

HHS DPA Authorities

- The Secretary of HHS has priority and allocation authorities for “Health Resources”
- Per EO 13603, “Health Resources” are defined as:
 - “drugs, biological products, medical devices, materials, facilities, health supplies, services, and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.”
- Health Resource Priorities and Allocation System (HRPAS) is the system of priority and allocation regulations issued by HHS
 - Same key features as DPAS
- Established as an interim final rule in July 2015

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HRPAS Approved Program Determinations

- Pharmaceuticals and biological related products required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Health, medical, and safety supply chains to ensure protection and restoration of activities deemed part of the healthcare and public health critical infrastructure sector.
- Health related equipment, devices, and material required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Vaccines including development, procurement and distribution operations required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Mental Health Care required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Mitigation Measures required to ensure that required health resources are available to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Facilities to ensure protection and restoration activities deemed part of the healthcare and public health critical infrastructure sector.
- Personal Protective Equipment required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act.
- Miscellaneous category for health resource activities and measures not addressed in other approved programs that are required to support emergency preparedness activities conducted pursuant to title VI of the Stafford Act or critical infrastructure protection and restoration.

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PRE-COVID-19 Use of DPA Authorities by HHS

- Very limited use of DPA authorities by the Secretary of HHS
 - HHS is the only Department that has not further delegated priority rating authority within the Department.
- 2009: HHS Secretary priority rated a BARDA contract for ancillary supplies in support of the 2009 H1N1 response
- 2017: HHS Secretary priority rated a durable medical equipment contract in support of FEMA hurricane response

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DPA Use for COVID-19 Response: Spring-Summer 2020

- Initial use was directed by Executive Orders
 - Priority ratings were applied to USG contracts to procure ventilators and personal protective equipment (PPE)
- EO 13911, issued March 2020, conditionally granted DHS equivalent DPA authorities for “health resources” for COVID-19 response efforts.
 - In April 2021, a MOU was signed by HHS and FEMA to coordinate and centralize use of all DPA authorities.
 - This MOU designated FEMA as the lead federal agency to determine when and how to utilize DPA authorities.
 - From April through September 2020, HHS and other Departments and Agencies submitted priority rating requests for health and medical resources through the FEMA DPA office to the FEMA Administrator.

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HHS Use of DPA for COVID-19 Response: Summer 2020

- In June 2020, HHS/ASPR created the Defense Production Act – Emergency Response Authorities (DPA-ERA) Office
 - This Office leads and centralizes all HHS DPA-related activities for the Department
 - Since MOU with FEMA expired in September 2020, the DPA-ERA Office has led and managed COVID (and non-COVID) DPA activities
- HHS/ASPRs DPA-ERA Office:
 - Established process for reviewing requests for priority rating authorization
 - Served as subject matter experts for advising on DPA and priority rating action
 - Established templates and process for routing and coordinating requests for Secretary review and approval
- Summer and fall 2020, priority ratings were primarily applied to USG contracts developing COVID-19 vaccines, therapeutics, and diagnostics.

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HHS Use of DPA for COVID-19 Response: 2021 - Present

- Fewer priority ratings were issued; many active ratings were rescinded when no longer required to manufacture COVID response supplies.
- In March 2021, DPA-ERA Office was tasked by EOP and HHS Leadership to review and triage requests from private sector partners experiencing challenges procuring raw materials and critical supplies needed to manufacture **COVID and non-COVID lifesaving therapies and medical devices**.
 - To date, the HHS/ASPR DPA-ERA Office has received, reviewed, and triaged hundreds of requests from domestic and international medical manufacturers.
 - HHS/ASPR DPA-ERA Office convenes SMEs from across HHS (and other Departments as appropriate) to review requests, develop recommendations for adjudication, and provide daily briefings of the COVID Interagency Coordination Team, led by EOP.
 - HHS/ASPR continues to refine and harmonize its new supply chain capabilities and associated portfolio.

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Overview of HHS use of DPA for COVID-19

- To date, HHS has issued 70 DPA Title I priority ratings under HRPAS and/or DPAS to support the COVID-19 response
 - 54 priority ratings for USG contracts for health resources (HRPAS)
 - For ventilators; PPE; needles/syringes; vaccines; diagnostics; therapeutics; swabs
 - 10 priority ratings for USG contracts for manufacturing expansion (DPAS)
 - For vaccine manufacturing; vaccine distribution; diagnostic manufacturing expansion; N95 manufacturing expansion; glass vial production expansion
 - 6 priority ratings under *Special Priorities Assistance* for non-USG contracts/purchase orders that indirectly supported the COVID-19 response
 - For COVID-19 diagnostics (x2); Closed suction catheters; CADD infusion pumps; Arterial Blood Sampling Kits; Tracheostomy Tubes

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Lessons from COVID-19

- During the COVID-19 pandemic, the supply chain saw significant disruption when global demand for critical material increased, and manufacturing levels simultaneously decreased
- These trends resulted in competition for limited quantities of needed supplies – the U.S.:
 - Struggled with pandemic response, woefully deficient stockpiles and inability to quickly increase industrial capacity
 - Lacked the national policies to support the allocation and distribution of scarce resources, and to support rapid and sustained manufacturing
- Decades of globalization and lean, just-in-time resourcing has led to a supply chain that could not meet U.S. or global demand during the COVID-19 pandemic
- COVID-19 supply chain challenges exposed the U.S.'s reliance on foreign manufacturing and lack of domestic manufacturing capabilities

- Effective response requires a resilient public health supply chain, anchored in domestic manufacturing capabilities, so that care and preventive measures can reach patients
- Sustaining the resilience of this supply chain is critical for national security – the U.S. public health supply chain is vulnerable (including medical countermeasures such as drugs, biological products, devices, diagnostics, PPE, and ancillary supplies)

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Infant Formula Response

- Presidential Determination 2022-13 tasked HHS with leveraging priority rating authorities to support domestic needs for infant formula.
- HHS/ASPR DPA-ERA Office has met with over 40 infant formula manufacturers and their suppliers to ensure the availability of raw materials needed to manufacture at capacity.
- Three critical constraints that required priority ratings to ensure domestic production of infant formula
 - Abbott – authorized to issue priority ratings on purchase orders for raw materials (corn byproducts)
 - Reckitt – authorized to issue priority ratings on purchase orders for MCT Oil
 - Cargill – authorized to issue priority ratings on select purchase orders supporting infant formula manufacturers