THORN RUN PARTNERS
GOVERNMENT RELATIONS

Memorandum *April 1, 2020*

MEDICAL DEVICES AND THE COVID-19 RESPONSE

INTRODUCTION

On March 27, the Senate passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748). The $2.2 trillion package followed two other COVID-19-related packages and provides expanded unemployment insurance, tax credits for affected industries, payments to the American public, and more. It also included provisions aimed at safeguarding the supply chain for drugs and medical devices. The CARES Act addresses several issues related to medical devices:

- A report on U.S. medical supply chain security, including for devices;
- New reporting requirements regarding shortages for medical device companies;
- Applying emergency liability protections to respirator manufacturers;
- Delaying reductions in durable medical equipment (DME) reimbursement in Medicare;
- Adding new requirements for medical devices to be stockpiled as part of the Strategic National Stockpile; and
- Permitting the Secretary of Transportation to require air carriers that receive loans under the CARES Act to maintain routes critical for the distribution of needed medical devices.

CORONAVIRUS III

Supply Chain Security Report

The Secretary of Health and Human Services (HHS) and the National Academies will jointly report on the security of the U.S. medical supply chain. The inquiry will include conversations with relevant stakeholders, including health care providers, medical product manufacturers, and medical professional societies. The purpose of this analysis is to evaluate U.S. dependence on private and foreign medical device manufacturing and provide recommendations to fill gaps in the U.S. supply chain.[1] The bill appropriates $1.5 million for this purpose.

The report may include recommendations to strengthen the U.S. supply chain through increased domestic manufacturing and to promote drug and device accessibility. It may also propose recommendations to promote supply chain redundancy and to improve planning for public health emergencies. The eventual report must not compromise national security through its contents.[2]

[1] CARES Act Sec. 3101
[2] CARES Act Sec. 3101

Device Shortage Reporting

To help prevent medical device shortages, the CARES Act clarifies that during a public health emergency, a medical device manufacturer is required to submit information about a device shortage or device component shortage upon request of the FDA.[3] Reporting is necessary when a device is discontinued or interrupted, and the explanation must include the reasons for such occurrences.[4]

Submission must be at least six months before the discontinuance or interruption (or as soon as possible). The information will then be made public unless the information will negatively affect public health, such as by encouraging hoarding. The HHS Secretary will keep an updated list of device shortages, and the following information that will be public:

- Name of device
- Name of manufacturer
- Reason for shortage, as determined by the Secretary
- Estimated duration of shortage[5]

In addition, medical device manufacturers must, for devices used for preparation or administration of any drug that is critical to public health during a public health emergency, must develop, maintain, and implement a risk management plan. This plan must identify risks to supply and how such risks may be mitigated through redundancy.[6] The CARES Act also requires additional manufacturer reporting in the case of drug shortages or breaks in the supply chain. This includes medical devices that are associated with the scarce drug's preparation or administration.[7]

Respiratory Devices as Covered Countermeasures

The CARES Act permanently categorizes respiratory protective devices as covered countermeasures. This change in classification provides permanent liability protection for manufacturers of personal respiratory protective equipment, such as masks and respirators, in the event of a public health emergency, to incentivize production and distribution.[8] The second COVID-19 response bill, the Families First Coronavirus Response Act (H.R 6201), had done a similar action but with a narrower approach that specifically referenced the current crisis.

DME

The legislation delays a scheduled for durable medical equipment (DME) described in the calendar year 2019 Medicare End-Stage Renal Disease (ESRD) prospective payment system (PPS) payment rule. These delays are put on hold for the duration of the emergency.

[3] CARES Act Sec. 3121
[4] CARES Act Sec. 3121
[5] CARES Act Sec. 3121
[6] CARES Act Sec. 3112
[7] CARES Act Sec. 3112
[8] CARES Act Sec. 3103

Strategic National Stockpile

To further seal gaps in the supply chain, the CARES Act requires strategic stockpiling of certain types of medical supplies required for the administration of drugs, vaccines, and biologics, and medical devices. These supplies, which include medical devices, are those that have been determined by the HHS Secretary to be "appropriate and practicable" for optimizing the health security of the U.S. during a public health emergency.[9] The Centers for Disease Control and Prevention (CDC) leads the procurement of medical countermeasures for the Strategic National Stockpile.

Distribution

The Secretary of Transportation will be able to require air carriers that receive loans and loan guarantees under the CARES Act to continue scheduled transport to help provide medical devices, drugs, and other necessary care. This is meant to close supply chain gaps in rural areas. The Secretary of Transportation's authority under this section expires on March 1, 2022.[10]

[9] CARES Act Sec. 3102
[10] CARES Act Sec. 4005