

Fact Sheet: Critical Medical Device List (CMDL)

Recommendations to Strengthen the Medical Device Supply Chain

OVERVIEW

In 2021, President Biden issued Executive Order 14001 on a Sustainable Public Health Supply Chain, calling for the government and industry to work together to improve supply chain resilience. In support of this goal, the Food and Drug Administration (FDA) coordinated a collaborative effort to develop a Critical Medical Device List (CMDL) to facilitate resilience through policy, regulatory, procurement, production, and inventory decisions across the medical device ecosystem.

To achieve this, a Task Group of Experts (“Task Group”) was established as part of the Healthcare and Public Health (HPH) Sector Joint Supply Chain Resilience Working Group under the [Critical Infrastructure Partnership Advisory Council \(CIPAC\)](#). The Task Group, representing a diverse set of medical device stakeholders, was convened to develop recommendations for a CMDL to inform actions to strengthen the medical device supply chain. The Task Group was coordinated by the FDA CDRH Resilient Supply Chain Program (RSCP) and leveraged inputs from clinical experts, a multi-stakeholder survey and other subject matter experts.

Task Group members included:

- Device manufacturers
- Distributors
- Group purchasing organizations (GPOs)
- Healthcare systems
- Healthcare providers

KEY RECOMMENDATIONS

Task Group recommendations included:



CRITERIA

3 criteria to identify critical medical devices based on their use in clinical settings



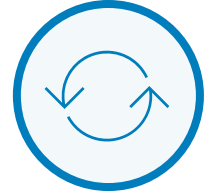
CRITICAL MEDICAL DEVICE LIST

142 device types across 5 clinical functions



RESILIENCE FRAMEWORK

A framework to guide efforts for building resilience across the medical device ecosystem



MAINTENANCE & UPDATES

Scheduled updates every 3 years, as well as out-of-cycle updates

CRITICAL MEDICAL DEVICE LIST

The Task Group identified 142 types of medical devices that met the criteria of a critical medical device. To facilitate use of the list across a broad set of stakeholders, the list was organized by device type—a group of devices with similar clinical use. These device types align with five clinical functions:



Care Delivery

109 Device Types



Clinical Diagnostic Assessment

12 Device Types



Clinical Laboratory Testing

12 Device Types



Infection Control

6 Device Types



Medical Imaging

3 Device Types

Critical Medical Device List (CMDL)

CRITERIA TO DETERMINE MEDICAL DEVICE CRITICALITY

The Task Group recommended criteria that prioritize clinical use of the devices during emergent medical situations and consider the the criticality of medical devices when used for the care of special patient populations (e.g., pediatrics, immunocompromised, pregnant women, etc.). The Task Group's criteria also consider the impact from potential unavailability of the devices.

1. Devices that are intended for use to diagnose, treat, monitor, or prevent a serious disease or medical condition AND
 - Are life-sustaining or necessary to address emergent medical situations AND
 - Unavailability of the device, and a lack of suitable alternatives is reasonably likely to lead to serious injury or death to patients or health care workers

OR

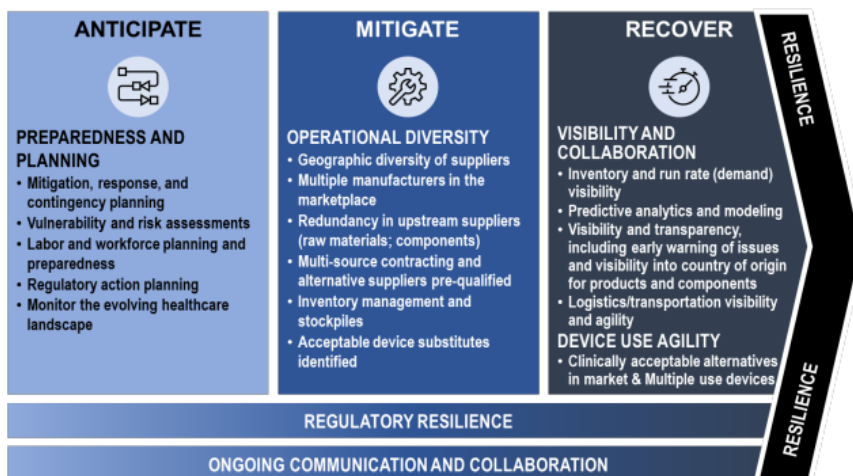
2. Devices expected to see increased demand from treating or diagnosing medical conditions arising from an emergency (e.g., natural disaster, pandemic, or Chemical, Biological, Radiological, Nuclear (CBRN) event) AND
 - Unavailability of the device, and a lack of suitable alternatives is reasonably likely to lead to serious injury or death to patients or health care workers

OR

3. Devices that are intended for use to diagnose, treat, monitor, or prevent a serious disease or medical condition used in care for special patient populations (e.g., children, pregnant women, or people with disabilities) AND
 - Unavailability of the device, and a lack of suitable alternatives is reasonably likely to lead to serious injury or death to patients or health care workers

RESILIENCE FRAMEWORK

The Task Group defined **resilience** as “the ability of the supply chain, in both ordinary and extraordinary circumstances, to sustain and meet clinical demand through anticipating, mitigating, and rapidly recovering from supply chain disruptions.” Using this definition, the Task Group developed a resilience framework that highlights strategies stakeholders should take to build resilience across the medical device supply chain.



MAINTENANCE & UPDATES

The Task Group's recommendations for frequency of updates to the list include:

- **Scheduled updates every 3 years:** Comprehensive review and update to criteria, device list, and framework; and
- **Out-of-cycle updates:** Unscheduled updates for circumstances such as emerging public health threats, clinical practice standard changes, emerging technologies or changes in materials or geopolitical threats.

More details, including the complete CMDL Recommendations Report, are available at <https://files.asprtracie.hhs.gov/documents/critical-medical-device-list-recommendations-report.pdf>.

Please contact us at RSCPShortage@fda.hhs.gov with any questions or comments.