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CARES Act: Implications for Healthcare and Life Science Companies and Investors

March 27, 2020

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act" or the "Act"). The CARES Act is a sweeping set of measures intended to provide relief to industries and employees impacted by the economic crisis caused by the novel coronavirus, COVID-19, and is expected to significantly impact healthcare and life sciences companies as well as investors in the space.[1] The Act includes a large fund for providers who are treating COVID-19 patients (including, but not limited to, hospitals), life science companies developing new vaccines, and manufacturers of products that are being used to respond to the current crisis; regulatory reforms governing the provision of drugs and supplies needed in the current environment; healthcare reimbursement reforms; and—in a development unrelated to COVID-19—a sweeping overhaul of the laws governing over-the-counter ("OTC") drugs. We address these key developments below.

The $100 Billion Provider Fund. For hospitals and other provider groups that have treated—or are preparing to treat—COVID 19 patients, the "Public Health and Social Services Emergency Fund" may be of vital significance. It provides an appropriation of $100 billion for the Department of Health and Human Services ("HHS") to distribute to eligible healthcare providers (defined to include both for-profit and not-for-profit entities and Medicare- or Medicaid-enrolled suppliers and providers) who provide "diagnoses, testing, or care for individuals with possible or actual cases of COVID-19." The Act provides few details regarding how HHS should distribute these funds, but provides that the funds are intended to "prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses … for healthcare

[1] We provided a separate client update regarding provisions of the Act that are applicable to the broader economy, including financial programs for businesses, bank regulatory changes, and tax reforms. We also provided a client update addressing a number of legal developments in the wake of the pandemic impacting healthcare and life sciences companies, including Food and Drug Administration ("FDA") regulatory developments.

related expenses or lost revenues that are attributable to coronavirus." The Act also includes provisions that describe a potentially narrower set of uses for these funds, including developing new facilities or retrofitting existing ones, obtaining necessary supplies and equipment, and developing surge capacity. HHS will have to decide how these funds are spent. In the meantime, providers who are treating COVID-19 patients or are preparing for a surge of such patients should keep detailed records of their expenditures, which may be essential for seeking reimbursement.[2]

Additional Medicare and Medicaid Expenditures. Through a variety of provisions, the Act provides additional Medicare and Medicaid expenditures that will either directly fund COVID-19-related treatments or provide additional funding to government healthcare programs, some of which are likely to filter to providers:

- The Medicare "sequester" will be lifted for the period starting May 1, 2020 through December 31, 2020. This action forestalls until the end of the year a two percent reduction in Medicare payments to hospitals, physicians, nursing homes and home health providers.[3]

- For the period of the COVID-19 emergency (as determined by HHS), Medicare will pay 20 percent above the amount of reimbursement it would otherwise pay to providers who treat COVID-19 patients.

- For the period of the COVID-19 emergency, there will be a postponement of the scheduled reductions in Medicare payments to durable medical equipment suppliers for equipment that helps patients transition from the hospital to the home (irrespective of whether or not the patient is suffering from COVID-19).

- The "Families First Coronavirus Response Act," which was signed into law by President Trump on March 18, 2020, included a provision increasing the portion of Medicaid costs borne by the federal government by 6.2 percent for the period between January 1, 2020 and the end of the COVID-19 emergency if certain requirements are satisfied. The CARES Act makes technical corrections to ensure that states are not disqualified from receiving the increased funding.

Funding for the National Strategic Stockpile. The Act provides $16 billion in funding for the national strategic stockpile, which likely will result in purchases of personal

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[2] It is uncertain how HHS will interpret "lost revenues," which, at its broadest, potentially could include revenue lost due to the postponement of nonemergency procedures either because of the need to prepare hospital beds for COVID-19 patients or because the risk of infection outweighs the need for an imminent procedure. In the meantime, providers should keep records of cancelled procedures in the event necessary for reimbursement.

[3] The sequester will be in effect from 2021 through 2030, unless it is subsequently modified.

protective equipment, ventilators and other supplies that are needed to respond to the COVID-19 crisis.

