



Presidential Executive Order Calls on HHS to Issue Priority Contracts and Allocate Scarce Medical Resources

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On March 18, 2020, the President issued an Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19 (the “EO”). The EO was issued pursuant to the Defense Production Act of 1950 (50 U.S.C. §4501 *et seq.*) (“DPA”), which allows the President to invoke special Federal Contracting powers to address shortages in medical resources needed to respond to the COVID-19 pandemic. The EO specifically mentions personal protective equipment and ventilators as necessary to curb the spread of COVID-19, but also delegates authority to the Secretary of Health and Human Services (“HHS”) to identify additional necessary health and medical resources such as drugs, medical devices, health supplies, and health services and equipment.

The DPA allows the executive branch to increase and allocate production of such critical supplies, as well as the provision of services, necessary for the “national defense,” which broadly encompasses public health emergencies. Accordingly, the President (or his Delegate) has the authority to require companies to prioritize the fulfillment and delivery of specific Government orders deemed to be “priority rated” orders over unrated Government orders and orders from commercial entities or state and local governments. It also allows for “allocation orders,” which are meant to control the distribution of supplies and services in the name of national defense. The EO is most likely to impact companies that hold contracts with HHS, the VA, and the Defense Health Agency.

The following set of FAQs breakdown the DPA and HHS implementing regulations. (The HHS regulations can be found at 45 C.F.R. § 101.) We hope this provides a better understanding of HHS’s priority rating and allocation system and what may be required of companies that receive rated orders or allocation orders pursuant to the EO.

What types of orders might I receive based on the EO?

The regulations describe two types of orders: (1) priority rated orders and (2) allocation orders. Each is described in detail below.

What is a priority rated order (or “rated order”)?

A rated order is an order for supplies or services that requires the recipient to prioritize fulfillment and delivery of the order over unrated orders placed by the Federal Government, state and local governments, or commercial entities. A rated order may be placed by a Government Agency, a higher tiered Federal Contractor, or another person with authority to place such order.

What are the levels of priority?

There are two levels of priority for rated orders: DX and DO.

All DO-rated orders have equal priority with each other and take precedence over all unrated orders.

All DX-rated orders have equal priority with each other and take precedence over all DO-rated orders and all unrated orders.

Note, however, that if HHS issues a “Directive” (discussed below) it will take priority over all DO- and DX-rated orders.

What does a rated order look like?

A rated order must include the following four elements:

- (1) Appropriate priority rating. Note that, in addition to a priority rating, a rated order will also be given a program identification symbol, such as “HR.” Thus, a rated order will be designated, for example, “DO-HR” or “DX-HR.”
- (2) The required delivery date(s). In general, this must be a specific date or dates. The words “immediately” or “as soon as possible” do not constitute a delivery date, however a “requirements contract” without a specific delivery date or dates may be sufficient if the associated purchase orders specify a required delivery date or dates.
- (3) Signature of authorized individual.
- (4) Certification Statement. A rated order must contain a statement that reads in substance: “This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System Regulation at 45 CFR Part 101.”

A purchase order may combine DX- and DO-rated orders from one customer or several customers if clearly stated. A purchase order may also combine rated and unrated order quantities if clearly stated and if the four elements of a rated order are included.

What should a company do when it receives a rated order?

Except in certain limited circumstances discussed below, a company **must accept** every rated order it receives and must fill every rated order regardless of any other rated or unrated orders that it already has accepted.

Further, a company may not discriminate against orders by, for example, charging higher prices or imposing different terms and conditions than for unrated orders.

When can a company reject a rated order?

Under certain limited circumstances, a company may be required or may choose to reject a rated order.

Mandatory rejection: A company **must reject** a rated order for delivery on a specific date if (1) the company is unable to fill the order by that date; or (2) accepting the order would interfere with the delivery of another previously accepted rated order. In these circumstances, however, the company must offer to accept the order based on the earliest delivery date otherwise possible.

Optional rejection: A company **may reject** a rated order under certain circumstances, including when (1) the person placing the order is unwilling or unable to meet the terms of the sale or payment; (2) the order is for an item not supplied or a service not performed in the normal course of business; (3) the order is for an item or service only for the supplier's own use, and no orders have been filled for two years prior to the date the rated order was received; (4) the person placing the order (if not the U.S. Government) makes the ordered item or performs the ordered service; or (5) acceptance of a rated order would violate any other law or regulation.

What are the time limits for accepting or rejecting a rated order?

DO and DX Orders: Generally, a company must accept or reject a DO order within **15 working days** after receipt of the order and must accept or reject a DX order within **10 working days** after receipt of the order. If the order is rejected, the company must provide reasons for the rejection.

If a company accepts a rated order and subsequently learns shipment or performance will be delayed, the company must immediately notify the customer and advise of a new shipment date.

