Critical Medical Device List: Summary and Recommendations

September 2023

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Executive Summary

Like most products, medical devices are vulnerable to supply chain disruptions that can be caused by a variety of events (e.g., natural disasters, business failures, recalls). For medical devices, these disruptions, if not mitigated, can lead to shortages in products needed to deliver healthcare and protect healthcare workers. The COVID-19 pandemic highlighted the need for resiliency in the medical supply chain, and, as a result, President Biden issued the Executive Order (EO) on a Sustainable Public Health Supply Chain (EO14001), calling for the government and industry to work together to improve supply chain resilience.[1] The resulting National Strategy for a Resilient Public Health Supply Chain ("National Strategy") provided the vision, goals, and objectives for developing a resilient public health supply chain.[2]

As part of the National Strategy, the government sought to develop a Critical Medical Device List (CMDL) to help government, business, and healthcare leaders focus supply chain resilience resources on those devices where disruptions can lead to serious injury or death to patients or providers. The intent of the CMDL is to facilitate resilience through policy, regulatory, procurement, production, and inventory decisions across the medical device supply chain.

The Critical Infrastructure Partnership Advisory Council (CIPAC) Healthcare and Public Health (HPH) Joint Supply Chain Resilience Working Group established a Task Group of Experts ("Task Group") to recommend a set of criteria for identifying a critical medical device and devices that should be included on a CMDL. The Task Group was also asked to develop recommendations for maintaining the CMDL and a framework for medical device supply chain resilience. The Task Group consisted of 18 members representing medical device manufacturers, group purchasing organizations, distributors, healthcare systems, and healthcare providers.

In developing the CMDL, the Task Group used an iterative process that leveraged input from a broad group of stakeholders through surveys and task group meetings. The Task Group was led by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), which provided logistics and facilitation support as well as access to FDA and external medical device and clinical experts.

The Task Group recommends three criteria, shown in Figure 1, for identifying critical medical devices that are used to prevent serious injury or death to patients or providers in 1) emergent medical situations, 2) emergency events, or 3) the treatment of special patient populations. A medical device would be considered critical if it met any one of the three criteria.

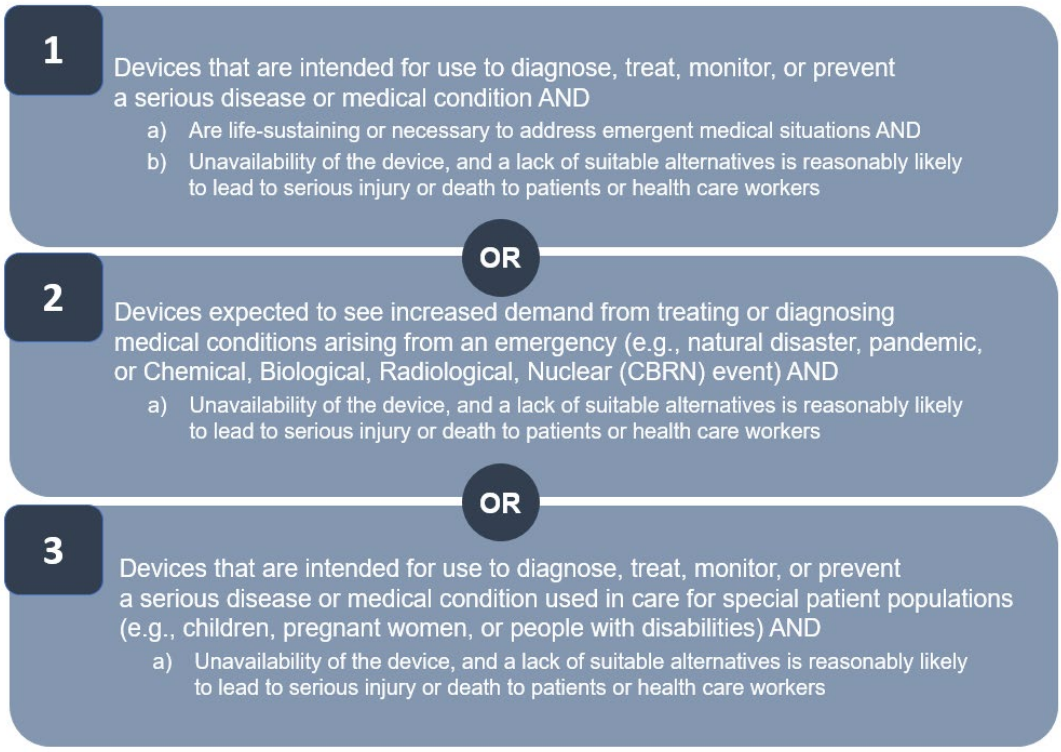

Figure 1. Critical Medical Device List Criteria

Using these criteria, the Task Group recommends 142 medical device types for inclusion on the CMDL. These medical devices are grouped into five clinical functional areas as shown in Table 1.

Table 1. Critical Medical Device List

Clinical Function	Critical Device Types
Care Delivery	109
Clinical Diagnostic Assessment	12
Clinical Laboratory Testing	12
Infection Control	6
Medical Imaging	3
Total	**142**

To understand and improve the resilience of the supply chains for medical devices on the CMDL, the Task Group developed a medical device resilience framework. This framework is based on anticipating, mitigating, and recovering from supply chain disruptions, as shown in Table 2. The resilience framework accounts for vulnerabilities commonly seen in medical device supply chains, such as fragile supply chain structures, rigid regulatory structures, vulnerabilities to disruptive events (e.g., geopolitical, climate, natural disasters), poor supply chain visibility, and proprietary or complex medical devices.

Table 2. Resilience Framework Elements

Anticipate	Mitigate	Recover
Comprehensive assessment of supply chain risks including the likelihood and severity of potential disruptions, ability to respond to disruptions, and vulnerabilities that may affect the supply chain's ability to recover.	Proactive steps to reduce the likelihood of disruptions and minimize their effects, including prepositioned regulatory flexibility, supply chain and contracting redundancy, inventory stockpiles, response planning, etc.	Prepositioned capabilities that improve the ability to respond and recover from a supply chain disruption, including using supply chain visibility to make informed operational and regulatory decisions and employing acceptable alternative medical devices and treatments to deliver care.

Medical device technologies, standards of practice, supply chains, and the healthcare landscape change over time. For that reason, the Task Group recommends the CMDL, and the resilience framework be updated at least every three-years to make sure they reflect the current medical device supply chain and healthcare environment. The Task Group also recommends a process for updating all or portions of the CMDL outside of the three-year cycle in response to emerging threats to public health.

Introduction/Background

The COVID-19 pandemic highlighted the need for a resilient medical product supply chain capable of providing patients and healthcare workers with safe and effective medical products when and where they are needed. During the pandemic, shortages of critical medical products, including medical devices such as respirators, gloves, gowns, ventilators, and test supplies, directly impacted patients and providers. This experience and others have highlighted the need for a proactive effort to prevent supply chain problems before they result in shortages of critical medical devices that negatively impact patient care.

To address these supply chain issues, President Biden issued two executive orders (EOs), Executive Order on a Sustainable Public Health Supply Chain (EO14001) on January 21, 2021, and Executive Order on America's Supply Chains (EO14017) on February 24, 2021.[3] EO14001 called for the creation of a strategy that outlines the U.S. Government's vision to protect the health and security of Americans by ensuring a supply chain for personal protective equipment (PPE), medical devices, medicines, and other public health supplies, that is resilient against disruptions.

The National Strategy for a Resilient Public Health Supply Chain ("National Strategy") was published in July 2021. The National Strategy outlines the vision, goals, and objectives for developing a resilient public health supply chain.

In response to the National Strategy, the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) led an effort to develop recommendations for device types that should be included on a critical medical device list (CMDL).

The CMDL plan of action and milestones (POAM) (Appendix H) set a plan to develop recommendations for: criteria to determine medical devices that should be included on the critical medical device list, a list of critical medical devices, frequency, and triggers for updating the list, and a medical device resilience framework. Furthermore, the POAM stated that the work conducted on this action plan will be facilitated through the Joint Supply Chain Resilience Workgroup (SCRWG), a joint public-private working group of the Healthcare and Public Health (HPH) Sector under the Critical Infrastructure Partnership Advisory Council (CIPAC) framework. The CIPAC framework was established to provide a forum in which government and private sector entities can engage to achieve consensus on policy, advice and recommendations on discrete critical infrastructure protection, security and resilience matters to be presented to the Department of Homeland Security and the Sector Risk Management Agency (SRMA) for each sector (Health and Human Services [HHS] is the SRMA for the HPH Sector). The SCRWG convened a Task Group of Experts (hereafter referred to as the Task Group) to generate consensus recommendations for the deliverables highlighted in the action plan.[4]

In early 2022, the Joint Supply Chain Resilience Working Group (SCRWG) was established under CIPAC. The working group facilitates engagements between government officials and representatives from the HPH sector supply chain owners and operators. The Joint SCRWG charter designates that the working group will coordinate and facilitate discussions and make

recommendations on resilience-building and efforts to strengthen medical device supply chains. The working group will also deliberate and form consensus positions to assist the government in implementing the National Strategy. In order to carry out these functions, the Joint SCRWG has established time-bound task groups that are intended to address specific working group priorities, as determined by the Joint SCRWG Leadership (Figure 2). The development of recommendations for a CMDL was defined as a priority by the Joint SCRWG Leadership and as such, a multi-stakeholder group, the CMDL Task Group was assembled.

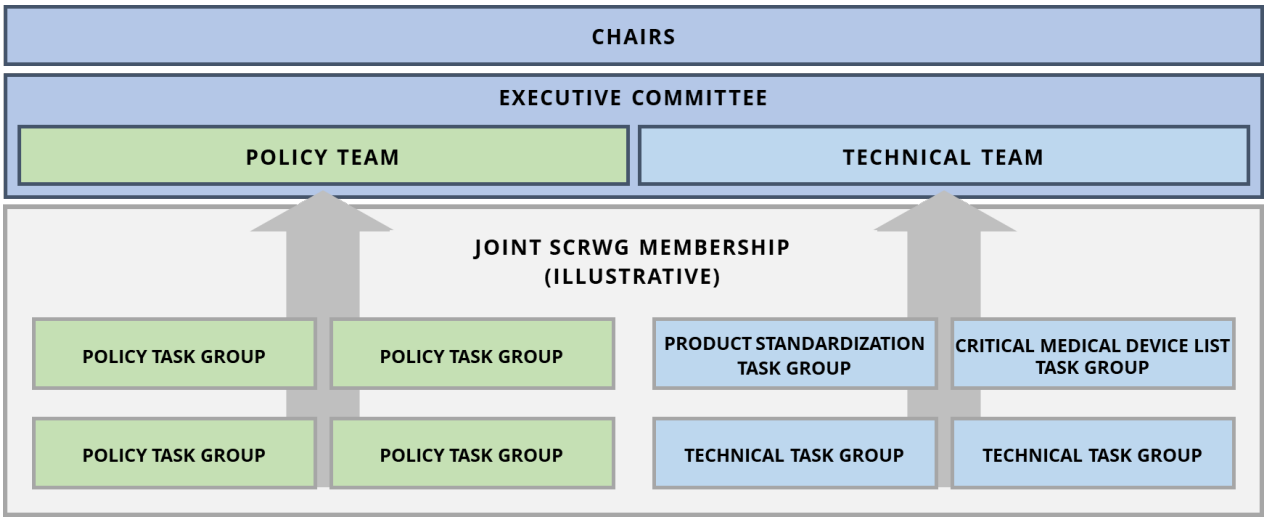

Figure 2. Joint SCRWG Leadership and Task Group Structure

Task Group members represent five medical device stakeholder groups: healthcare providers, healthcare systems, medical device distributors, medical device manufacturers, and group purchasing organizations (GPOs). Stakeholder groups are defined in Appendix L. A list of the Task Group members can be found in Appendix B.

The Task Group convened for the first time in April 2022 and met regularly through October 2023, their work culminating in a set of recommendations for consideration by the Joint SCRWG.

This report shares the recommendations of the Task Group, including:

1. A list of criteria for determining critical medical devices
2. The CMDL: A list of critical medical devices
3. The frequency and triggers for updating the CMDL
4. A resilient medical device framework

The Task Group has delivered this initial report within the context of the recommended comprehensive three-year reviews and when required, out of cycle reviews. Although the Task Group identified a comprehensive list of devices, it should be noted that it may not be all inclusive.

Methods and Organization of the CMDL

The CMDL was developed through an iterative process that leveraged input from stakeholders through surveys and task group meetings (Figure 3). A list of contributors can be found in Appendix B through Appendix F.

