

Center for Devices and Radiological Health Resilient Supply Chain Program

Collaboration May Foster a Resilient Supply Chain

Coordinated efforts between the federal, state, and local government, nonprofits, the private sector, and the public are critical for addressing complex challenges and achieving impactful outcomes. FDA's Center for Devices and Radiological Health (CDRH) has both led and participated in a variety of supply chain outreach activities with many stakeholders. CDRH continues to work closely with manufacturers, distributors, healthcare delivery organizations, trade associations, patient groups, and professional organizations to better understand supply chain challenges and enhance resiliency.

The Resilient Supply Chain Program (RCSP) aims to strengthen public health supply chains and promote availability of medical devices by proactively monitoring, assessing, and communicating risks and vulnerabilities. Our ability to sustain and leverage ongoing collaborations, as well as build new opportunities for engagement is critical to the success of CDRH's medical device RCSP. It is only through a strong and robust partnership with all sectors of the medical device ecosystem that we will be able to assure patients and healthcare providers have access to safe and effective, high quality medical devices.

Some examples of collaborations among public and private stakeholders that have and can be used to inform supply chain activities include the following:

Healthcare Public Health Sector Joint Supply Chain Resilience Working Group

HHS has engaged experts from the private sector and across the government to share information and best practices, identify threats, and mitigate risks to make U.S. supply chains stronger. The Joint Supply Chain Resilience Working Group provides a mechanism for near-real-time information-sharing and collaboration to tackle steady state and emerging risks and build toward a more agile, visible, and robust U.S. public health supply chain. More than 200 industry and government partners have come together to establish the Joint Supply Chain Resilience Working Group as a formal working group of the Critical Infrastructure Partnership Advisory Council. Through subject-specific task groups of experts, the Joint Supply Chain Resilience Working Group brings together implementation teams, federal experts, and the private sector to achieve three priority objectives: (1) foster information-sharing, (2) collaborate to identify supply chain resilience priorities, and (3) ensure that the path to a more resilient health care and public health supply chain is jointly established by the federal government and industry partners.

Defense Production Act (DPA) 708 Plans of Action

The Federal Emergency Management Agency (FEMA) established a voluntary agreement under the DPA in 2020 for enhanced coordination and cooperation with private sector manufacturers, distributors, and industry representatives to provide critical healthcare resources. The goal of this voluntary agreement is to share pertinent information over the next five years, which will help the federal government work with industry in providing needed Personal Protective Equipment (PPE) and medical resources as quickly as possible during a public health emergency, including during the Sars-CoV2 COVID-19 pandemic. CDRH actively participates in the medical device-



related DPA 708 Plans of Action, which addresses issues including PPE, diagnostic test kits, other medical devices, and national multi-modal healthcare supply chains.

Collaborative Communities

Collaborative communities are continuing public forums where public and private sector members proactively work together to achieve common objectives and outcomes, solve shared challenges, and leverage collective opportunities in an environment of trust, respect, empathy, and openness. Collaborative communities are convened by interested stakeholders and appear "organically" rather than at the direction or request of the FDA. They may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. This mutually beneficial relationship is reinforced by shared responsibility and accountability for achieving results toward common goals.

FDA CDRH currently participates in 12 Collaborative Communities.