Emergency Response Conditions: If the rated order is placed for the purpose of emergency preparedness, the company must accept or reject a rated order within **two days** after receipt if (1) the order is in response to a "hazard" that has occurred, or (2) the order is issued to prepare for an imminent "hazard." For such rated order, the Certification Statement on the order will include the following language: "This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within two (2) days after receipt of the order if: (1) The order is issued in response to a hazard that has occurred; or (2) The order is issued to prepare for an imminent hazard, as specified in 45 C.F.R. § 101.33." *Note: Hazard is defined in the regulations as "an emergency or disaster resulting from (1) a natural disaster; or (2) an accidental or human-caused event."*

What if my company requires additional supplies or material from another supplier in order to fulfill the rated order?

A company must use rated orders – with the priority rating indicated in the customer’s order – to obtain items or services from a supplier where such items or services are needed to fulfill a rated order. The priority rating from the original customer’s order must be used in each successive order in the supply chain if the items or services ordered are to be used to fill a customer’s rated order.

How should a company proceed once it has accepted a rated order?

When a company accepts a rated order, the company must schedule operations, including the acquisition of items needed to produce the items, in a timely manner in order to satisfy the rated order’s delivery requirements.

Can a rated order be changed or cancelled?

Yes. HHS or the originating agency that placed the rated order may change or cancel the order. If a company no longer needs items or services to fill a rated order, any rated orders placed with suppliers for such items or services must be cancelled.

If a priority rating is added to an unrated order, or is changed or cancelled, all suppliers must be promptly notified in writing.

What if a conflict arises between a company’s rated orders?

The regulations provide procedures for companies to follow when delivery or performance against any accepted rated orders conflicts with the delivery or performance against other rated orders of equal priority status. In such circumstances, the company must give precedence to the orders in the sequence in which they are to be delivered/performed (not to the receipt dates). However, if the orders are to be delivered on the same day, the company must give preference to the order that was first received.

If a company is unable to resolve the conflict, it must promptly seek special priority assistance from HHS.

If a company is unable to purchase production items needed in time to fill a rated order by the required delivery date, it must fill the rated order using production items in its inventory and may use a rated order to replace such items.

What if my company runs into other issues with fulfilling a rated order?

HHS provides special priorities assistance to help companies expedite deliveries, resolve delivery conflicts, place rated orders, locate suppliers, or verify information supplied by customers and vendors, among other things. To obtain special priority assistance, a company must submit a timely request to the Secretary of HHS.

What is an “allocation order”?

An allocation order is an order to control distribution of supplies or services in order to promote national defense. An allocation order, when used, will be distributed equitably among suppliers of the materials, services, or facilities being allocated. Therefore, no company will be required to relinquish a disproportionate share of the civilian market.

There are three types of allocation orders: (1) a **set-aside order** requires a company to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders; (2) a **directive order** requires a company to take or refrain from taking certain actions in accordance with its provisions (e.g., stop production of an item); and (3) an **allotment order** specifies the maximum quantity of a material, service, or facility authorized for a specific use.

What does an allocation order look like?

An allocation order must include the following five elements:

- (1) Detailed description of required allocation actions.
- (2) Specific start and end calendar dates for each required allocation action.
- (3) Signature of the Secretary of HHS.
- (4) Certification Statement that reads in substance: “This is an allocation order certified for national defense use. [Company] is required to comply with this order, in accordance with the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR part 101, subpart A), which is part of the Federal Priorities and Allocations System.”
- (5) Current copy of the Health Resources Priorities and Allocations System regulation.

Is compliance with an allocation order mandatory?

Yes. A company is required to accept and comply with every allocation order received. If compliance is not possible, the company must immediately notify the Secretary of HHS and explain why compliance is not possible. This notification to the Secretary does not relieve a company from working to comply with the order to the fullest extent possible. Changes or cancellations of an allocation order can be made by official action of HHS.

What is a “Directive”?

A “Directive” is a separate official action taken by the Government that requires a company to take or refrain from taking certain actions. Compliance with a Directive is mandatory.

A Priorities Directive takes precedence over all DX- and DO-rated orders, as well as all unrated orders (unless the Directive provides instructions to the contrary).

An Allocations Directive takes precedence over all Priorities Directives, all DX- and DO-rated orders, and all unrated orders (unless the Directive provides instructions to the contrary).

What happens if a company fails to comply with the DPA or relevant regulations?

Any company who places or receives a rated order must comply with the DPA and relevant regulations, including the HHS regulations at 45 C.F.R. § 101. Willful violation of the provisions is a criminal act that may be punished under the DPA and/or by fine, imprisonment, or both. Additionally, the Government may seek an injunction to prohibit the continuance of any violation of, or to enforce compliance with, the DPA, applicable regulations, or an official action. The regulations also provide for Government audits and investigations to ensure the provisions are being followed.

Are there any special benefits for companies who fulfill rated orders?

Possibly. In order to reduce current or projected shortfalls of industrial resources, technology, or materials essential for the national defense, the DPA authorizes the President to provide loans to private businesses for the creation, maintenance, expansion, protection, or restoration of capacity, the development of technological processes, or the production of essential materials. See 50 U.S.C. § 4532.

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