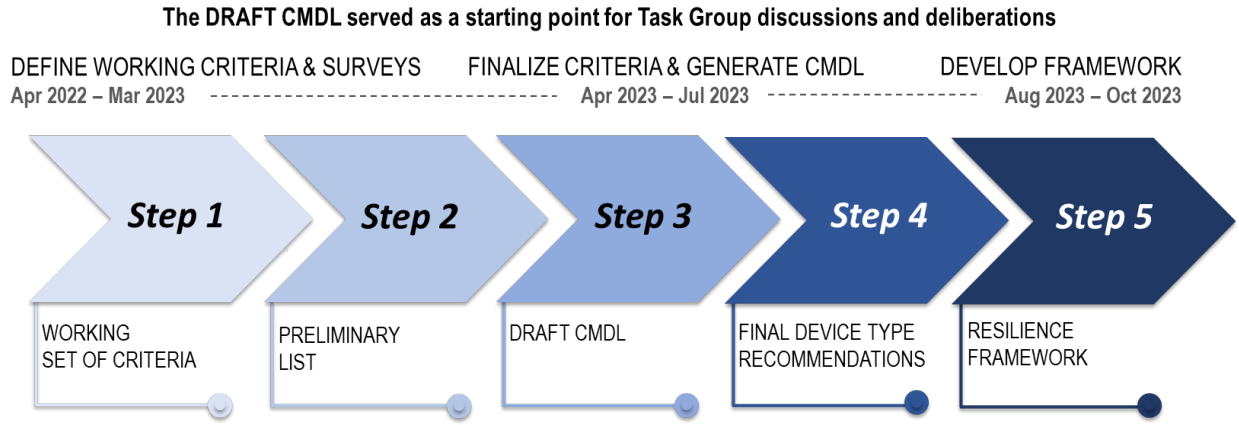

Figure 3. Task Group Process

The Task Group developed a working set of criteria that was used in concert with the survey analysis to develop a draft list (the starting point for developing the CMDL). Task Group discussions and polling on medical device type criticality began after the recommendations for final criteria were established. During each task group meeting, member organizations were provided the opportunity to discuss and ask questions about medical device types under consideration.

Recommendations were informed by a polling process in which Task Group members were asked whether the medical device type "met" or "did not meet" the criteria. Task Group members were also given the option of abstaining. If a member organization failed to provide a response for a specific medical device type, for the purposes of that poll, they were considered to have abstained. Quorum was defined as: at least 75% of Task Group members present or submitting responses to the polls via email.

For purposes of formulating the recommendations [in this draft report], a medical device was identified as critical (by consensus) if the following three conditions were met:

- 75% of members that responded critical or not critical agreed that the medical device was critical,
- over 50% of the Task Group identified the medical device as critical, and
- the majority of stakeholder sectors (Figure 4) deemed the medical device critical.

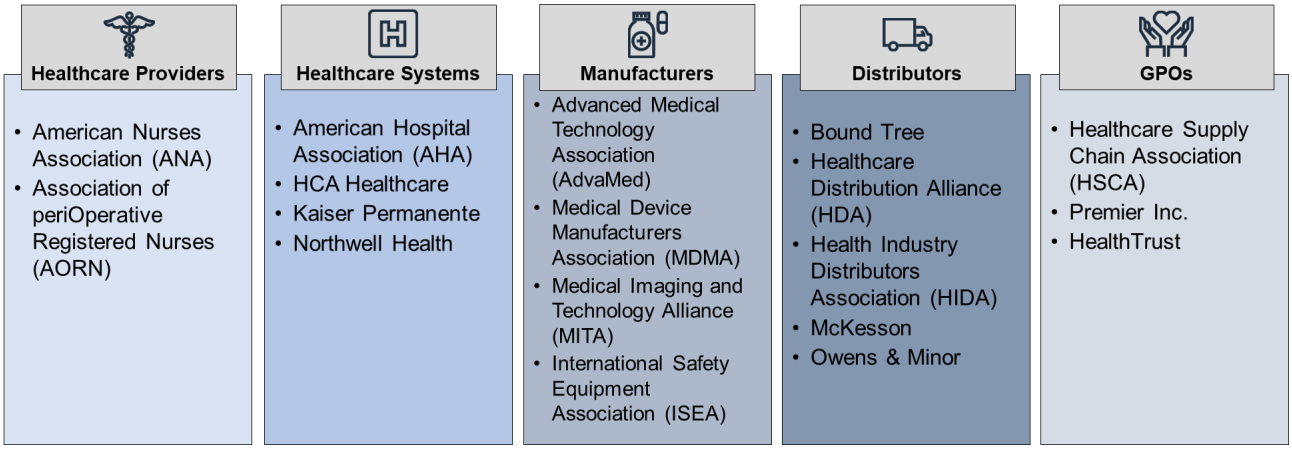

Figure 4. Task Group Members Grouped by Sector

Stakeholder Surveys

Surveys were distributed to five stakeholder sectors (medical device manufacturers; healthcare providers; healthcare systems; GPOs; and distributors). The purpose of the surveys was to solicit feedback on 1) proposed criteria and specific types of medical devices that should be considered for inclusion on a CMDL and 2) information on supply chain vulnerabilities and risks potentially impacting the availability of critical medical devices. Participation in the survey was voluntary. Data from the surveys informed Task Group discussions and recommendations. A summary of the survey results can be found in Appendix I.

CMDL Structure

The CMDL organizational hierarchy was developed after careful review of available device classification schemes (e.g., Global Medical Device Nomenclature System) and other regulatory product frameworks (e.g., FDA Product Codes), and consultation with clinical experts.

The CMDL is organized by medical device types – groups of devices with similar clinical use – with higher-level hierarchies for medical device categories, sub-functions, and functions (Figure 5). Organization of the list in this manner facilitated review by Task Group members, who were more familiar with clinical aspects of medical device utilization than regulatory product codes. This format also promotes utility for a broad and diverse set of future stakeholders.

- **Clinical Function:** Types of clinical service needed to deliver effective care to a patient.
    - The CMDL is organized into five clinical functions:
        - Care Delivery
        - Clinical Diagnostic Assessment
        - Clinical Laboratory Testing
        - Infection Control
        - Medical Imaging
- **Clinical Subfunction:** Clinical activities necessary to fulfill the clinical function.
    - The CMDL has 15 subfunctions.
- **Device Categories:** Groups of medical device types needed to deliver the functional care.

    - The CMDL is organized into 40 medical device categories.
- **Device Type:** Group of medical devices with similar clinical use.
    - The CMDL contains 142 medical device types.

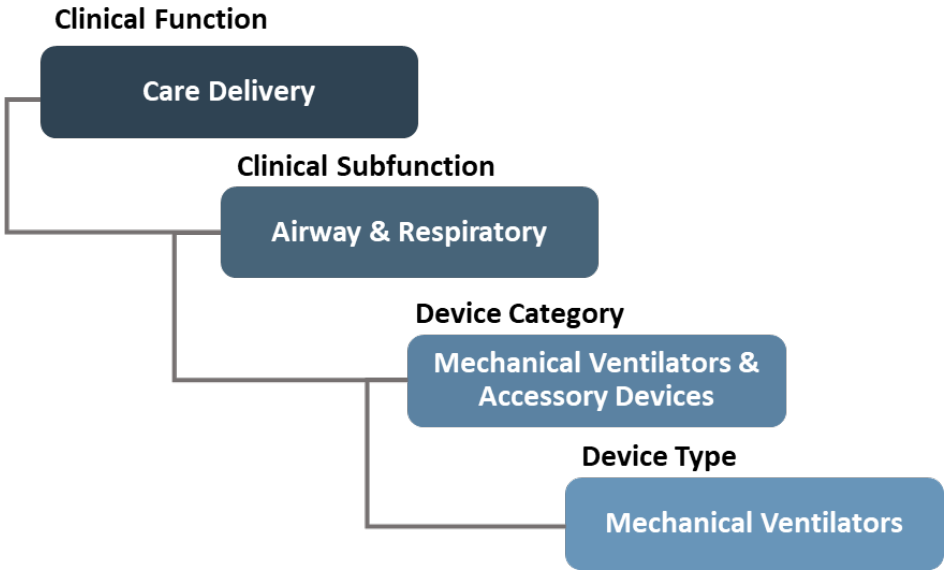

Figure 5. Critical Medical Device List Structure with Examples

Task Group Recommendations

Critical Medical Device Criteria

Task Group recommendations for criteria that should be used to determine medical device criticality can be found in Figure 6. A medical device that meets any one of the three criterion is deemed "*critical.”* As such, the criteria account for inclusion of both medical devices that are intended to address emergent medical situations and those that are needed for Chemical, Biological, Radiological, and Nuclear (CBRN) events or other public health emergencies (PHEs). The criteria also consider the criticality of medical devices when used for the care of special patient populations (e.g., pediatrics, immunocompromised, pregnant women) where they otherwise may not meet the definition of a critical medical device.

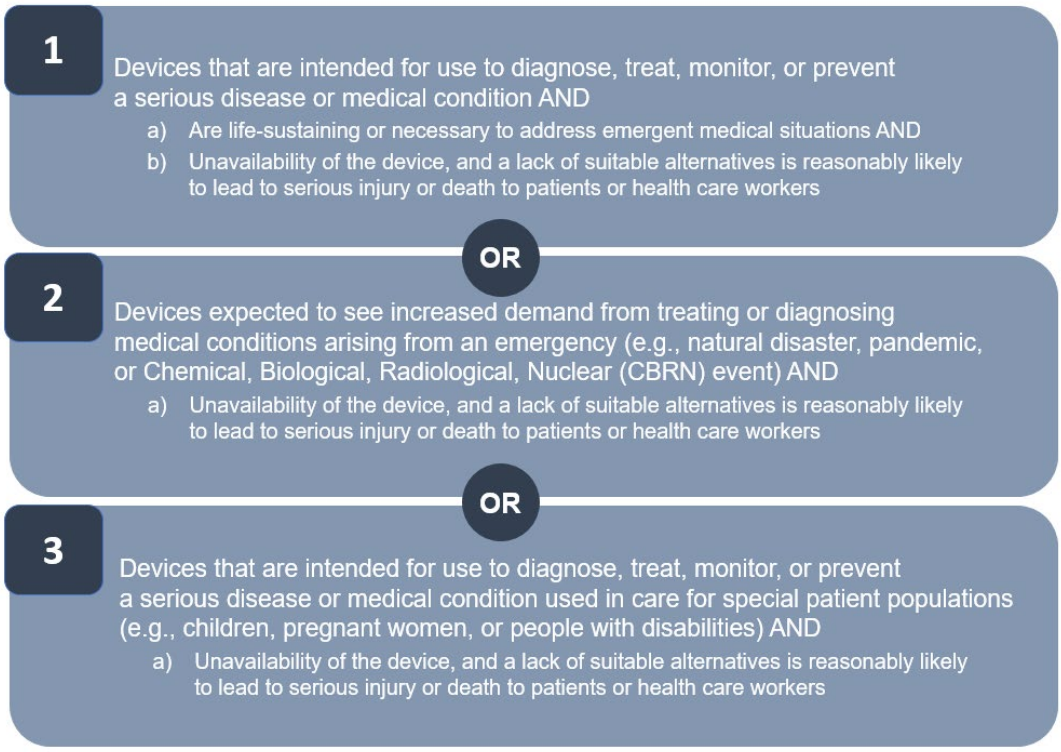

Figure 6. Critical Medical Device List Criteria

The Task Group discussed and debated several iterations of criteria before agreeing to use the final version as presented in this report. Notably, the Task Group members deliberated the use of "***and***" and "***or***" throughout the development of the criteria and the use of the words "permanent" or "serious" to describe "injury" that could result if a medical device type or suitable alternative was unavailable. A "suitable alternative" has been defined as an alternate FDA approved medical device, procedure, drug, or other intervention that could be used to address a medical condition or disease. During the deliberations, some Task Group members agreed that "or" should be used to separate each of the three criterion from the sub-bullets and believed "serious" should be used to describe the injury that could result from a lack of availability of the given medical device.

Others preferred "and" to separate the criteria from associated sub-bullets and believed "permanent" was the more appropriate term to describe injury that could result from a lack of availability of a critical medical device.

Ultimately, the Task Group settled on "and" as a separator between the criteria and associated sub-bullets and "serious" to describe injury resulting from a lack of availability of a suitable alternative. It should be noted however, that while consensus (over 50% of the Task Group agreeing) on the version of the criteria using "and" and "serious" was achieved, a considerable percentage (46%) of the Task Group preferred the use of "or" and "permanent." These criteria capture two key components of medical device criticality. The first is criticality related to emergent medical situations where the inability to access the necessary medical devices and deliver adequate care would likely result in a serious injury or death to a patient or provider. The

second is the criticality related to responding to emergency scenarios where medical devices would both be critical to the response and likely to see a significant increase in demand.

Critical Medical Device List

The Task Group averaged 91% participation throughout the polling process. However, it should be noted that, although Task Group members had an opportunity to discuss and ask questions about specific medical device types during each meeting and subject matter experts were consulted, some members still felt they did not have the expertise to determine criticality for certain medical device types. As such, they abstained for those polls. This was not entirely unexpected, as Task Group members were recruited for their participation based on their expertise and representation of specific market or clinical sectors.

