March 11, 2021, President Biden signed into law the America Rescue Plan Act of 2021 (the "Act"), which provides nearly two trillion dollars in funding for various government programs, including many related to public health. Like previous spending bills enacted since the start of the pandemic, this one includes a variety of programs that are likely to have a significant impact on healthcare and life science companies. The Act includes, among other things, funding aimed at expanding access to health insurance; funding for vaccines, therapeutics, testing, contact tracing and medical equipment related to the pandemic; and funding for rural healthcare providers. The Act also contains a provision that will remove a cap on the amount of rebates that innovator drug companies must provide to the Medicaid program starting in 2024. We address these and other provisions below.

## PROGRAMS TO EXPAND ACCESS TO HEALTHCARE

The Act includes a variety of provisions that are aimed at expanding the number of people who receive health insurance either through the Medicaid program or through private insurance.

### Incentives to Expand Medicaid

Before enactment of the Affordable Care Act ("ACA"), state Medicaid programs typically offered coverage only to certain types of low-income people—principally children and their parents. The federal government reimburses between 50–80 percent (depending on the state) of the state's Medicaid expenses—known as the Federal Medical Assistance Percentage ("FMAP"). The ACA expanded Medicaid to cover childless adults with incomes up to 138 percent of the federal poverty level. For this "expansion" population, the federal government reimburses 90 percent of the state's Medicaid costs. To date, 38 states and Washington, D.C. have expanded Medicaid; 12 states have not. As an incentive, the Act provides that if a state decides to accept the expansion, it will receive an increase in the FMAP reimbursement level by five percent in each of the following eight quarters.

### Increase in the Advance Premium Tax Credit ("APTC")

APTCs are subsidies for people making between 100% and 400% of the federal poverty level ("FPL"), which are used to reduce the cost of health insurance plans sold on ACA marketplaces. The size of an APTC is determined by taking the cost of the second-lowest cost silver plan available in the market (known as the "benchmark plan") and subtracting a required "contribution" (an amount determined by multiplying income by a specified percentage; the percentage is higher for individuals with greater incomes). The Act makes two significant changes. First, it significantly lowers the contribution percentages (to zero, for individuals making less than 200% of the FPL), thereby increasing the size of the APTCs. Second, it makes APTCs available for the first time to individuals making more than 400% of the FPL.

### COBRA Continuation Coverage

Individuals who are terminated from their employment are entitled to purchase the group health insurance coverage that was available to them through their former employer for a period of time (usually referred to as "COBRA continuation"). Typically, such individuals would have to pay 102% of the premium. The Act provides that individuals who were involuntarily terminated are eligible for COBRA continuation coverage that is completely subsidized from April to September 2021 (with the government providing the applicable plan, employer or health insurer with tax credits to cover the cost of premiums).

The initiatives described above have the potential to lead to more people enrolling in health insurance. Expanded APTC subsidies will make the out-of-pocket cost of plans sold on the ACA marketplace considerably cheaper for many consumers; that should translate into increased demand for such plans. Any states choosing to expand Medicaid should benefit insurers that administer Medicaid plans and healthcare technology vendors that offer benefits administration and care management software solutions to such plans. Further, additional enrollment in Medicaid or ACA marketplace plans should result in greater demand for provider services, devices and drugs.

## FUNDING FOR RURAL HEALTHCARE PROVIDERS

Unlike pandemic-related legislation enacted last year (discussed here and here), the Act does not offer additional funding that is generally available for healthcare providers who treat possible or actual COVID patients. The Act does, however, provide $8.5 billion in funding for rural healthcare providers that meet applicable criteria.

## FUNDING FOR COVID-19 VACCINES, THERAPEUTICS, TESTING AND MEDICAL SUPPLIES

The Act allocates $6.05 billion for the research, development, manufacturing and purchase of vaccines, therapeutics and ancillary products and supplies to address COVID-19 or future diseases with pandemic potential. The Act also directs $7.5 billion to the Centers for Disease Control and Prevention ("CDC") to fund the distribution, administration and tracking of COVID-19 vaccines. In addition to funding a nationwide effort to distribute the vaccines, Congress directs the CDC to provide grants or other assistance to local health authorities to enhance their capabilities, particularly in underserved areas. The Act provides an additional $1 billion to the CDC to strengthen vaccine confidence by providing information and education to the public.

