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Defense Production Act

A webinar discussing the basics of the Defense Production Act and its application to the medical technology industry

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Introduction

Thank you for joining today's Webinar on the Defense Production Act. The Reed Smith attorneys who have prepared today's materials are:

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Overview: Defense Production Act

The Defense Production Act of 1950 (“DPA”):

- Initially passed during the Korean War
- Originally for the purpose of ensuring military capability and readiness.
- It has since been expanded to address a variety of national emergencies.
- Most familiar to federal contractors as a result of the priorities and allocations authority that is implemented by the Defense Priorities and Allocation System (“DPAS”).
- DPA is regularly re-authorized and is presently authorized through September 30, 2025.

The DPA provides the President of the United States with broad authority to:

- Manage national defense preparedness programs
- Maintain and enhance the domestic industrial base.
- Authority is delegated through Executive Order 13603 to various department and agency heads.

We have DPA because, according to Congress:

The security of the United States is dependent on the ability of the domestic industrial base to supply materials and services for the national defense and to prepare for and respond to military conflicts, natural or man-caused disasters, or acts of terrorism within the United States, and to ensure the vitality of the domestic industrial base.

Overview (cont'd)

DPA applies to US Companies:

The DPA applies only to US Companies. US companies need to pay close attention to foreign companies in their supply chain.

Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of Covid-19 (Issued March 18, 2020)

- Delegates expanded authority to HHS to require performance of contracts or orders; to allocate materials, services, and facilities; to determine nationwide priorities and allocation of all health/medical resources, including the distribution of materials and applicable services in the civilian market, and provides for the issuance of orders and establishment/revision of rules and regulations to effect this authority.

Key Authorizations under the DPA

The DPA authorizes the President of the United States and delegates to take several actions, the most common of which are:

- **Prioritizations:** Subchapter I (aka Title I) - To prioritize the performance of certain contracts and orders (other than contracts of employment) to promote the national defense.
- **Expansion of Productive Capacity and Supply:** Subchapter II (aka Title III): To reduce current or projected shortfalls of certain resources, items, or materials needed for national defense purposes, through the use of, among others, loan guarantees and purchase commitments.
- **General Provisions:** Subchapter III (aka Title VII): Authority to establish regulations and orders, create voluntary agreements with private industry, block actions that threaten national security such as proposed or pending foreign corporate mergers, acquisitions, or takeovers, and employ and/or establish a volunteer pool of industry executives who could be called to government service in the interest of the national defense.

The DPA contains other authorities which are less common, for example:

- **Allocation Authority:** Allocate or control materials, services, facilities (and perhaps technical data) in any manner needed for the National Defense. Wage and price controls possible, but requires joint resolution of Congress. Not used since Cold War.
- **Loan Authority:** Direct loans and loan guarantees to address prospective shortfalls. Not used for 30 years.
- **Experts / Industry Agreements:** President may employ experts and enter into voluntary agreements with industry.

How Key Authorizations are Invoked:

DPA Authorities Are Invoked in Various Ways:

Prioritizations: Contracts are issued as “rated orders”. Two levels of priority ratings: “DO” (lower priority) and “DX” (higher priority). DO orders must be prioritized over nonrated orders. DX orders take priority of DO orders. Contractors must accept and fill rated orders by the delivery date demanded or promptly communicate a date the order can be filled, or explain why they cannot fulfill the order. Orders must be accepted or rejected within 15 working days of receiving a DO-rated order, or 10 working days of receiving a DX-rated order. Rated orders flow through the supply chain.

Purchase Commitments: President makes a non-delegable determination that there is a “domestic industrial base shortfall” for a particular industrial resource, material, or critical technology item that threatens the national defense and that purchase commitments or other actions are required to meet the need. Projects costing more than \$50 million (cumulative) requires Congressional authorization, and 30 day notice for comments. President can waive the determination and notification provisions in periods of national emergency or in similar critical situations.

General Authorities: The general authorities provided under Subchapter III of the DPA, have varying procedures described in the DPA. For example, the authority to establish regulations, procedures, or forms are to be issued pursuant to section 25 of the Office of Federal Procurement Policy Act and must conform to any government-wide procurement policy or regulation issued pursuant to section 6 or 25 of that Act.

How has DPA Authority been Used?