A total of 216 medical device types across five clinical functional areas: 1) Care Delivery, 2) Clinical Diagnostic Assessment, 3) Clinical Laboratory Testing, 4) Infection Control, and 5) Medical Imaging were considered for inclusion on the CMDL. One hundred and forty-two medical device types, or 66%, were considered "critical" by the task group while 74 medical device types, or 34%, were considered "not critical." Seventy-seven percent of the medical device types identified as critical were mapped to the care delivery function. Within this functional grouping, airway & respiratory support, cardiovascular support, liver and kidney support, general supportive care, and surgical intervention accounted for 75% of critical medical device types on the CMDL. The complete list of medical device types recommended for inclusion by the Task Group can be found in Appendix A.

Table 3. Device Type Polling Results

	Not Critical Device Types	% of Total	Critical Device Types	% of Total	Total Device Types Discussed
Care Delivery	**45**	**29%**	**109**	**71%**	**154**
Airway & Respiratory Support	10	22%	35	78%	45
Cardiovascular Support	4	24%	13	76%	17
General Supportive Care	11	29%	27	71%	38
Glucose Management	4	67%	2	33%	6
Liver & Kidney Support	0	0%	12	100%	12
Neurological Intervention	2	100%	0	0%	2
Skin & Dermatological Support	1	100%	0	0%	1
Surgical Intervention	13	39%	20	61%	33
Clinical Diagnostic Assessment	**2**	**14%**	**12**	**86%**	**14**

	Not Critical Device Types	% of Total	Critical Device Types	% of Total	Total Device Types Discussed
Diagnostic Testing	0	0%	2	100%	2
Monitoring	2	17%	10	83%	12
Clinical Laboratory Testing	**13**	**52%**	**12**	**48%**	**25**
Consumables	3	43%	4	57%	7
Lab Equipment	6	86%	1	14%	7
Tests and Test Systems	4	36%	7	64%	11
Infection Control	**4**	**40%**	**6**	**60%**	**10**
General Protective Equipment for Public Use	0	0%	1	100%	1
PPE	4	57%	3	43%	7
Reprocessing and Reusing Devices	0	0%	2	100%	2
Medical Imaging	**10**	**77%**	**3**	**23%**	**13**
General Medical Equipment	1	25%	3	75%	4
Imaging Devices	9	100%	0	0%	9
Total	**74**	**34%**	**142**	**66%**	**216**

Key Themes

Medical Device Criticality vs. Resilience

Task Group members debated the criticality of several medical device types in relationship to their "resiliency," noting that while certain device types are critical (e.g., dialysis machines, anesthesia gas machines, beds, stretchers, and medical imaging equipment) they are also likely to be resilient because they are durable equipment. While this was a recurring topic in conversation at each meeting, the Task Group generally agreed that – consistent with the CMDL criteria – the resiliency of a medical device type should not be a factor when determining its criticality. Key take-aways from a broader discussion on medical device resilience can be found in the Resilience Framework section of this document.

Criticality vs. Suitable Alternatives and Standard of Care

When determining how medical device criticality and resiliency should be evaluated, the Task Group explored the meaning and interpretation of the phrase "suitable alternatives." For the purposes of developing the CMDL criteria, the Task Group defined "suitable alternative" as "an alternate FDA approved medical device, procedure, drug, or other intervention that could be used to address a medical condition or disease."

The Task Group discussed whether the phrase "suitable alternative" referred to alternatives "within a medical device type" (e.g., devices that have multiple manufacturers) or "to a medical device type" (alternative device types or interventions that could lead to the same or equivalent clinical outcome). Specifically, discussions centered around whether a medical device type produced by multiple manufacturers (alternatives within the device type) met the criteria of a "suitable alternative." Task Group members agreed that although a medical device type with multiple manufacturers may be more resilient, this factor alone did not equate to a lack of criticality. The Task Group felt that a medical device should be considered critical if a lack of its availability or a suitable alternative (meaning alternative "to a device type" [e.g., automated dosing devices vs. manual dosing; and prefilled flush syringes vs. manual flush]) would likely lead to serious injury or death to patients and healthcare workers. For example, syringes were considered critical because a lack of alternatives would likely lead to serious injury or death secondary to an inability to deliver medications; whereas a prefilled saline syringe would not be considered critical because manual flushes can be used in their absence.

The Task Group also weighed the use of "suitable alternatives" in the context of "standard of care." As an example, continuous glucose monitoring systems and automated dosing medical devices were determined by consensus of the group to lack criticality because of the availability of suitable manual alternatives. However, healthcare providers noted that "although there are manual alternatives to these devices, their use has become 'standard of care' and therefore they should be considered 'critical.'"

For some medical devices, the Task Group discussed whether a "makeshift" alternative would be adequate. For example, there may be makeshift alternatives to breathing tube support and endotracheal tubes fixation devices (tape), but they questioned whether those substitutes have equivalent clinical performance. During the same discussion, emergency medical services (EMS) representatives on the Task Group highlighted the importance of these medical devices for first responders and emergency services. Medical device types deemed "not critical" by the Task Group but "critical" to EMS services are listed in Appendix G. In other cases, medical devices were determined to be critical because the available alternatives may only be adequate for certain patients or under certain circumstances. As an example, nasal cannulas may be used as an alternative to oxygen masks for certain patients, but other patients may only be able to tolerate oxygen masks.

Criticality During Emergent or Emergency Situations vs. Longer Term Care

The Task Group also discussed whether the proposed medical devices are life-sustaining or necessary to address emergent medical situations. In several cases, there were different views about how "life-sustaining" should be defined. For example, some members of the Task Group questioned whether medical devices that may save lives over a longer period are critical, such as bronchoscopes and biopsy-related devices used to diagnose life-threatening diseases. There was also disagreement on the criticality of medical devices that are not immediately lifesaving but may support or preserve critical health care resources. As an example, home ventilators may keep patients out of the hospital, making life-saving hospital beds available to patients who need them. Oxygen conservers may help hospitals use less oxygen, making oxygen available to more patients and reducing the likelihood that oxygen supplies run out.

Maintaining the List

The CMDL should remain current and relevant for all stakeholders; therefore, the Task Group recommends a comprehensive review at least every three-years. The proposed scope of the three-year review and rationale is included in Table 4. The Task Group also recommends a process for updating the CMDL outside of this three-year cycle (off-cycle updates), for example when there is a new public health threat or significant change in a clinical practice standard.

Table 4. CMDL Review Cycle

Update	Description	Rationale
Three-Year Update	A comprehensive review and update will be performed at least every three-years.	Scheduled, comprehensive reviews of the criteria and CMDL will help ensure the list continues to reflect changes in the medical device landscape (e.g., changes in technology, medical practice, manufacturing, and regulation), clinical needs and be responsive to national health priorities. The three-year update cycle balances the importance of formal, periodic reviews with the fiscal and resource intensive burden of organizing the reviews (government) and participating in the reviews (stakeholders).

Update	Description	Rationale
Out-of-Cycle Updates	Circumstances such as an emerging public health threats, clinical practice standard change, emerging technologies or changes in materials or geopolitical threats are examples of situations that may prompt an out-of-cycle update before the three-year update window. Out-of-cycle reviews are expected to be infrequent.	Having a provision for unscheduled updates to the criteria or CMDL affords important flexibility for circumstances that may arise. The evidence must be clear and compelling to justify the effort and resources to conduct an out-of-cycle update.

Process for Reviewing the List

Three-Year Review Process

The three-year review should include input from FDA medical device and supply chain experts; healthcare providers; healthcare systems; industry representatives, including manufactures and distributors and/or their trade associations; GPOs; and other government agencies.

This review should include:

1. Evaluating the CMDL criteria and updating as needed
2. Evaluating the CMDL to add or remove medical devices as recommended
3. Identifying gaps in the list based on misalignment with current practices or clinical guidelines and stakeholder feedback collected during the preceding three-years

Off-Cycle Review Process

Situations that may warrant an off-cycle review include an emerging public health threat, geopolitical events, declaration of a PHE, or a significant change in clinical practice in one or more of the medical device categories on the list.

The scope of the review could be broad or limited to a specific medical device function or category, depending on the situation. At a minimum, the review process should include a detailed analysis of in-scope medical device(s).

Medical Device Supply Chain Resiliency Framework

The CMDL forms the foundation of a supply chain resilience strategy by identifying critical devices that are medically necessary. However, steps must be taken to ensure that the supply chain for these medical devices are resilient and capable of providing critical products to patients where and when they are needed.

Resilience is 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.

The Task Group discussions on resiliency focused on development of 1) an assessment of supply chain risks and vulnerabilities, 2) a list of attributes that contribute to supply chain resiliency, and 3) a set of recommended strategies to promote resiliency.

Supply Chain Risks and Vulnerabilities

The Task Group identified characteristics of vulnerable supply chains and factors that lead to increased risks. They were grouped into four categories: 1) supply chain structure, 2) device characteristics, 3) limited visibility, and 4) collaboration and communication. Attributes of vulnerable supply chains include but are not limited to 1) geographic dependencies on finished medical devices and raw materials, 2) lack of qualified, alternative suppliers, 3) sole and single source contracts, 4) cybersecurity risks, and 5) the proprietary nature of components and accessories required for using a finished medical device. The complete list of vulnerabilities and risks identified by the Task Group can be found in Figure 7.

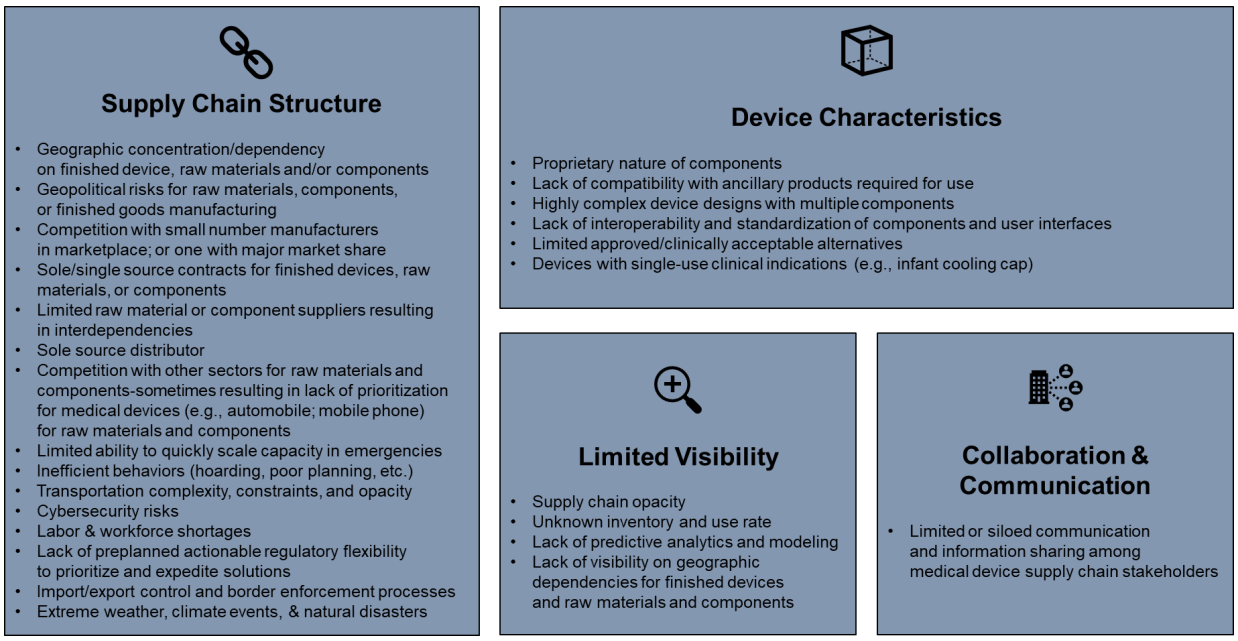

Figure 7. Medical Device Supply Chain Vulnerabilities and Risks

Attributes of a resilient medical device supply chain (Figure 8) include: 1) geographic diversity of suppliers, 2) considering multi-source contracting, 3) redundancy in upstream suppliers for raw materials and components, and 4) visibility and transparency.