Expanded Access to Telehealth. As we described in a prior update, the federal government has relaxed certain regulations governing the use of telehealth services to provide care remotely during the COVID-19 crisis. The CARES Act further expands access to telehealth services as provided below:

- The Act includes appropriations to federal agencies including the Veterans Administration, the Department of Defense, the Federal Communications Commission, and Indian Health Services to fund various initiatives that are designed to facilitate the provision regarding telehealth services.

- For consumers with qualifying high-deductible health plans and accompanying health savings accounts, such plans will be permitted to cover telehealth services prior to the patient reaching the deductible (for plan years beginning before December 31, 2021). In other words, a high-deductible plan can cover telehealth services for patients who have not incurred significant medical expenses that would exceed their deductibles.

- The Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (enacted on March 6, 2020) allowed HHS to waive certain restrictions governing telehealth, but it applied only to qualified providers who had treated the patient at issue within the prior three years. The CARES Act eliminates that qualification. Therefore, if the other relevant criteria are satisfied, Medicare will provide reimbursement to telehealth providers who are treating patients they may never have met.

Drug and Device Shortages. The CARES Act includes a number of provisions aimed at preventing or mitigating shortages of lifesaving drugs and devices. In addition to creating an obligation for drug and medical device companies to notify FDA in the event of a shortage during a public health emergency, FDA will be able to expedite and prioritize the review of product applications and facility inspections where appropriate to mitigate or prevent shortages of lifesaving products. Independent of the CARES Act, FDA has taken other measures to address drug and device shortages. For example, FDA has relaxed requirements for hand sanitizers through guidance,[4] provided instructions

[4] FDA News Release, Coronavirus (COVID-19) Update: FDA Provides Guidance on Production of Alcohol-Based Hand Sanitizer to Help Boost Supply, Protect Public Health (Mar. 20, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost.

to facilitate the importation of personal protective equipment,[5] and issued Emergency Use Authorizations for COVID-19 diagnostic tests and ventilators.[6]

Funding for Vaccines and Therapeutics. The CARES Act benefits the drug industry by including $11 billion for COVID-19 vaccines, therapeutics, and diagnostics of which $3.5 billion is dedicated to the construction, manufacturing, and purchase of vaccines and therapeutics.

Delay of Drug Pricing Reform. The drug industry is expected to indirectly benefit from the extension of certain health funding legislation to November 2020. House Speaker Nancy Pelosi and Senate Finance Committee Chairman had signaled that they would use the reauthorization, originally set for May 2020, as a vehicle to work on drug pricing reform. With the reauthorization now moved to the end of 2020, it seems unlikely that drug pricing reform will be pursued any earlier and there is a low likelihood that Congress would pass a significant reform bill during the lame-duck period after the general election in November 2020.

FDA Appropriations. The CARES Act allocates $80 million to FDA to respond to the COVID-19 pandemic by supporting the development of necessary medical countermeasures and vaccines, advancing domestic manufacturing for medical products, and monitoring medical product supply chains.

OTC Drug Reform. Although unrelated to the COVID-19 pandemic, the CARES Act includes major reforms to the FDA regulatory regime governing OTC drugs. Most OTC drugs sold in the United States are marketed pursuant to OTC drug monographs developed by FDA through the "OTC Drug Review." Although the OTC Drug Review started in the early 1970s, many OTC drug monographs are still not finalized. The Act creates an expedited mechanism for FDA to update and issue monographs through an administrative order rather than the lengthy notice-and-comment rulemaking process. In addition, the Act encourages innovation by granting 18 months of marketing exclusivity in certain circumstances which a company has conducted human studies and successfully petitions FDA to modify a monograph. The Act also authorizes FDA to collect OTC drug user fees beginning in fiscal year 2021.

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[5] FDA Statement, Coronavirus (COVID-19) Update: FDA Takes Action to Increase U.S. Supplies Through Instructions for PPE and Device Manufacturers (Mar. 24, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-increase-us-supplies-through-instructions-ppe-and-use-authorization.

[6] *See* list of Emergency Use Authorizations available here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency.

For more information regarding the coronavirus, please visit our Coronavirus Resource Center.

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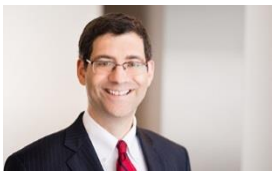

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