Priorizations:

- Authority is delegated to 6 different Cabinet secretaries via Executive order 13603. Priorities authority may be shared by other federal agencies.
- Prioritizations are routinely used by the Department of Defense.
- DPA authority is also used by civilian agencies such as FEMA, to respond to natural disasters through the prioritization of contracts for products such as food and bottled water, and restoration of electrical services.
- Typical prioritizations involve contracts for materials, services, and the like that are assigned priority ratings that prioritize performance under the contract for the purpose of national defense. Contracts of employment are excluded.

Purchase Commitments:

- The DOD report on its annual industrial capability states:
 - DOD actively manages a portfolio of over \$1B in combined government investment and industry cost-share.
 - In 2017, the DOD actively managed 22 projects and oversaw 7 projects in the monitoring phase. Three projects were completed, eight projects were in active acquisition, and seven projects were explored as potential future efforts. Details unavailable due to classification.

DPA, COVID-19 & Medical Technology

DPA has not, prior to COVID-19, previously been used to address public health emergencies

- By analogy, in 2014, DOD was granted authority by the Secretary of HHS to place priority ratings on orders for the Adenovirus vaccine.
- On March 4, HHS announced that it would use DPA authority to purchase 500 million N95 respirators for the Strategic National Stockpile.

The President invoked DPA on March 18, 2020 in response to COVID-19:

- Likely use will include speeding the acquisition and/or production of technology that is necessary to confront COVID-19, such as the production of equipment such as ventilators, as well as the production of supplies such as face masks, gloves, and gowns.
- This could be accomplished through the issuance of prioritized orders which must be accepted and filled, unless certain exceptions apply. Also may involve issuance of purchases and purchase commitments.
- The use of other authorities such as allocations authority, is used less often and, accordingly, there is less experience as to how these authorities would be used in the Medical Technology Industry.

Limitations on the use of DPA authority

- DPA authority cannot be used to control wages or prices (such as for protective equipment or vaccines) unless it is accompanied by a joint resolution of Congress;
- Budget authority for loans must be included in an appropriations act passed by Congress;
- Projects established under 50 U.S.C. 4533 that exceed \$50M must be authorized by Congress and provide a 30 day notice period for comments. President has ability to waive during national emergencies.

DPA & HHS

Executive Order 13603 (Issued March 16, 2012)

- Delegates authority to issue rated orders to HHS, as well as permits rated orders to other agencies, including DOD, DHS, and Department of Commerce.

HHS Prioritized Orders:

- HHS has issued Health Resources Priority and Allocations System (HRPAS) regulations to implement its authority to issue rated orders.
- See Interim Final Rule at <https://www.federalregister.gov/documents/2015/07/17/2015-17047/health-resources-priority-and-allocations-system-hrpas>
- This authority can be, but has not yet been delegated to other agencies.

HHS Purchase Commitments:

- HHS announced, on March 4, 2020, that it would use its authority under the DPA to procure supplies for the Strategic National Stockpile and purchase 500 million N95 respirators

Risks and Benefits to Medical Device Companies

Prioritizations:

- Medical technology contractors should check their contracts to understand if they are issued with priority ratings
- Failure to abide by the terms of a rated order, may result in severe penalties for contractors, particularly if the failure was willful. See Section 4513 of the DPA which provides: “[a]ny person who willfully performs any act prohibited, or willfully fails to perform any act required, by the provisions of this subchapter or any rule, regulation, or order thereunder, shall, upon conviction, be fined not more than \$10,000 or imprisoned for not more than one year, or both.”
- Compliance with DPA rules carries with it liability protection. See Section 4557 of the DPA which provides: “No person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this chapter, notwithstanding that any such rule, regulation, or order shall thereafter be declared by judicial or other competent authority to be invalid.”

Purchase Commitments:

- The DPA may provide fast-moving opportunities for medical device companies to increase business with the Federal government. For example, the HHS effort to procure N95 Respirators was opened on March 4, 2020, with proposals due by March 18, 2020
- Purchase commitments can help the medical technology industry increase production capacity

Increased Cost of Performance: Invoking prioritization under the DPA may increase cost of performance. Medical device companies should monitor and track, and request equitable adjustments if necessary.

Delays on Non-Rated Orders: Exercise of prioritization and other authorities may result in delays on non-rated orders. Medical device companies should check contracts for excusable delay provisions, and will need to advise COs and mitigate where possible.

Other Considerations

Export Controls

Foreign Investment Controls

Questions?

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