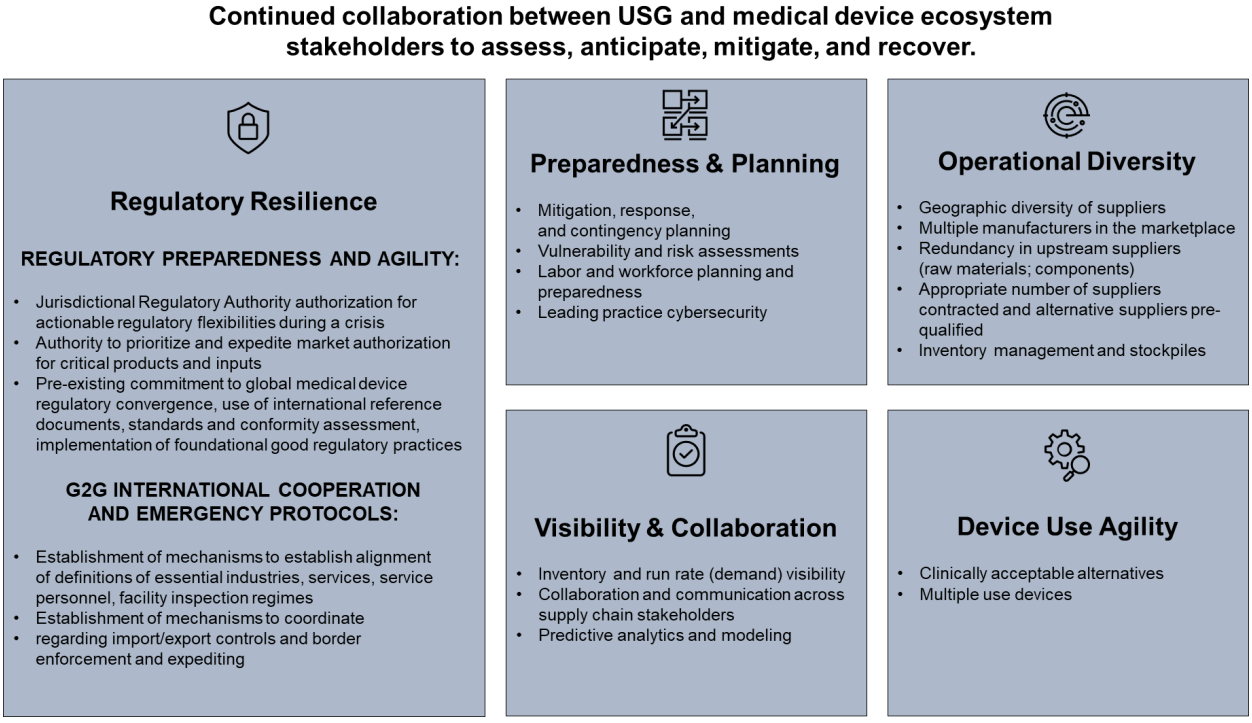

Figure 8. Attributes of Resilient Medical Device Supply Chain

Several additional factors that impact medical device resiliency were noted during Task Group discussions. These include:

- Type of Emergency: During localized emergencies, it may be possible to transport equipment (e.g., beds, neonatal incubators) between hospitals and regions. Emergencies that affect a broader geographical area may require different strategies to ensure resilience. Certain types of emergencies, such as large-scale trauma events, may require larger inventories of certain medical devices, such as neck braces and abdominal binders.
- Single Use Medical Devices vs. Reusable Medical Devices: Supplies, such as beds, dialysis machines, and blood storage devices are clinically critical but are types of durable capital equipment that would remain available for some time, even if the supply of new devices were disrupted or demand increased. Medical devices such as syringes, needles, PPE, and other single use technologies tend to be more vulnerable to acute supply chain disruptions or increases in demand. In health systems, single-use medical devices may be preferrable because they eliminate the need to disinfect devices between uses, especially during large-scale trauma events.
- Multiple Components and Accessories: Many medical devices rely on multiple components and required accessories to function. For example, testing equipment may rely on test strips or reagents, and physiological monitors may rely on cables and electrodes. When these components and/or accessories are unavailable, it may not be possible to manufacture or use the medical device. In addition, a medical device may become more vulnerable to supply disruptions if the components are made only by one manufacturer or if the components or accessories are not interchangeable.
- Capital Equipment Purchases: Some medical device types (e.g., medical imaging devices) are made-to-order and not made-to-stock. When these types of devices are needed, they typically must be purchased months in advance, manufactured and installed. These types of devices may be less vulnerable to supply chain disruptions.
- Availability of Medical Devices in Healthcare Settings: The Task Group stressed the importance of redundancy in equipment. As one Task Group member noted, “We can’t assume a perfect distribution system. Having some give in the system when we might run low is useful.” The Task Group noted that certain medical devices, such as infant warmers, may have redundancy in certain health systems and other healthcare settings, which would allow those devices to remain available even during an influx of patients who require care.

Developing a resilient supply chain for medical devices requires participation and broad collaboration by stakeholders across the entire medical device ecosystem. There are three key segments of this ecosystem that should be engaged in these activities: government, medical device industry, and healthcare providers and systems. While each segment of the ecosystem can carry out some of these strategies on their own, coordination across the segments and within each segment will be necessary to promote a more comprehensive approach to resiliency building.

Recommended Strategies to Support Medical Device Supply Chain Resiliency

The Task Group developed a resilience framework that highlights strategies stakeholders should take to support resilience across the medical device supply chain.

To support the continued availability of critical medical devices, the supply chain must minimize or avoid the patient harm that occurs when a disruptive "trigger event" takes place, such as a pandemic that increases demand; a problem at a manufacturing facility that requires it to significantly reduce or stop production of a critical medical device or a component of a critical medical device; or a natural disaster that damages medical device production facilities and transportation networks. To achieve this, supply chain stakeholders must:

- Identify and anticipate these disruptive events
- Take proactive action to mitigate impact to patients
- Rapidly recover

To support these goals, the Task Group recommends coordinated action across three areas of Preparedness and Response (Figure 9):

1) **Anticipate:** Supply chain stakeholders should undertake a comprehensive assessment of supply chain risks. This assessment should include an analysis of the likelihood and severity of potential disruptive events, the supply chain's ability to respond to those events and vulnerabilities that may affect the supply chain's ability to respond.
2) **Mitigate**: Supply chain stakeholders should take proactive steps to reduce the likelihood of trigger events and minimize their effects, such as supply chain redundancy, inventory stockpiles, multi-source contracting practices, proactive response planning, qualified alternative suppliers, etc.
3) **Recover**: Supply chain stakeholders should also take proactive steps to improve the medical device ecosystem's ability to respond and recover from a supply chain disruption or shortage to minimize patient impact and avoid harm.

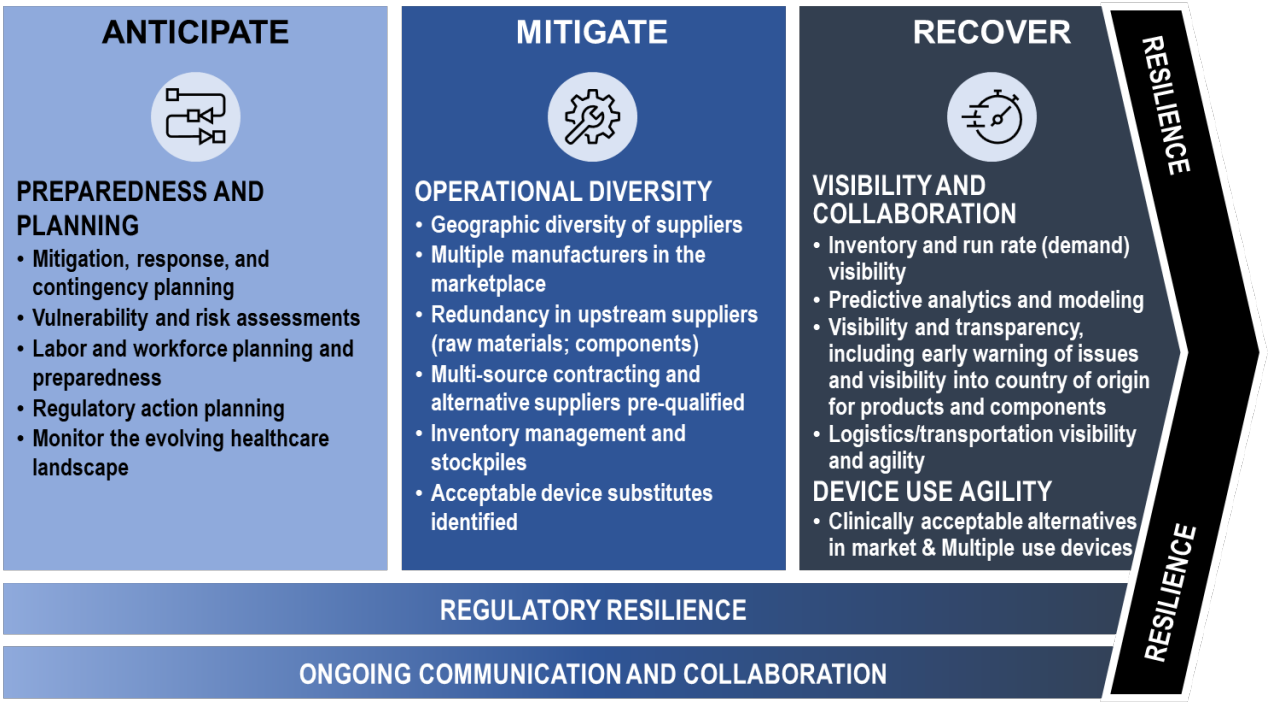

Figure 9. Medical Device Resilience Framework

The Task Group recommends the medical device resilience framework be reviewed on the same three-year cycle as the CMDL to make sure the framework remains relevant.

Utilizing the List and Applying the Recommendations

The CMDL was developed in the context of providing a comprehensive list of critical medical devices necessary for promoting public health and strengthening healthcare and the public health critical infrastructure. The list is intended for use by a broad set of stakeholders to include clinicians; hospital systems; GPOs; medical device industry; and state, local, territorial, and tribal governments. Potential uses for this list include:

- Policy Decisions
    - Industrial based expansion investments
    - Government stockpiling investments
    - Prioritizing programmatic and resource allocations to resiliency building efforts
    - Informing trade, commerce, and other government supply chain decisions
    - Prioritizing international cooperation and agreements on supply chain activities
    - Informing regulatory decisions/flexibility for strengthening supply chains
    - Promoting supply chain visibility for the most critical medical devices
- Clinical and Hospital System Planning
    - Stockpiling
    - Purchasing
    - Multi-source contracting
- Medical Device Industry

- Promoting strategies to strengthen supply chains to component products and materials used for finished medical devices
- Focused development and implementation of risk management plans for critical medical devices
- Distribution strategies

Ultimately, the utility and use of this list and recommendations in this report should be considered in the context of "fitness for purpose." The medical device resilience framework can serve as a guide for broad stakeholder collaboration and cooperation for building resiliency for the supply chains of the medical device types included on the CMDL.

Limitations

A discussion of the limitations in the report's design is included in Appendix J.

Appendix A – Critical Medical Device List

Care Delivery

- Subfunction: Airway and Respiratory Support
  - Airway Needles
  - Airway Connectors, Tubing, and Circuits
  - Airway Monitors
  - Anesthesia Gas Machines
  - Aspiration Pumps
  - Breathing Tube Support
  - Bronchoscope Accessories
  - Bronchoscopes
  - Carbon Dioxide Absorbent
  - Condensers
  - Continuous Ventilator Attachment
  - Endotracheal Tubes
  - Filters
  - Flowmeters
  - Gas Analyzers
  - Gas Cylinder Pressure Regulators
  - Gas Mixers
  - High-Flow Oxygen Delivery Devices
  - Humidifiers
  - Intermittent Mandatory Ventilation (IMV) Attachment
  - Laryngoscopes
  - Manual Resuscitators
  - Mechanical Ventilators
  - Nasal Cannulas
  - Nasal Drug Delivery Devices
  - Nasopharyngeal Airways
  - Nebulizers
  - Oropharyngeal Airways
  - Oxygen Masks
  - Positive End Expiratory Pressure (PEEP) Attachments
  - Portable Oxygen Sources
  - Stylets and Endotracheal Tubes (ETT) Changers
  - Suction Tubes and Catheters
  - Tracheostomy Tubes
  - Valves
- Subfunction: Cardiovascular Support
  - Automated External Defibrillators (AEDs)
  - Angioplasty Catheters
  - Artificial Heart
  - Cardiopulmonary Bypass-related devices
  - Direct Current (DC) Defibrillators
  - Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump
  - Endovascular Graft Systems
  - Extracorporeal Carbon Dioxide Removal System
  - Intra-aortic Balloon Pump System (IABP) System
  - Implantable Valvular Devices
  - Oxygenator
  - Stents
  - Ventricular Assist Devices (VADs) Graft Systems
  - Stents
- Subfunction: General Supportive Care
  - Abdominal Binders
  - Beds, Stretchers, and Gurneys
  - Blood Clot Prevention Devices
  - Catheters & Ports
  - Collection Devices
  - Enteral Infusion Pumps
  - Fluid Warmers
  - Gastrointestinal Tubes
  - Gauze / Sponge
  - Infant Warming Devices
  - Infusion Filters
  - Infusion Pumps
  - Intravenous (IV) Containers
  - Intravenous (IV) Stopcocks
  - Lancets
  - Needles
  - Orthoses
  - Percutaneous Catheterization Dilators

