COVID-19: PROTECTING CRITICAL HEALTH RESOURCES TO PREVENT THE SPREAD OF COVID19: PRESIDENT TRUMP'S EXECUTIVE ORDER GIVES HHS SECRETARY AZAR BROAD SUPPLY CHAIN AUTHORITY

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U.S. Health Care and Government Contracts Alert

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On Wednesday, President Trump issued an Executive Order ("E.O.") granting broad control to U.S. Health and Human Services ("HHS") Secretary Alex Azar over the production and distribution of health resources needed to prevent the spread of COVID-19.[1] The President issued the E.O. pursuant to the Defense Production Act of 1950 (the "DPA"), a federal law that authorizes the President to prioritize and/or allocate resources necessary and appropriate to promote the national defense, including providing for the protection of critical infrastructure under emergency conditions.[2]

Specifically, the E.O. delegates Presidential powers under 50 U.S.C. § 4511 to Secretary Azar, granting him the authority: (i) to determine "proper nationwide priorities and allocation of all health and medical resources," including controlling the distribution within the market of materials and services necessary to respond to COVID-19 and (ii) to resequence or accelerate the performance of certain contracts or orders that further the ability of our health care system to respond to COVID-19, over the performance of other contracts or orders.

The DPA provides Secretary Azar two main mechanisms through which to increase the availability of critical items in response to the COVID-19 emergency: "rated orders" or "allocation orders." First, the Secretary may act to place a "rated orders," which would "require preferential acceptance and performance of contracts and orders supporting certain approved national defense and energy programs and to allocate materials, services, and facilities in such a manner as to promote these approved programs."[3] Alternatively, or additionally, the Secretary may seek to place "allocation orders," which would require companies to "allocate materials, services, and facilities" in the manner(s) deemed necessary by the Secretary.[4] The applicable regulations that govern the means by which the Secretary may carry out this delegated authority are detailed in HHS's implementing regulations, the Health Resources Priorities and Allocation Systems (the "HRPAS").[5] Specifically how Secretary Azar chooses to act pursuant to the HRPAS remains to be seen.

Through the E.O., the Administration aims to ensure that critical health and medical resources needed to allow our health care system to surge capacity and capability are distributed where and when needed. Although specifically referencing personal protective equipment and ventilators, the E.O. suggests that all "health and medical resources needed to respond to the spread of COVID-19" meet the criteria under the Act. In other words, resources that fit the bill may be ones that are scarce and critical to the national defense, and that sufficient

availability of these resources cannot be met without creating "a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship."[6] Moreover, the E.O. allows the Secretary to identify additional specific health and medical resources that meet the "critical and strategic materials" requirement of section 4511(b) of the Act.

In furtherance of this authority, the Secretary must, as appropriate and to the extent practicable, consult with other federal agency heads, and must issue final rules that establish standards and procedures that implement the priorities and allocation authority.[7] As of now, the Secretary has not announced next steps pursuant to the newly-delegated authority. While it is unclear at present how, and how quickly, the Secretary intends to implement this authority, we will continue to monitor and report developments as information becomes available.

K&L Gates' government contracts and procurement policy team previously issued an Alert addressing some of the specifics of government contractor, subcontractor, and supplier rights and obligations when performing under DPA rated orders issued by the Department of Defense (the "DOD") and implemented through the Defense Priorities and Allocation System (the "DPAS"). We note that HHS rated orders issued pursuant to the HRPAS operate substantively and procedurally in a very similar manner to DOD rated orders issued pursuant to the DPAS.

K&L Gates' health care and government contracts teams continue to monitor the emerging impacts of COVID-19 on performance rights and obligations, including impacts associated with invocation and implementation of the DPA.

[1] Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of Covid-19 (Mar. 18, 2020), *available at* https://www.whitehouse.gov/presidential-actions/executive-order-prioritizing-allocating-health-medical-resources-respond-spread-covid-19/.

[2] 50 U.S.C., Title 50, Ch. 55.

[3] 50 U.S.C. § 4511(a).

[4] Id.

[5] 45 CFR Part 101.

[6] 50 U.S.C. § 4511(b).

[7] *Id.* § 4511(d).

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