The Act also provides $47.8 billion for testing, contact tracing, surveillance and mitigation efforts and an additional amount for genomic sequencing of the virus. Among other things, the Act provides that these funds may be used to acquire, construct or renovate non-federally owned facilities for the production of diagnostics and ancillary medical supplies if necessary. Similarly, $10 billion is allocated to the production and purchase of medical supplies such as diagnostics, vaccines and personal protective equipment under the Defense Production Act. This may also include the construction or renovation of private facilities as necessary.

## FOOD AND DRUG ADMINISTRATION ("FDA") APPROPRIATIONS

The Act allocates $500 million for the FDA to: (1) monitor the efficacy of vaccines and therapeutics against new COVID-19 variants; (2) facilitate advanced continuous manufacturing activities of vaccines and related materials; (3) conduct inspections of drug and device manufacturers delayed or cancelled due to the pandemic; (4) review medical devices for the treatment, prevention or diagnosis of COVID-19; and (5) oversee the supply chain and mitigate shortages of COVID-19-related vaccines, therapeutics and devices.

## CONSUMER PRODUCT SAFETY FUND

The Act allocates $50 million to the Consumer Product Safety Commission ("CPSC") to protect consumers from potentially dangerous products related to COVID-19—products with risks that have been significantly affected by COVID-19 or whose sales have materially increased as a result of the pandemic. The CPSC is directed to use these funds

to: (1) enhance surveillance of imported products at the border; (2) monitor websites for violative consumer products; (3) increase awareness and communication of COVID-19 product related risks; and (4) improve data collection, focusing on consumer product safety risks to vulnerable populations resulting from the pandemic.

## ELIMINATION IN 2024 OF CAP ON MEDICAID REBATES

As we discussed here, innovator pharmaceutical companies participating in state Medicaid programs are required to enter into agreements with the Department of Health and Human Services that typically include the following rebates:

- The greater of (i) 23.1% of the "average manufacturer price" ("AMP") of a drug or (ii) the difference between a drug's AMP and "best price."

- The difference between the drug's AMP for the current quarter and the baseline AMP (defined as the AMP in the first full quarter after launch), adjusted by the Consumer Price Index for All Urban Consumers.

Currently, the above-listed rebates are capped at 100% of AMP.[1] The Act provides that this rebate cap will be eliminated starting on January 1, 2024. As a result, some manufactures of innovator drugs whose prices have increased substantially since their launch may be required to make larger rebate payments starting in 2024. It should be noted, however, that the cap will not be eliminated for almost three years, giving industry an opportunity to lobby for reinstatement of the cap.

## A NOTE ABOUT FRAUD AND ABUSE

The Act provides trillions of dollars of government spending in addition to the extraordinary amount the government has spent since the start of the pandemic. Entities that seek to participate in programs funded by these COVID-related spending bills typically must comply with detailed terms and conditions specified by the applicable government agencies. Failure to comply with these rules may, depending on the circumstances, constitute violations of the False Claims Act ("FCA"). FCA violations may result in treble damage awards and large statutory penalties. The Department of Justice has repeatedly cautioned that it is on the lookout for pandemic-related fraud arising from misuse of government funds. Entities that seek government funds should therefore confirm eligibility before taking such money, comply with applicable rules,

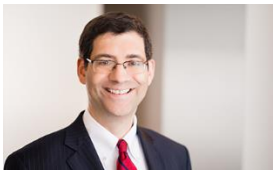
[1] State Medicaid programs also typically require manufacturers to provide supplemental rebates.

maintain a robust and well-resourced compliance program and document the steps taken to ensure compliance so there is a complete record available in the event of an external audit. Similarly, potential acquirers of entities that have accepted government funds should diligence the circumstances under which the funds were taken, the eligibility of the entity and the compliance efforts undertaken by the entity.

* * *

Please do not hesitate to contact us with any questions.

## NEW YORK

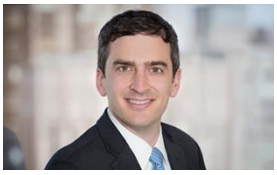

Andrew L. Bab
albab@debevoise.com


Jennifer L. Chu
jlchu@debevoise.com


Mark P. Goodman
mpgoodman@debevoise.com


Maura Kathleen Monaghan
mkmonaghan@debevoise.com


Kevin Rinker
karinker@debevoise.com


Jacob W. Stahl
jwstahl@debevoise.com


Kim Le
kle@debevoise.com


Benjamin Leb (Law Clerk)
bjleb@debevoise.com


Hannah R. Levine
hrlevine@debevoise.com

## WASHINGTON, D.C.


Paul D. Rubin
pdrubin@debevoise.com


Melissa Runsten
mrunsten@debevoise.com