    - Suction Catheters
    - Syringes
    - Tape and Adhesive Bandages
    - Thermoregulatory Devices
    - Tourniquets
    - Transfusion and Plasmapheresis Devices
    - Tubing
    - Urinary Catheters and Related Devices
    - Wound Dressings
- Subfunction: Glucose Management
    - Glucose Sensors
    - Inulin Infusion Pumps
- Subfunction: Liver and Kidney Support
    - Blood Filters
    - Blood Tubing Connectors
    - Dialysate Tubing
    - Dialyzers
    - Hemodialysis Catheter End Caps
    - Hemodialysis Catheters
    - Hemodialysis Circuit Accessories
    - Hemodialysis Dialysate
    - Hemodialysis Dialysate Delivery Systems
    - Kidney Perfusion Systems
    - Peritoneal Dialysate Delivery Systems
    - Peritoneal Dialysis Catheters
- Subfunction: Surgical Intervention
    - Cautery Devices
    - Clip Appliers
    - Clips
    - Cerebrospinal Fluid (CSF) Shunts and Drains
    - Dural Substitutes
    - Endoscopes & Accessory Devices
    - Gastrointestinal (GI) Stents
    - Hemostatic Agents
    - Injectable Embolic Agents
    - Intrauterine Tamponade Balloon
    - Ligators
    - Neurosurgical Instruments
    - Neurovascular Embolization Devices
    - Operating Room (OR) Suction Apparatus
    - Spinal Catheters
    - Spinal Needles
    - Surgical Drapes
    - Sutures
    - Thrombus Retriever Catheters
    - Tissue Adhesive for Embolization

Clinical Diagnostic Assessment

- Subfunction: Diagnostic Testing
    - Electrocardiogram (ECG) System
    - Stethoscopes
- Subfunction: Monitoring
    - Apnea Monitors
    - Blood Pressure Cuff
    - Thermoregulatory Monitors
    - Blood Pressure System
    - Cables
    - Cardiac Monitors
    - Fetal Monitors
    - Intracranial Pressure Monitors
    - Oximeters
    - Physiological Monitors

Clinical Laboratory Testing

- Subfunction: Consumables
    - Antimicrobial Testing Devices
    - Media Culture
    - Specimen Collection Devices
    - Transport Medium
- Subfunction: Laboratory Equipment
    - Blood Bank Supplies
- Subfunction: Tests and Test Systems
    - Blood Gas
    - Cardiac Enzymes
    - Coagulation Tests

    - Complete Metabolic Panel (CMP) Tests
    - Lactate Dehydrogenase
    - Magnesium
    - Nucleic Acid Amplification Test System

Infection Control

- Subfunction: General Protective Equipment for Public Use
    - Public Use Respirators
- Subfunction: Personal Protective Equipment (PPE)
    - Non-Sterile PPE (Gloves, Masks)
    - Non-Sterile PPE (Gowns)
    - Surgical PPE (Gloves, Gowns)
- Subfunction: Reprocessing and Reusing Devices
    - Disinfection & Pasteurization
    - Sterilization

Medical Imaging

- Subfunction: General Medical Equipment
    - Aprons
    - Radiation Attenuating Gloves
    - Shields

The following medical device type descriptions were developed for the purpose of the CMDL and are intended to be used as a resource to assist stakeholders in determining which medical devices may fall within the identified medical device types.

Table 5. Airway & Respiratory Support Device Type Descriptions

Medical Device Types	Descriptions
Airway Connectors, Tubing, and Circuits	Airway connectors, tubing, and circuits are used during anesthesia. An airway connector joins a breathing gas source to a tracheal tube, tracheostomy tube, or mask. Tubing are flexible or rigid tubes intended to deliver pressurized medical gases. Circuits are used to administer medical gases to a patient, providing both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.
Airway Monitors	Airway monitors are used to measure the pressure in a patient's upper airway. These devices may include a pressure gauge and alarm.
Airway Needles	Airway needles are used to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.
Anesthesia Gas Machines	Anesthesia gas machines are used to administer continuous or intermittent anesthetics to maintain a patient's ventilation. These devices may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.
Aspiration Pumps	Aspiration pumps are used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system during surgery or at the patient's bedside.
Breathing Tube Support	Breathing tube support are used to support and anchor a patient's breathing tube(s).
Bronchoscope Accessories	Bronchoscope accessories are devices which attach to a bronchoscope and are intended to be used to examine or treat the larynx and tracheobronchial tree. The generic type of device includes, but is not limited to flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube.
Bronchoscopes	Bronchoscopes are a tubular endoscopic device used to examine or treat the larynx and tracheobronchial tree. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, and nonrigid bronchoscope.
Carbon Dioxide Absorbent	Carbon dioxide absorbents are devices consisting of an absorbent material that is used to remove carbon dioxide from the gases in the breathing circuit during anesthesia.
Condensers	Condensers are used to warm and humidify gases breathed in by a patient when positioned over a tracheotomy or tracheal tube.
Continuous Ventilator Attachment	Continuous ventilator attachments are used in conjunction with a continuous ventilator to control or assist a patient in breathing by delivering a predetermined percentage of oxygen in the breathing gas.

Medical Device Types	Descriptions
Endotracheal Tubes	Endotracheal tubes are used to maintain an open airway by inserting tubes into a patient's trachea via the nose or mouth for various respiratory diagnoses, including poor respiratory drive, hypoxia, airway obstruction, respiratory failure, and hypercarbia. Includes, but it not limited to tracheal and tracheal/bronchial differential ventilation tubes, inflatable tracheal tube cuff, and connectors.
Filters	Filters are used to remove microbiological and particulate matter from the gases in the breathing circuit during anesthesia.
Flowmeters	Flowmeters are used to calibrate gas flowmeters and accurately measure gas flow.
Gas Analyzers	Gas analyzers are used to measure the concentration of gas (i.e., carbon monoxide, carbon dioxide, and/or oxygen) in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status.
Gas Cylinder Pressure Regulators	Gas cylinder pressure regulators are used to convert medical gas pressure from a high variable pressure to a lower, more constant working pressure. Includes, but is not limited to mechanical oxygen regulators. Also referred to as pressure-reducing valves.
Gas Mixers	Gas mixers are used in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.
High-Flow Oxygen Delivery Devices	High-flow oxygen delivery devices are used to deliver high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.
Humidifiers	Respiratory gas humidifiers are used to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Includes, but is not limited to cascade, gas, heated, and prefilled humidifiers.
Intermittent Mandatory Ventilation Attachment	Intermittent mandatory ventilation attachments are attached to a mechanical ventilator that allows spontaneous breathing while providing mechanical ventilation at a preset rate.
Laryngoscopes	Laryngoscopes are used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.
Manual Resuscitators	Manual resuscitators, also referred to as a non self-inflating manual resuscitator or hyperinflation system, are a manual ventilator intended to ventilate a patient by forcing a volume of fresh gas into the patient via compression of the ventilator bag; a source of compressed breathing gas is required to inflate the bag.
Mechanical Ventilators	Mechanical ventilators are used to aid patients with respiratory insufficiencies in clinical settings, as well as at home. Includes, but is not limited to continuous, non-continuous, intermittent, minimal use, high frequency, emergency, positive airway pressure, non-life-supporting, powered, and manual ventilators.
Nasal Cannulas	Nasal cannulas are used to administer oxygen to a patient through both nostrils.
Nasal Drug Delivery Devices	Nasal drug delivery devices are used to administer drugs via the nasal cavity.

Medical Device Types	Descriptions
Nasopharyngeal Airways	Nasopharyngeal airways are used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.
Nebulizers	Nebulizers are used to spray liquids, in aerosol form, into gases that are delivered directly to the patient for breathing. Includes, but not limited to heated, ultrasonic, gas, venturi, and refillable nebulizers.
Oropharyngeal Airways	Oropharyngeal airways are inserted into a patient's pharynx through the mouth to provide a patent airway.
Oxygen Masks	Oxygen masks are placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.
Portable Oxygen Sources	Portable oxygen sources are used to supplement gases to be inhaled by a patient. Includes, but is not limited to liquid oxygen portable units and portable oxygen generators.
Positive End Expiratory Pressure (PEEP) Attachments	PEEP attachments are used with a ventilator to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.
Stylets and ETT Changers	Stylets and ETT changers are used temporarily to aid in the insertion of endotracheal tubes into a patient.
Suction Tubes and Catheters	Suction tubes and catheters are used to help clear secretions from a patient's airway by attaching one end to a suction machine and the other end into an endotracheal tube, airway, or other orifice.
Tracheostomy Tubes	Tracheostomy tubes are used to facilitate ventilation to the lungs when placed into a surgical opening of the trachea.
Valves	Valves are used to direct breathing gas flow to the patient and vents exhaled gases into the atmosphere.

Table 6. Cardiovascular Device Type Descriptions

Medical Device Types	Descriptions
Angioplasty Catheters	Angioplasty catheters are used to provide percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, popliteal, femoral, and iliofemoral. Includes, but is not limited to drug-eluting peripheral transluminal angioplasty catheters and catheter introducers.
Artificial Heart	Artificial hearts are used as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.
Automated External Defibrillators (AEDs)	AEDs are used to detect and interpret an electrocardiogram and deliver an electrical shock. These devices may include wearable or non-wearable defibrillators and may be purchased over the counter.

Medical Device Types	Descriptions
Cardiopulmonary Bypass-related devices	Cardiopulmonary bypass-related devices are used during cardiopulmonary bypass surgeries to support, adjoin, or connect components to the circuit, or to aid in the setup of the extracorporeal line. Includes, but is not limited to adaptors, stopcocks, manifolds, fittings, catheters, cannulas, tubing, temperature, suction, and pump speed controllers, valves and gauges, detectors, filters, generators, monitors and consoles, blood reservoirs, sensors, and oxygenator.
Direct Current (DC) Defibrillators	DC defibrillators are used to deliver an electrical shock of energy (via paddles placed either directly across the heart or on the surface of the body) to defibrillate the atria or ventricles of the heart, or to terminate other cardiac arrhythmias.
Endovascular Graft Systems	Endovascular graft systems are used to repair or replace damaged or diseased vessels of the aortic arch and descending thoracic aorta via vascular grafts and/or stent grafts.
Extracorporeal Carbon Dioxide Removal System	Extracorporeal carbon dioxide removal systems are used in the removal of carbon dioxide from a patient's blood during acute respiratory failure. These devices include but are not limited to the console (hardware), software, gas exchanger, blood pump, cannulae, tubing, filters, monitors, detectors, sensors, and connectors.
Extracorporeal Membrane Oxygenation (ECMO) Cannulas, System, and Blood Pump	ECMO cannulas, system, and blood pumps are used to assist with extracorporeal circulation and physiologic gas exchange of a patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure. Includes, but is not limited to the ECMO system, pump, controller, and single or dual cannulas.
Implantable Valvular Devices	Implantable valvular devices are used to replace patients aortic and mitral heart valves. They are placed percutaneously and do not require open chest surgery or a cardiotomy for placement.
Intra-aortic Balloon Pump System (IABP)	IABP systems consist of an inflatable balloon placed in the aorta which are used to improve cardiovascular functioning during certain life-threatening emergencies and a control system used to regulate the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.
Oxygenator	Oxygenators are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.
Stents	Stents are used to maintain the lumen in a vein or artery. Includes, but is not limited to aortic, coronary, iliac, carotid, femoral stents.
Ventricular Assist Devices (VADs)	VADs are used to assist the left or right ventricle in maintaining circulatory blood flow.

Table 7. General Supportive Care Device Type Descriptions

Medical Device Types	Descriptions
Abdominal Binders	Abdominal binders are used to stabilize the abdomen following surgical procedures or injury.
Beds, Stretchers, and Gurneys	Beds, stretchers, and gurneys are used in patient examination and care, and for the movement of patients requiring medical care. Includes, but is not limited to bariatric, powered/adjustable, air fluidized, hydraulic, manual, pediatrics, rotation, and rocking beds, hand carried, restraint, and wheeled stretchers, cots, litter, trolley, and carts.
Blood Clot Prevention Devices	Blood clot prevention devices are used to apply controlled pressure to a limb to prevent pooling of blood resulting in deep vein thrombosis, and aids in treatment and healing from stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limb. Includes, but is not limited to compressible limb sleeves and stockings.
Catheters & Ports	Catheter and ports are used for repeated access to the vascular system for the infusion of fluids and medications, and the sampling of blood.
Collection Devices	Collection devices are used to aspirate, remove, or sample fluids or semisolids. The device is powered by an external source of vacuum. Includes, but is not limited to vacuum regulators, vacuum collection bottles, suction catheters, and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
Enteral Infusion Pumps	Enteral infusion pumps are used to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate.
Fluid Warmers	Fluid warmers are used to warm intravenous (IV) fluids and blood products to maintain normal temperature or prevent hypothermia, and during surgical procedures for surgical site irrigation or lavage in different areas of the body.
Gastrointestinal Tubes	Gastrointestinal tubes are flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.
Gauze / Sponge	Gauze and sponges are a sterile or nonsterile device intended for external use which are placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose.
Infant Warming Devices	Infant warming devices are used to maintain an infant's body temperature by means of radiant heat.
Infusion Filters	Infusion filters are used in IV administration to filter out particulate matter, bacteria, and air emboli, and protect a patient from phlebitis due to particulates or infection from bacteria.
Infusion Pumps	Infusion pumps are used to pump fluids into a patient in a controlled manner.

