Hogan Lovells

The Defense Production Act and the PREP Act: Key tools in the fight against COVID-19

20 March 2020

As the coronavirus (COVID-19) pandemic rapidly evolves, the United States faces unprecedented needs, which are quickly challenging existing supplies and disrupting supply chains. Having already declared a National Emergency, the Trump Administration has begun to activate emergency contracting measures that can be used to procure goods and services needed to fight the virus, including the Defense Production Act of 1950 (DPA) and the Public Readiness and Emergency Preparedness Act (PREP Act), as described further below.

The DPA and Executive Order on prioritizing and allocating health and medical resources to respond to the spread of COVID-19

On 18 March 2020, the President issued an Executive Order (EO) on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19. The EO invokes the DPA, as amended (50 U.S.C. 4501 et seq.), which is a statute that allows the President to (1) require companies to offer priority treatment to certain orders that are issued in support of national defense and energy programs, and (2) allocate certain materials, facilities, and services to further national defense and/or energy needs. Title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) has extended the DPA's priorities and allocations authority to the area of emergency preparedness activities.

Specifically, the EO determines that personal protective equipment and ventilators, as well as other health and medical resources that may be identified by the Secretary of Health and Human Services (HHS), are "scarce and critical material[s] essential to the national defense" such that the Presidency can exercise its powers under the DPA to control the general distribution of such materials in the marketplace. In doing so, the EO requires prioritization of so-called "rated orders," as described below. It also permits the Secretary to determine the proper nationwide priorities and allocation of all health and medical resources, including controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 within the U.S.

Beyond the EO, many government contractors already hold contracts subject to the DPA and its implementing regulations. As the nation's efforts to combat the COVID-19 evolve, the government may consider an even broader application of the DPA.

So what does this mean for government contractors? Essentially, the U.S. government can require that manufacturers of ventilators, personal protective equipment, and other medical resources as identified by HHS fill government orders before commercial orders.

The government may exercise this authority through the use of "rated orders," which are priority ratings that are assigned to certain government contracts. Notably, rated orders may be issued even to those companies that do not currently hold a government contract. In addition, the DPA allows the government to issue "allocation" orders "when there is insufficient supply of a material, service, or facility to satisfy national defense requirements through the use of the priorities authority or when the use of the priorities authority would cause a severe and prolonged disruption in the supply of materials, services, or facilities available to support normal U.S. economic activities." See 15 C.F.R. § 730(a).

Rated orders

Under the Defense Priorities and Allocation System (DPAS), which are the implementing regulations for the DPA, certain federal agencies such as DOD, DOE, HHS, USDA, and DOT may issue a rated order that is classified as one of two categories – a "DX" rated order and a "DO" rated order. A program identification symbol showing the approved program will follow the DO or DX rating. See 15 C.F.R. § 700.11. All DO rated orders have equal priority with each other and take precedence over any unrated order, such as a commercial order. DX rated orders also have equal priority among themselves but take precedence over both unrated orders and DO rated orders.

In order to activate the priority provisions of the DPAS, a rated order must include certain key elements, including a required delivery date. Where the order is placed for the purpose of emergency preparedness requirements and expedited action is necessary or appropriate, the order must also include the following language: "This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within [insert a time limit no less than the minimum applicable time limit specified in §700.13(d)(2)]." See 15 C.F.R. § 700.12.

Assuming that a rated order meets these requirements, the DPAS requirements are triggered. These include:

a) Mandatory acceptance of the order (absent application of limited exceptions).

b) Priority scheduling (operations must be scheduled in such a manner as to ensure compliance with the delivery date of a rated order. Essentially, DO rated orders must be given preference over unrated orders and DX orders must be given preference over DO and unrated orders).

c) Mandatory extension (this concept refers to placing rated orders with one's suppliers to ensure receipt of items needed to fill the rated order).

As noted, there are limited circumstances under which a contractor can reject a rated order. However, a contractor has only a limited period of time in which to determine whether an exception applies. An accept/reject decision must be made within 15 working days of the receipt of a DO rated order and within 10 working days of the receipt of a DX rated order. See 15 C.F.R. § 700.13(d).

Allocation orders

Allocation orders may be utilized when there are insufficient supplies to meet national defense requirements. Allocation orders may not be used to control distribution of material in the civilian market unless: (1) the material is both scarce and critical to the national defense, and (2) national defense requirements cannot be met without a disruption of the normal supply chain that would result in "appreciable hardship." See 15 C.F.R § 700.32.

Allocation orders can take several different forms. First, are "set-asides" that require a company "to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders." See 15 C.F.R. § 700.33. Second, are "directives" that require a company "to take or refrain from taking certain actions in accordance with its provisions. For example, a directive can require a person to: stop or reduce production of an item; prohibit the use of selected materials, services, or facilities; or divert the use of materials, services, or facilities from one purpose to another." Id. Third, are "allotments" that specify "the maximum quantity of a material, service, or facility authorized for a specific use to promote the national defense." As is the case with rated orders, allocations can be rejected in limited circumstances.

PREP Act

The PREP Act authorizes the Secretary of HHS to issue a declaration that provides immunity from claims resulting from the administration or use of countermeasures to address public health emergencies. The PREP Act offers the Secretary considerable discretion in identifying and declaring public health emergencies, as well as in crafting a focused declaration that is limited to specific countermeasure development activities. Any disease, health condition, or other threat to health may constitute a public health emergency. Prior occasions on which the Secretary has invoked the PREP Act include countermeasures related to Anthrax, Zika, and Ebola.

After making a determination that a disease or health condition constitutes a public health emergency, the PREP Act authorizes the Secretary to make a formal declaration identifying a covered countermeasure to combat the condition, specifying the recommended activities relating to the covered countermeasure, and naming the covered persons who will receive immunity for engaging in those specified activities. A "covered person" includes manufacturers and distributors of covered countermeasures. See 42 U.S.C. § 247d-6d(h)(2).

On 4 February 2020, HHS issued a PREP Act declaration for medical countermeasures against COVID-19. Under the declaration, the Secretary expressly extended the PREP Act's liability immunity to activities such as the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures. "Covered countermeasures" are defined broadly to include "qualified pandemic or epidemic products," or "security countermeasures," or "drugs, biological products, or devices authorized for investigational or emergency use."

The effect of the declaration is to extend liability immunity to those engaging with the government through (1) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (2) activities authorized in accordance with the furthering the public health during an emergency.

The DPA and the PREP Act are designed to optimize the role of existing government contractors and private companies in the current state of emergency. These emergency authorities can and do raise complex questions for both existing government contractors and commercial companies. If you have any questions about how use of these expanded procurement tools may affect your company, please do not hesitate to contact the Government Contracts team.

Contacts

Michael J. Vernick
Partner, Washington, D.C.
T +1 202 637 5878
mailto: michael.vernick@hoganlovells.com

Michael F. Mason
Partner, Washington, D.C.
T +1 202 637 5499
mailto:michael.mason@hoganlovells.com

Marta A. Thompson
Senior Associate, Washington, D.C.
T +1 202 637 6562
marta.thompson@hoganlovells.com

Annie D. Vanselow
Senior Associate, Washington, D.C.
T +1 202 637 5592
annie.vanselow@hoganlovells.com