How the CARES Act Impacts Medical Device and Drug Manufacturers

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On March 27, 2020, the United States Congress passed the Coronavirus Aid, Relief, and Economic Security Act. ("CARES Act"). The growing concern for potential shortages of critical drugs and medical equipment is addressed in Sections 3101-3121.

If your company Is part of the US supply chain for drugs and medical equipment, implementation of the CARES Act could affect the way you do business. Here's a primer on what you need to know.

Section 3101 – National Academies Report on US Medical Product Supply Chain

The CARES Act requires the Department of Health and Human Services to partner with the National Academies of Sciences, Engineering and Medicine to issue a report on the security of the medical product supply chain. The report will evaluate America's dependence on foreign sources for critical drugs and medical supplies and take into account the public health and national security risks associated with such dependence. The report will also contain recommendations to address any perceived vulnerabilities to the supply chain for critical drugs and medical devices.

Section 3102 – Strategic National Stockpile of Medical Supplies

The CARES Act amends the Public Health Service Act ("PHSA"), 42 U.S.C. § 247d-6b, to qualify the term "other supplies" to specifically 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 in the stockpile."

In other words, the Homeland Security Secretary is now empowered to add the types of medical supplies needed to combat the COVID-19 epidemic to the strategic national stockpile of medical supplies.

Section 3103 –Respiratory Protective Devices Are Covered Countermeasures

The PHSA's definition of a "covered countermeasure" has been amended to include "a respiratory protective device that is approved by the National Institute for Occupational Safety and Health…and that the Secretary determines to be a priority for use during a public health emergency declared under section 319."

The main takeaway from this amendment is that manufacturers and distributors of such devices are now entitled to the PHSA's liability protections in the event the Secretary of Health and Human Services ("HHS Secretary") declares a public health emergency.

Section 3111. Priority Given to Review of Drug Applications

The CARES Act amends the Federal Food, Drug and Cosmetic Act ("FDCA") to strengthen the HHS Secretary's authority to prioritize the review of new drug applications and the inspection of facilities where such drugs are manufactured, processed and packaged.

Section 3112. Additional Reporting Requirements for Manufacturers

In the event that a public health emergency is declared by the HHS Secretary, manufacturers of drugs critical to public health are now required to notify the Secretary of any discontinuance or interruption in their manufacture of such drugs if it is likely to disrupt the supply to the American public.

Any such notification must include the following information:

- The reasons for the discontinuation or interruption;
- The expected duration of the discontinuation or interruption;
- Whether the reason relates to an associated device used to prepare or administer the drug;
- Whether the reason relates to a specific pharmaceutical ingredient, and if so, the manufacturer must provide the ingredient's source and known alternative sources; and
- Any other information the HHS Secretary may require.

In addition, manufacturers of such drugs, along with manufacturers of any pharmaceutical ingredients or associated medical devices used in their preparation and administration, must implement a risk management plan that identifies and evaluates risks to the supply of these products. This plan is subject to inspection and copying by the HHS Secretary.

Finally, any person registered for the manufacturing, processing or preparation of a drug pursuant to the requirements of 21 U.S.C. § 360 must also provide annual reports to the HHS Secretary concerning the amount of each drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

The HHS Secretary may also require the reporting of such information at the time of any public health emergency declared under the PHSA.

Section 3121. Discontinuance or Interruption in the Production of Medical Devices.

Manufacturers of devices that are critical to public health also face new reporting requirements concerning their operations in the event of either a public health emergency or should the HHS Secretary determine that information on potential supply disruptions is needed.

Should that occur, manufacturers must notify the HHS Secretary of any permanent discontinuance or interruption in the manufacture of a device if it is likely to cause a meaningful disruption in its supply. In such cases, manufacturers are also required to provide the reasons for the discontinuance or interruption. Notifications must be given at least six months prior to the date of the discontinuance or interruption, or if that is not possible, as soon as is practical.

The HHS Secretary is empowered to share this information with physicians, healthcare providers, patient organizations and supply chain partners. The HHS Secretary is further empowered to keep such information from the public if deemed necessary to prevent the over-purchase of such devices or their component parts.

Failure to comply with these requirements will lead to issuance of a letter by HHS Secretary, to which the recipient must respond within thirty days by setting forth the reasons for noncompliance and by providing the previously required information. Unless the HHS Secretary determines there was a reasonable basis for noncompliance, the letter and response will be made available to the public on the Food and Drug Administration's website.

If it is determined that a device shortage is likely to occur, the HHS Secretary shall prioritize and expedite the necessary review and inspection processes for devices and their manufacturers that could help mitigate or prevent the shortage.

The HHS Secretary shall maintain an up-to-date Device Shortage List to include the following information:

- The category or name of the device;

- The name of each manufacturer of the device; and
- The reason for the shortage, including manufacturing practices, regulatory delay and shortage or discontinuance of component parts.

The HHS Secretary will make the Device Shortage List publicly available, subject to protections for trade secrets and other confidential and proprietary information and/or the need to protect the public health from the effects of over-purchase or hoarding.

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