Medical Device Types	Descriptions
Intravenous (IV) Containers	IV containers are used to hold a fluid mixture to be administered to a patient through an intravascular administration set.
Intravenous (IV) Stopcocks	IV Stopcocks are used to connect intravenous infusion lines or tubing set to regulate flow of fluids and/or medication.
Lancets	Lancets are used to puncture the skin to obtain a drop of blood for diagnostic purposes.
Needles	Needles are used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
Orthoses	Orthoses is used to support or to immobilize fractures, strains, or sprains of the neck and spine.
Percutaneous Catheterization Dilators	Percutaneous catheterization dilators are placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
Suction Catheters	Suction catheters are used to aspirate or remove liquids, semisolids, or sample body fluids.
Syringes	Syringes are used to inject fluids into, or withdraw fluids from, the body.
Tape and Adhesive Bandages	Tape and adhesive bandages are used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.
Thermoregulatory Devices	Thermoregulatory devices are used to regulate a patient's temperature.
Tourniquets	Tourniquets are used when bleeding is uncontrollable due to a severe wound.
Transfusion and Plasmapheresis Devices	Transfusion and plasmapheresis devices *are* used to collect and reinfuse blood lost due to surgery or trauma.
Tubing	Tubing is used for instilling fluids into or withdrawing fluids from the vascular system.
Urinary Catheters and Related Devices	Urological catheters and related devices are used to pass fluids to or from the urinary tract via a flexible tube that is inserted through the urethra. Includes, but is not limited to foley and balloon catheters, urine collection containers and bags, and stylets.
Wound Dressings	Wound dressings are used to cover a wound and to absorb exudate.

Table 8. Glucose Management Device Type Descriptions

Medical Device Types	Descriptions
Glucose Sensors	Glucose sensors are used to measure glucose levels, detect trends, and track patterns in patients with diabetes.
Insulin Infusion Pumps	Insulin infusion pumps are used to deliver insulin in a controlled manner to a patient's bloodstream to aid in the management of diabetes.

Table 9. Liver and Kidney Support Device Type Descriptions

Medical Device Types	Descriptions
Blood Filters	Blood filters are testing mechanisms used to detect residual chlorine following hemodialysis equipment disinfection.
Blood Tubing Connectors	Blood tubing connectors are joint apparatuses used to connect tubing during hemodialysis.
Dialysate Tubing	Dialysate tubing is used in dialysis to facilitate the flow of tiny molecules in solution based on differential diffusion.
Dialyzers	Dialyzers, also referred to as an artificial kidney system, are used in the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration.
Hemodialysis Catheter End Caps	Hemodialysis catheter end caps are mechanisms that close the end of a catheter, prohibiting microbial contamination. These devices can reduce hub infections in patients receiving hemodialysis.
Hemodialysis Catheters	Hemodialysis catheters are tubular devices used to access the intravascular space or intraperitoneal space for the treatment of patients with renal failure or toxemic conditions. These catheters can be flexible or rigid, implanted or non-implanted, and single or double lumen.
Hemodialysis Circuit Accessories	Hemodialysis circuit accessories are devices used in conjunction with the dialysate delivery system and the extracorporeal circuit during hemodialysis. These devices may include needles, stopcocks, bloodlines and chambers, connectors, clips, and ports.
Hemodialysis Dialysate	Hemodialysis dialysate is a concentrate of liquid or powder used in the dialyzer to extract waste products from blood.
Hemodialysis Dialysate Delivery Systems	Hemodialysis dialysate delivery systems are used as an artificial kidney system to control and monitor the blood flow from a patient into an extracorporeal blood system for the treatment of patients with renal failure or toxemic conditions. The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer.

Medical Device Types	Descriptions
Kidney Perfusion Systems	Kidney perfusion systems are used to support donated or cadaver kidneys and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient.
Peritoneal Dialysate Delivery Systems	Peritoneal dialysate delivery systems are used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used.
Peritoneal Dialysis Catheters	Peritoneal dialysis catheters are a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long-term peritoneal catheter.

Table 10. Surgical Intervention Device Type Descriptions

Medical Device Types	Descriptions
Cautery Devices	Cautery devices are used to remove tissue and control bleeding by use of high-frequency electrical current.
Cerebrospinal fluid (CSF) Shunts and Drains	CSF shunts and drains are used to monitor and divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume or preventing spinal cord ischemia or injury during procedures that require reduction in central nervous system pressure. These devices may include catheters, valved catheters, valves, connectors, pressure monitors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.
Clip Appliers	Clip appliers are used to ligate tubular structures, such as veins, during laparoscopic and other procedures.
Clips	Clips are used to connect internal tissues to aid healing.
Dural Substitutes	Dural substitutes are used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.
Endoscopes & Accessory Devices	Endoscope and accessory devices are used to provide access, illumination, and allow for observation or manipulation of body cavities, hollow organs, and canals. Includes, but is not limited to cleaning supplies for endoscopes, photographic accessories for endoscopes, electrosurgical unit, electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, and electrical clamp.
Gastrointestinal (GI) Stents	GI Stents are expandable, metallic tubes used to treat obstructions in the large and small intestines.

Medical Device Types	Descriptions
Hemostatic Agents	Hemostatic agents are used to produce hemostasis by accelerating the clotting process of blood.
Injectable Embolic Agents	Injectable embolic agents are used to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations.
Intrauterine Tamponade Balloon	Intrauterine tamponade balloons are used to temporarily control or reduce postpartum uterine bleeding.
Ligators	Ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.
Neurosurgical Instruments	Neurosurgical instruments are used in neurological and spinal surgeries. Includes, but is not limited to aneurysm clip appliers, clips, cranial drills, burrs, and trephines, spinal epidural electrodes, chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, head holders, spinal fixation implants, fusion and bone grafts, and pedicle screw and rod systems.
Neurovascular Embolization Devices	Neurovascular embolization devices are used to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations.
Operating Room (OR) Suction Apparatus	OR suction apparatuses are used to aspirate, remove, or sample body fluids during surgical procedures.
Spinal Catheters	Spinal catheters are used to inject local anesthetics to provide continuous regional anesthesia.
Spinal Needles	Spinal needles are used to inject local anesthetics into a patient's spine to administer regional anesthesia.
Surgical Drapes	Surgical drapes are used as protective patient coverings, such as to isolate a site of surgical incision and to cover surgical instrumentation to prevent microbial and other contamination.
Sutures	Sutures are used to close surgical sites or other wounds. They may be absorbable sterile or non-absorbable sterile, monofilament or multifilament (braided) in form, uncoated or coated, undyed or dyed, needled or unneedled, and stainless steel.
Thrombus Retriever Catheters	Thrombus retriever catheters are used to restore blood flow by removing thrombus or clots in patients experiencing ischemic stroke.
Tissue Adhesive for Embolization	Tissue adhesive for embolization is uses in embolization of cerebral arteriovenous malformations when presurgical devascularization is desired.

Table 11. Clinical Diagnostic Assessment Device Type Descriptions

Medical Device Types	Descriptions
Apnea Monitors	Apnea monitors are used to measure or monitor a patient's respiratory rate in a clinical or home setting. Select monitors can also monitor heart rate and other physiological parameters linked to the presence or absence of adequate respiration and may be equipped with an audible or visible alarm.
Blood Pressure Cuff	Blood pressure cuffs are used to determine a patient's blood pressure through use of an inflatable bladder in an elastic sleeve (cuff) with a mechanism for inflating the bladder.
Blood Pressure System	Blood pressure systems are used to detect signals from which systolic, diastolic, mean, or any combination of the three pressures can be derived via tranducers placed on the surface of the body.
Cables	Cables are used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.
Cardiac Monitors	Cardiac monitors are used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor.
Electrocardiogram (ECG) System	ECG systems are used to measure the hearts electrical activity to diagnose heart abnormalities, conditions, and diseases. Includes, but is not limited to electrodes, transmitters and receivers, and monitors.
Fetal Monitors	Fetal monitors are used to detect, measure, and record fetal heart sounds and condition during labor or pregnancy obtained from the maternal abdomen with external electrodes or ultrasonic energy.
Intracranial Pressure Monitors	Intracranial pressure monitors are used for short-term monitoring and recording of intracranial pressures and pressure trends. These devices include but are not limited to transducer, monitor, and interconnecting hardware.
Oximeters	Oximeters are used to measure blood oxygen saturation or cerebral tissue saturation.
Physiological Monitors	Physiological monitors are used to transmit and receive a patient's vital physiologic parameters (e.g., central monitoring station).
Stethoscopes	Stethoscopes are used to project the sounds associated with the heart, lungs, arteries, veins, and other internal organs to detect medical conditions.
Thermoregulatory Monitors	Thermoregulatory monitors are used to measure and regulate a patient's temperature.

Table 12. Clinical Laboratory Device Type Descriptions

Medical Device Types	Descriptions
Antimicrobial Testing Devices	Antimicrobial testing devices are used in diagnostics of infections and diseases. Includes, but is not limited to discs, strips, reagents.
Blood Bank Supplies	Blood bank supplies are used for in vitro use in blood banking. Includes, but is not limited to pipettes, slides, tubes, racks, and reagents.

Medical Device Types	Descriptions
Blood Gas	Blood gas test systems are used to measure certain gasses in the plasma, serum, and blood to detect acid-based disturbances.
Cardiac Enzymes	Cardiac enzyme test systems are used to measure proteins in the blood (biomarkers) to detect heart conditions or diseases.
Coagulation Tests	Coagulation test systems are used to measure a patient's ability and the amount of time it takes for blood to clot to detect coagulation abnormalities or disorders.
Complete Metabolic Panel (CMP) Tests	CMP tests are used to detect a wide array of conditions and diseases from specimens of bodily fluids (e.g., blood, plasma, sweat, serum, urine). Includes, but is not limited to glucose, sodium, potassium, urea nitrogen, aspartate amino transferase, alanine amino transferase, calcium, bilirubin, bicarbonate/carbon dioxide, chloride, and creatinine tests.
Lactate Dehydrogenase	Lactate dehydrogenase test systems are used to measure the activity of the enzyme lactate dehydrogenase in a patient's blood or other body fluids to detect tissue damage.
Magnesium	Magnesium test systems are used to measure magnesium levels in serum and plasma to detect hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
Media Culture	Media cultures are used in the cultivation and identification of certain pathogenic microorganisms.
Nucleic Acid Amplification Test System	Nucleic acid amplification test systems are used to measure and sort multiple signals generated my multiple probes, intercalating dyes, or other ligands in an assay from a clinical sample.
Specimen Collection Devices	Specimen collection devices are used to collect, store, or transport bodily fluids (e.g., blood, plasma, urine, mucus). Includes, but is not limited to bag, bottle, vials, swabs, paper, tubes, serum separators, bottles, vacuum, suction catheter, tips, and regulators.
Transport Medium	Transport mediums are used to collect and transport patient specimens to detect respiratory viruses including coronavirus.

Table 13. Infection Control Device Type Descriptions

Medical Device Types	Descriptions
Disinfection & Pasteurization	Disinfection and pasteurization devices are used to clean, decontaminate, disinfect, and dry medical devices. Includes, but is not limited to disinfectants, disinfectors, hot water pasteurizations, and reprocessing instruments for ultrasonic transducers (e.g., liquid, mist).
Non-Sterile PPE (Gloves and Masks)	Non-sterile PPE gloves and masks are used by healthcare providers to minimize exposure during patient examinations and surgical procedures from a variety of hazards (e.g., infectious materials, contaminants). Includes, but is not limited to gloves (e.g., patient examination, specialty, surgeon) and surgical masks (e.g., procedure mask).

Medical Device Types	Descriptions
Non-Sterile PPE (Gowns)	Non-sterile PPE gowns are used to cover the front and back of the body (from the top of shoulders to the knees) and the arms (down to the wrist cuff). Includes, but is not limited to surgical isolation gowns and non-sterile non-isolation gown.
Public Use Respirators	Public use respirators are used to cover the nose and mouth of the wearer to protect the wearer from splash and spray of body fluid and help reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as influenza pandemic. Includes but is not limited to National Institute for Occupational Safety & Health (NIOSH) Approved® N95® filtering facepiece respirators.[5]
Surgical PPE (Gloves and Gowns)	Surgical PPE gloves and gowns are used to cover the front and back of the body (from the top of shoulders to the knees), the arms (down to the wrist cuff), and the hands. Includes, but is not limited to sterile surgical gowns and gloves.
Sterilization	Sterilization devices are used by healthcare providers to sterilize medical products. Includes, but is not limited to liquid chemical sterilant, high level disinfectants, sterilization equipment (e.g., chemical, dry heat, ethylene-oxide gas, steam), sterilization equipment accessories (e.g., wraps, trays, containers).

