What Biopharmaceutical and Medical Device Manufacturers Need to Know About the CARES Act

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On March 27, 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), the third and by far the largest stimulus package passed by Congress to respond to the COVID-19 outbreak. As discussed in our main alert, the $2 trillion CARES Act amounts to what will be the biggest economic stimulus package in American history.

This alert focuses on those key provisions of the Act that directly impact biopharmaceutical and medical device manufacturers. Our CARES Act alerts focused on employers, loan provisions, the healthcare provider industry, and labs/diagnostics are available on Foley Hoag's website or by contacting your Foley Hoag attorney.

In immediate response to COVID-19, the Act requires health insurance plans (that satisfy minimum essential coverage) to cover an evidence-based item or service that has in effect an A or B rating from the United States Preventive Task Force (USPTF) or an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control (CDC). It also requires Medicare Part B and Medicare Advantage prescription drug plans (MA-PDs) to cover COVID-19 vaccines, and requires MA-PDs and standalone Part D plans (PDPs) to allow beneficiaries to fill their Part D prescriptions for a maximum of 90-days, with exceptions for drugs with safety edits. Finally, the Act suspends the 2% sequestration cut under Medicare, which effectively increases the payment for Medicare Part B drugs, and it provides reimbursement relief for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

The CARES Act also addresses general emergency and pandemic preparedness. It expands the National Stockpile to include not only drugs and biologicals, but also personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests, and it treats classifies respiratory protective devices as covered countermeasures. The Act also imposes on manufacturers requirements to notify the Secretary of shortages not only for drugs, but also potential shortages in the manufacture of active ingredients for such drugs and for medical devices necessary to address a public health emergency. Finally, the legislation directs the Food and Drug Administration (FDA) to prioritize review of certain drug approvals that could help combat a public health emergency.

Apart from the changes directly related to the COVID-19 crisis and general emergency preparedness, the Act also proposes sweeping changes to the over-the-counter (OTC) monograph process. The OTC process has long been criticized for being extraordinarily administratively burdensome for the Food and Drug Administration (FDA) to initiate, and therefore the proposed replacement would significantly modernize the process and provide for more regular updates. The proposed new OTC process would involve the issuance of administrative orders, financed by a new user fee program, that would include an abbreviated public comment process, formal dispute resolution, hearings, and judicial review of final agency actions. OTC products that are marketed but do not pursue the administrative order process would be considered misbranded—OTC products that are currently marketed would be grandfathered in and considered GRASE.

Key Points

Covering COVID-19 Products and Services. Requires group health plans and health insurance issuers offering group or individual health insurance to cover, within 15 days of the recommendations below and without cost-sharing, any qualifying coronavirus preventive service. A "qualifying coronavirus preventive service" includes an evidence-based item or service that has in effect an A or B rating from the USPTF or an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the CDC.

The CARES Act also requires coverage COVID-19 vaccines under Medicare Part B and Medicare Advantage and waives beneficiary cost-sharing.

Increasing Payment For Part B Drugs and DMEPOS. Suspends the 2% sequestration payment cuts under Medicare until December 31, 2020, which affects payment for drugs and biologicals and effectively increases payment from approximately ASP + 4% to ASP + 6%. It also ensures that payment for DMEPOS in rural and noncontiguous areas is maintained at its current payment amount through December 31, 2020 as originally planned, or longer if the public health emergency is still in place. Furthermore, the legislation provides a slight payment relief for DMEPOS furnished in areas other than rural or noncontiguous areas by providing a blended payment amount of 75% of the adjusted fee schedule and 25% of the unadjusted fee schedule (instead of 100% of the adjusted fee schedule) through December 31, 2020.

Allowing 90-Day Refills Under Medicare Part D. Requires MA-PD and Part D plans to allow beneficiaries to obtain a three-month supply of a Part D drug notwithstanding any cost and utilization management the plan has in place, except where safety edit applies.

Expanding the Strategic National Stockpile. Expands the medical products that the United States maintains in the Strategic National Stockpile to explicitly include "personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests". The legislation also classifies respiratory protective devices as covered countermeasures.

Combating Zoonotic Diseases. Requires the Secretary to prioritize the review, upon the sponsor's request, of zoonotic animal drug applications that indicates it could potentially prevent or treat zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences in humans.

Addressing Drug Shortages. Requires the Secretary to prioritize the review of supplemental drug approvals and abbreviated new drug applications that could mitigate potential shortages of relevant drugs. It also requires manufacturers to notify the Secretary of potential disruptions in the supply of drugs critical to a declared public health emergency, including disruptions in the manufacture of an active pharmaceutical ingredient that is likely to lead to a shortage of such a drug, and medical devices necessary to respond to a public health emergency. For identified drugs/active ingredients, the manufacturer is also required to develop a "risk management plan" that identifies and evaluates risks to the supply of the drug.

Report on Securing Domestic Product Supply Chains. Commissions the National Academies of Sciences, Engineering and Medicine to examine the security of the United States product supply chain. The objective is to assess and evaluate the dependence of the United States on critical drugs and devices that are sourced or manufactured outside the country. This includes assessing the potential economic impact of increasing domestic manufacturing.

Reforming the OTC Process. Modifies the OTC drug monograph review process, deeming currently marketed OTC drugs as GRASE. It directs the Secretary to report to Congress an evaluation of the cough and cold monograph with respect to children under age six. It replaces the existing process with an administrative order process, which includes an abbreviated public comment process, formal dispute resolution, hearings, and judicial review of final agency actions. The process also allows for an 18-month exclusivity period for the requestor of an administrative order to help spur innovation. To support this new process, the legislation establishes a user fee program, and OTC drugs that do not comply with the monograph requirements are considered misbranded.

Looking Ahead

The CARES Act, especially as it relates to the biopharmaceutical industry, was remarkably self-contained to the COVID-19 public health emergency and did not include any of the controversial drug pricing policies proposed by the 116th Congress in other drug pricing legislation. The most significant non-COVID-19 provisions in the CARES Act involves the sweeping reforms to the OTC process, and despite the new user fee program created to help the FDA administer the OTC process, it is unclear how quickly the FDA could implement these changes given the ongoing public health emergency.

At least for the short-term, we are doubtful that Congress will pick up any deeply controversial drug pricing reform package as Congress will mostly be focused on ensuring an adequate healthcare response to COVID-19 and on shoring up the economy as it falters during this steep cessation of economic activity. As Congress prepares for another likely COVID-19 package in May, that may be drug pricing reform policies included in the package, but any such changes, if at all, are likely to be limited and incremental in nature.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus

(COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney. For guidance on CARES Act biopharmaceutical and medical device manufacturers issues, please contact Paul Kim, Areta Kupchyk, or Christian Springer.

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