Table 14. Medical Imaging Device Type Descriptions

Medical Device Types	Descriptions
Aprons	Aprons are used to cover the body of the patient, the operator, or other persons from unnecessary radiologic exposure.
Radiation Attenuating Gloves	Radiation attenuating gloves are used to shield hands and wrists from scattered radiation exposure during medical or surgical procedures involving radiation. The gloves also offer protection from transmission of infectious agents.
Shields	Shields are barriers used to attenuate radiation during radiologic procedures to protect the patient, the operator, or other persons from unnecessary exposure.

Appendix B – Task Group of Experts

The Task Group was composed of 18 individuals representing organizations from a cross-section of the medical device ecosystem.

Distributors

Veronica Crawford, BSN, RN
Director of Clinical Strategy
McKesson Medical-Surgical Government Solutions

Christina Lavoie, JD
Director, Policy
Health Industry Distributors Association (HIDA)

Mike Marchlik, MS
Vice President, Quality Assurance and Regulatory Affairs
Owens & Minor, Incorporated

Jaidalyn Rand, MSPH
Director, Industry Relations
Healthcare Distribution Alliance (HDA)

Tim Rubert, MS
Vice President, Government Affairs
Bound Tree Medical

Group Purchasing Organizations

Jocelyn Bradshaw
Senior Vice President of Strategic Sourcing
HealthTrust

Todd Ebert, R.Ph., MS
President and Chief Executive Officer (CEO)
Healthcare Supply Chain Association (HSCA)

Sharon Roberts, RN, BSN
Vice President Clinical Services and Contract Operations
Premier, Incorporated

Healthcare Providers

Erin Kyle, DNP, RN, CNOR, NEA-BC
Editor in Chief, Guidelines for Perioperative Practice
Association of periOperative Registered Nurses (AORN)

Jonah Mainzer, JD
Senior Policy Advisor in Policy and Government Affairs
American Nurses Association (ANA)

Healthcare Systems

Nancy Foster
Vice President for Quality and Patient Safety Policy
American Hospital Association (AHA)

Melissa Harvey, RN, BSN, MSPH
Assistant Vice President for Enterprise Emergency Operations & Medical Transport
HCA Healthcare

Mark P. Jarrett, MD, MBA, MS
Senior Health Advisor
Northwell Health

Skip Skivington
Vice President, Healthcare Continuity and Support Services
Kaiser Permanente

Manufacturers

Dan Glucksman
Senior Director, Policy
International Safety Equipment Association (ISEA)

Clayton Hall
Executive Vice President of Government Affairs
Medical Device Manufacturers Association (MDMA)

Abby Pratt
Senior Vice President, Global Strategy and Analysis
Advanced Medical Technology Association (AdvaMed)

Peter Weems
Senior Director, Policy, and Strategy
Medical Imaging and Technology Alliance (MITA)

Appendix C – Interagency Working Group

The Interagency Working Group developed and coordinated activities under the POAM.

Tammy Beckham, DVM, PhD
Associate Director
FDA, CDRH, Office of Strategic Partnerships and Technology Innovation (OST), Resilient Supply Chain Program (RSCP)

Katie Capanna, MBA
Acting Associate Office Director
FDA, CDRH, OST

Wayland Coker, MBA, CSCP
Chief Supply Chain Strategist, Office Director, Supply Chain Optimization, Industrial Base Management & Supply Chain
Administration for Strategic Preparedness and Response (ASPR)

Maryann D'Alessandro, Ph.D.
Director
Centers for Disease Control and Prevention (CDC), NIOSH, National Personal Protective Technology Laboratory (NPPTL)

Joe Figlio
Branch Chief
ASPR, Pandemic Vaccine Preparedness Capabilities & Readiness, Division of Pharmaceutical Countermeasures & Infrastructure (PCI), Biomedical Advanced Research and Development Authority

Jacqueline Gertz, PhD
Policy Analyst
FDA, CDRH, Office of Product Evaluation and Quality (OPEQ), Clinical and Scientific Policy Staff (CSPS)

Will Harris, JD
Senior Advisor
Office of Administrator at Centers for Medicare & Medicaid Services (CMS)

Robert Hayes
President and CEO of Community Healthcare Network
Indian Health Service (IHS)

Michael Hoffman
Biomedical Engineer
FDA CDRH, OPEQ, CSPS

Caroline Johnson, MPH
Manager, Government and Public Services: Strategy and Analytics
Deloitte Consulting, LLP

Matt Miller, PharmD, MHA, BCGP
CDR United States Public Health Service
Deputy Director, National Supply Service Center (NSSC) Operations
IHS

Carl Newman, PhD, MS
Senior Technical Advisor
FDA, CDRH, OST, RSCP

Linda Ricci, MME, MPH
Acting Deputy Office Director
FDA, CDRH, OST

Alison Ross
Consultant, Government and Public Services
Deloitte Consulting, LLP

Suzanne Schwartz, MD, MBA
Director of the Office of Strategic Partnerships and Technology Innovation (OST)
FDA, CDRH

Michelle Tarver, MD, PhD
Deputy Center Director for Transformation
FDA, DCRH

Eli Tomar
Associate Director, Office of Policy
FDA, CDRH, Office of Policy (OP)

Kimberly Viola, JD
Regulatory Counsel
FDA, CDRH, OP

Charles Weir, PhD, MPH
Executive Director, Joint Supply Chain Resilience Workgroup
Office of Critical Infrastructure Protection, Office of Preparedness, ASPR

Appendix D − Physician and Clinical Subject Matter Experts

The following individuals provided clinical expertise to the Task Group during their deliberations.

Francis X Campion, MD, FACP
Internal Medicine Physician
The MITRE Corporation

Susan Haas, MD
Obstetrician Gynecologist
The MITRE Corporation

Ryan Luginbuhl, MD
General Physician
The MITRE Corporation

Alex Mays, MD
Pathologist
The MITRE Corporation

Rakhee Palekar, MD, MPH
Board-certified Family Medicine Physician
The MITRE Corporation

Gregg Pane, MD, MPA, CPE, FAAPL
Emergency Medicine Physician
The MITRE Corporation

Juan A. Sanchez, MD, MPA, CPE, FACS, FACC, FACHE
Associate Professor of Surgery, Cardiothoracic Surgeon
Johns Hopkins University School of Medicine

Yahya Shaikh, MD, MPH
Preventive Medicine Physician
The MITRE Corporation

Caresse Spencer, MD, MBA, MA
Board-certified Anesthesiologist and Critical Care Intensivist
The MITRE Corporation

Amy Stiner, RN, MBA, MPA
Registered Nurse
The MITRE Corporation

Appendix E − Contributors

The following individuals contributed to Task Group deliberations.

Nate Brown, JD
Partner
Akin Gump Strauss Hauer and Feld LLP
AdvaMed

Sheri Devinney
Director of Operations and Executive Assistant to the President
MDMA

Dave Douglas, MBA
Director, Category Management
Owens & Minor, Incorporated

Alisha Enrico, MPA
Director, Product Management and Vendor Relations
Bound Tree

Tara Federici
Vice President
AdvaMed

Deborah Haywood
Vice President Government Solutions
McKesson Corporation

Mark Howell, JD
Director of Policy and Patient Safety
AHA

Kevin Johns
Senior Director, Supply Assurance
Vizient, Incorporated

Shoshana Krilow, JD
Senior Vice President, Public Policy, and Government Relations
Vizient, Incorporated

Mark Leahey, JD, MBA
President and CEO
MDMA

Jennell Lengle, MS
Assistant Vice President, Clinical Services
HealthTrust

Anita Nosratieh, PhD
Associate Vice President, Technology and Regulatory Affairs
AdvaMed

Geeta Pamidimukkala, MS
Vice President, Technology and Regulatory Affairs
AdvaMed

Jennifer Pennock
Associate Director, Government Affairs
AORN

Zach Rothstein, JD
Executive Director, AdvaMedDx
AdvaMed

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier, Incorporated

Mitch Saruwatari
Director, National Emergency Management
Kaiser Permanente

Michael Schiller
Senior Director, Supply Chain
AHA, Association for Health Care Resource & Materials Management

Meredith Serdakowski
Director of Policy
MDMA

Lisa Stand
Director, Policy, and Regulatory Advocacy
ANA

Janet Trunzo
Senior Advisor to the President and Senior Executive Vice President, Technology and Regulatory Affairs
AdvaMed

Michael Wargo, RN, BSN, MBA, PHRN, CMTE
Vice President and Chief, Enterprise Emergency Operations and Medical Transport
HCA Healthcare

Jamie Wolszon, JD
Associate Vice President, Technology and Regulatory Affairs
AdvaMed

Appendix F – FDA Support

The FDA support team provided operational, analytical, and administrative support to the Task Group.

Lauren Acierto
Communications and Outreach Strategist
The MITRE Corporation

Alexandra Cha, PhD, MA
Chief Scientist
Booz Allen Hamilton

Jerome Cordts, EdD
Principal, Biomedical and Food Regulation
The MITRE Corporation

Lisa Daigle, MS, MA
Lead, Health Policy Analyst
The MITRE Corporation

Jonathan Davis
Lead, Organizational Change Management
The MITRE Corporation

Laila Handoo, MS, MPH
Intermediate, Public Health, Environmental and Life Sciences
The MITRE Corporation

Karen Honess, MS
Health Program Analyst
The MITRE Corporation

Ryan Kristjason
Associate, Supply Chain Management
Booz Allen Hamilton

Adam Kroetsch, MS
Principal, Clinical Quality and Data Science
The MITRE Corporation

Allyson Smith, MS
Principal, Health Systems Engineering and Process Integration
The MITRE Corporation

Megan Smith, MS
Principal, Health Strategy, Operations and Systems
The MITRE Corporation

Ryan Triche, CSCP
Lead Logistics Engineer
Booz Allen Hamilton

Taylor Wilkerson, MBA
Principal, Health Strategy, Operations and Systems
The MITRE Corporation

Melissa Wilson, MS
Program Manager, Health Transformation and Research
The MITRE Corporation

Appendix G – Medical Device Types Identified Not Critical for CMDL but Critical for EMS

During Task Group discussions, several medical devices were specifically noted as being critical for use in emergency response. The Task Group did not make a determination on EMS applicability for each medical device type discussed, therefore, the medical devices list in Table 15 should not be considered a comprehensive list.

Table 15. Medical Device Types Identified as "Not Critical" for CMDL but Critical For EMS

Function	Subfunction	Device Category	Device Type
Care Delivery	Airway & Respiratory Support	Airway Instrumentation, Suction, and Related Devices	Airway Forceps
			ETT Fixation Devices
	Cardiovascular support	CPR Support	Mechanical CPR Support
		Pacemaker	Pacemaker Programmers
			Temporary Pacemaker Electrodes
	General Supportive Care	General Supportive Care	Gait and Mobility Assist Devices
	Surgical Intervention	Orthopedic Devices	Traction Devices

Appendix H – Plan of Action and Milestones (POAM)

Establish a Critical Medical Device List
Action ID: 31
Plan of Action and Milestones
National Strategy for a Resilient Public Health Supply Chain
Executive Order 14001, Section 4

Context

This action supports the interagency commitment to the implementation of the *National Strategy for a Resilient Public Health Supply Chain* (the Strategy), developed in response to Section 4 of the Executive Order (EO) 14001 on a Sustainable Public Health Supply Chain. This effort supports the nation's preparedness to respond to a public health emergency (PHE) by designing, building, and sustaining a long-term capability in the U.S. to manufacture supplies for future PHEs, including pandemics and biological threats. This plan of action and milestones (POAM) provides a clear pathway to achieve those goals and supporting objectives. This POAM outlines the steps necessary to ensure resources are available and to communicate the timeline, risks, and responsible persons for each step.

Overview

The Food and Drug Administration (FDA) regulates thousands of medical devices to assure that patients and providers have access to safe, effective, and high-quality medical devices. To this end, the FDA monitors medical device supply chains for vulnerabilities, risks, and disruptions. The Coronavirus Disease 2019 (COVID-19) pandemic highlighted our nation's preparedness and supply chain vulnerabilities. During the first weeks of COVID-19 and throughout the course of the pandemic, medical devices that are essential for the safety of healthcare workers (e.g., personal protective equipment (PPE)) and vital for patient health (e.g., ventilators, diagnostic tests) have been in short supply. In addition, there are other emergencies or situations (e.g., recalls) that can result in supply chain disruptions and shortages that can have significant impact on patient health.

This POAM outlines the development of a critical medical device list and resilience framework. This Action Plan will outline the process and milestones for the development of a set of recommendations for FDA consideration, and will focus on the following topics:

1) Criteria for inclusion of medical devices on the critical device list

2) A list of critical medical devices

3) Criteria for updating the list, including frequency and potential triggers

4) the medical device resilience framework[6]

This Action Plan and its deliverables will help focus activities and build resiliency in the medical device supply chain. The resulting list will support resiliency for those devices that are deemed most vulnerable to supply chain disruptions and critical to U.S. public health (i.e., those medical devices that are critical to have available for use at all times). In addition, the list can be utilized to support U.S. government actions including, but not limited to:

- Investments
    - Advanced manufacturing capabilities, processes, and technologies
    - Industrial-Base Expansion (IBX)
    - Stockpiling
        - Purchasing, stockpiling, and distribution approaches
- Building Resiliency in the Medical Device Supply Chain
    - End-to-end supply chain visibility and predictive analytics to prevent supply chain disruptions and/or shortages

Scope

In accordance with the Strategy, the FDA Center for Devices and Radiological Health (CDRH), in collaboration with the project team, will work with a broad representation of public health experts and clinicians in the government, non-profit, and private sectors to develop a recommended list of medical devices (including device materials, components, parts, or accessories) that are essential to have on hand at all times for patients, healthcare workers, and the U.S. public because of their clinical need.

The work outlined in this Action Plan will be facilitated through the Health Care and Public Health Sector Critical Infrastructure Partnership Advisory Council (CIPAC). CIPAC will convene a Task Group of experts (hereafter referred to as "the Task Group of Experts (TGoE)") to generate consensus recommendations regarding a list of essential medical devices. In addition, the TGoE will develop a recommended list of criteria that will be used to support recommendations for inclusion of a medical device on this list and the frequency and/or situations that would prompt an update of the list and/or criteria. The TGoE's recommendations will be informed by surveys and virtual meetings. The list and criteria will be developed in collaboration with government partners, external stakeholders (medical device experts, manufacturers, distributors), clinicians and other healthcare workers.

When developing recommendations for the devices on this list, the TGoE will consider factors including, but not limited to:

- Devices that are used to diagnose, treat, monitor, or prevent a serious disease or medical condition

- Devices that are critical to public health, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care (including emergency medical transport) or during surgery
- Supply chain resiliency/vulnerabilities, interdependencies, and risks
- Impact on patient care if the device is unavailable
- Utilization in care for special patient populations (e.g., pediatric populations, pregnant women, immunocompromised patients)
- Demand in an emergency scenario (e.g., weather event like hurricanes, Chemical, Biological, Radiological, Nuclear (CBRN) event, PHE)
- Broad utility across a variety of patient populations
- Ability to be utilized across multiple conditions or diseases
- Lack of suitable alternatives

The Action Plan focuses on medical devices and, where appropriate, considers key materials, components, parts, and accessories.

The TGoE's will also develop recommendations for a resiliency framework that will be considered by the FDA and deliver an evaluation of the vulnerabilities and risks facing essential devices, such as:

- Reliance on foreign components and materials
- Reliance on foreign manufacturing
- Insufficient domestic manufacturing capacity and/or capabilities
- Complex supply chains and manufacturing processes
- Significant product quality controls
- Costs of materials and manufacturing
- Costs of limited supply runs
- Costs of onshore or nearshore production

Interdependencies

This Action Plan has interdependencies with the following actions/tasks in the implementation plan:

1) Action 3: Create enduring federal, state, local, tribal, and territorial (SLTT), and private-sector stockpiling plan.
2) Action 7: Create a long-term, operational industrial base expansion plan.

3) Action 11: Maintain end-to-end supply chain visibility through expanded and continuous supply chain surveillance.
4) Action 17: Secure additional funding appropriations for public health supply chain investments (e.g., stockpiling, IBX).
5) Action 23: Launch a new product standardization task force.
6) Action 27: Develop preemptive supply chain demand management capabilities.
7) Action 30: Establish priority of "Critical Drugs" from the FDA List of Essential Medicines, Medical Countermeasures and Critical Inputs.

Work Streams in Parallel with the Action Plan

- HHS will perform an evaluation of Essential Devices that went into shortage during the COVID-19 pandemic and those that have been previously determined to have significant vulnerabilities and risks, to determine major drivers, including mapping their supply chains to characterize their redundancy, diversity, and manufacturing quality.
- HHS will develop capabilities to support end-to-end visibility and predictive analytics for the medical device supply chain.

Team Roles and Responsibilities

This project team and development of the Action plan is coordinated by HHS/FDA/CDRH and is supported by members from across government. This team is also supported by contractor staff. Additional Federal agencies will be surveyed and/or interviewed during the development of the recommendations for the Critical Medical Device List include:

- Centers for Disease Control & Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- U.S. Department of Veterans Affairs (VA)
- Indian Health Service (IHS)

Appendix I – CMDL Survey Summary and Results

Introduction

Stakeholder surveys were conducted to inform Task Group deliberations and inform development of criteria, a critical medical device list and medical device resilience framework. Five online surveys, one for each stakeholder group within the medical device ecosystem:

- Healthcare providers (e.g., physicians, nurses, lab technicians, and other clinical staff)
- Healthcare systems (e.g., hospital administrators and other management roles)
- Medical device manufacturers (e.g., executives and supply chain managers)
- Medical device distributors (e.g., executives and production managers)
- Medical device GPO's (e.g., executives and procurement officers)

Each stakeholder group received a tailored survey. Survey responses were voluntary, and all questions were optional. Survey results were analyzed for key findings within and across stakeholder groups.

CMDL Survey Results

Demographics

The majority of survey responses (94% of 101 received responses) came from healthcare providers and medical device manufacturers (Figure 10). The limited number of survey responses observed from GPO's and distributors was expected, as there are fewer organizations that exist within those stakeholder groups. Although a single response was received from the healthcare systems group, many respondents from the healthcare provider group self-identified as part of larger healthcare systems, suggesting that the healthcare provider group responses may also be representative of the healthcare systems perspective.

Figure 10. Survey Response Breakdown

Survey respondents within the manufacturing, distributor, and GPO stakeholder groups had senior or executive level job titles. Survey respondents' job roles within the healthcare industry were diverse, including physicians, nurses, and laboratory technicians. Respondents had an average of 20 years of experience in the healthcare field.

Twenty-three medical specialties (as defined by the American Board of Medical Specialties) were represented among the respondents of the healthcare providers and manufacturers surveys.[7] The survey respondents were primarily clinicians from pediatrics, surgery, cardiology, pulmonology, and critical care medicine.

Survey respondents were geographically diverse and reported working in various facility types; hospital inpatient being the most common response (Figure 11). Similarly, respondents reported support across all types of communities; urban being the most common response (Figure 12).

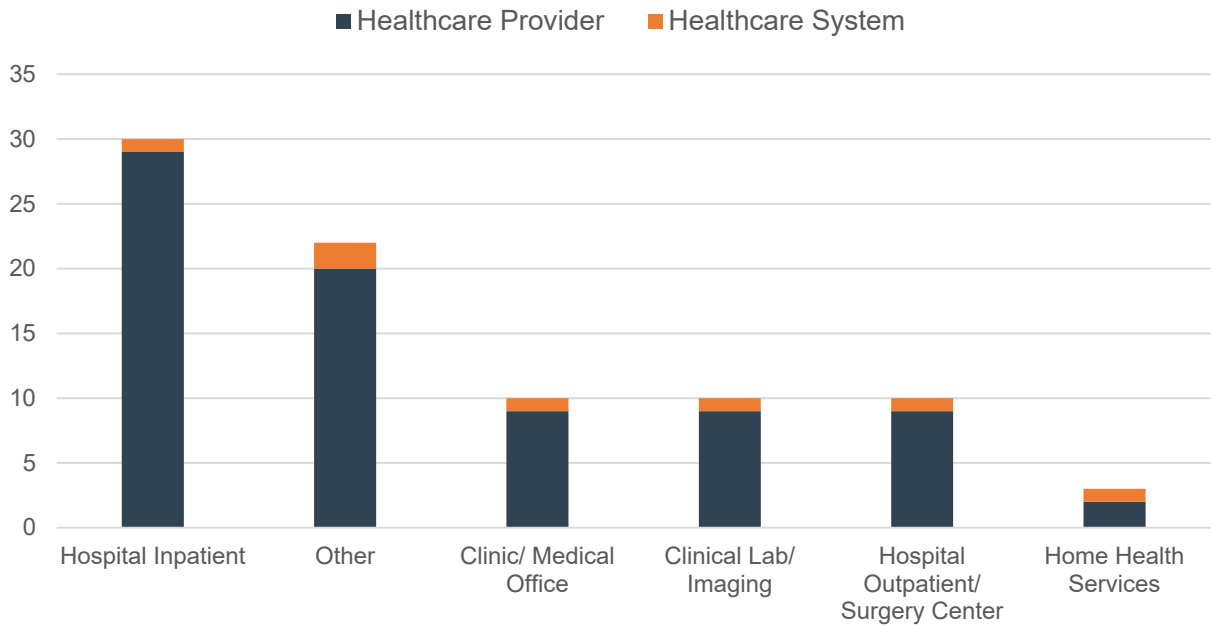

Figure 11. Facility Types

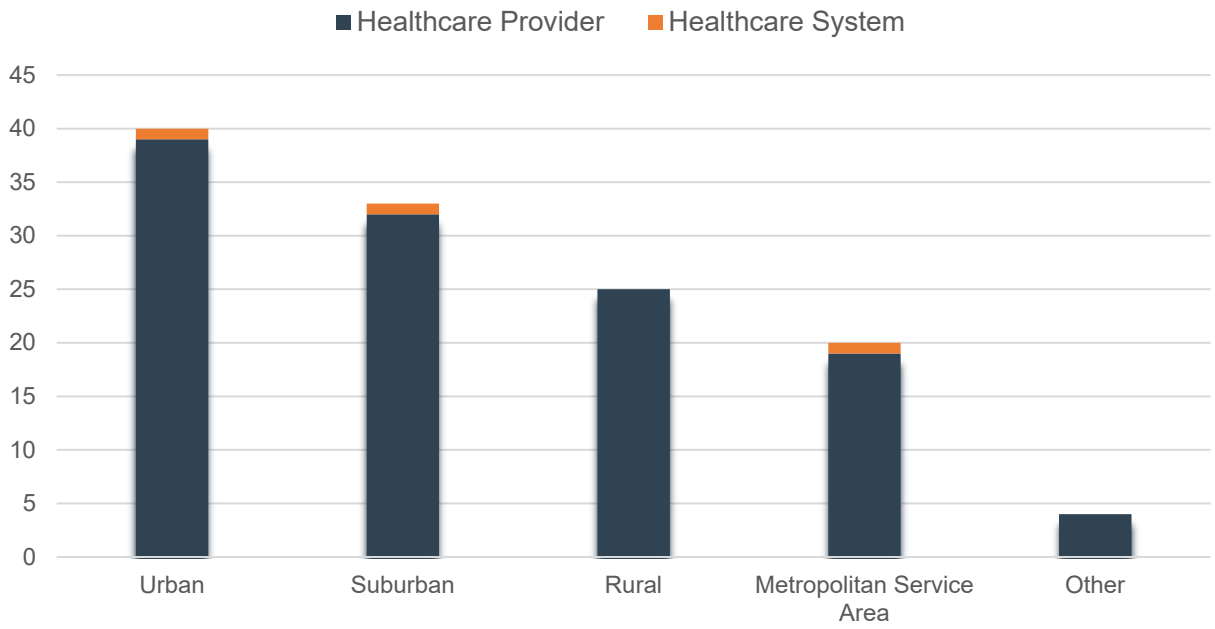

Figure 12. Communities Served

Criteria for Establishing a CMDL

Fifty-one percent of respondents ranked the following criteria as being most important when identifying critical medical devices:

1. Likely to cause permanent injury or death if unavailable
2. Used in life-sustaining treatment
3. Used in care of serious diseases or medical conditions
4. Necessary to address emergent medical situations
5. Used to treat a medical condition or disease

Critical Medical Devices

Free text responses were mapped to 193 medical device types (Table 16).

Table 16. Summary of 193 Medical Device Types by Function and Subfunctional Areas

Function	Subfunction	Percent
Care Delivery (70%)	Airway & Respiratory Support	19%
	General Supportive Care	18%
	Surgical Intervention	16%
	Cardiovascular Support	7%
	Liver & Kidney Support	6%
	Glucose Management	2%
	Neurological Intervention	1%
	Skin & Dermatological Support	1%
Clinical Laboratory Testing (13%)	Tests and Test Systems	6%
	Consumables	4%
	Lab Equipment	3%
Clinical Diagnostic Assessment (7%)	Monitoring	6%
	Diagnostic Testing	1%
Infection Control (5%)	PPE	4%
	Reprocessing and Reusing Devices	1%
Medical Imaging (5%)	Imaging Devices	3%
	General Medical Equipment	2%

The clinical functions with the largest number of critical medical devices were Care Delivery (70%) and Clinical Laboratory Testing (13%).

Survey responses were cross referenced to the preliminary list, generated from the working set of criteria (Figure 13).

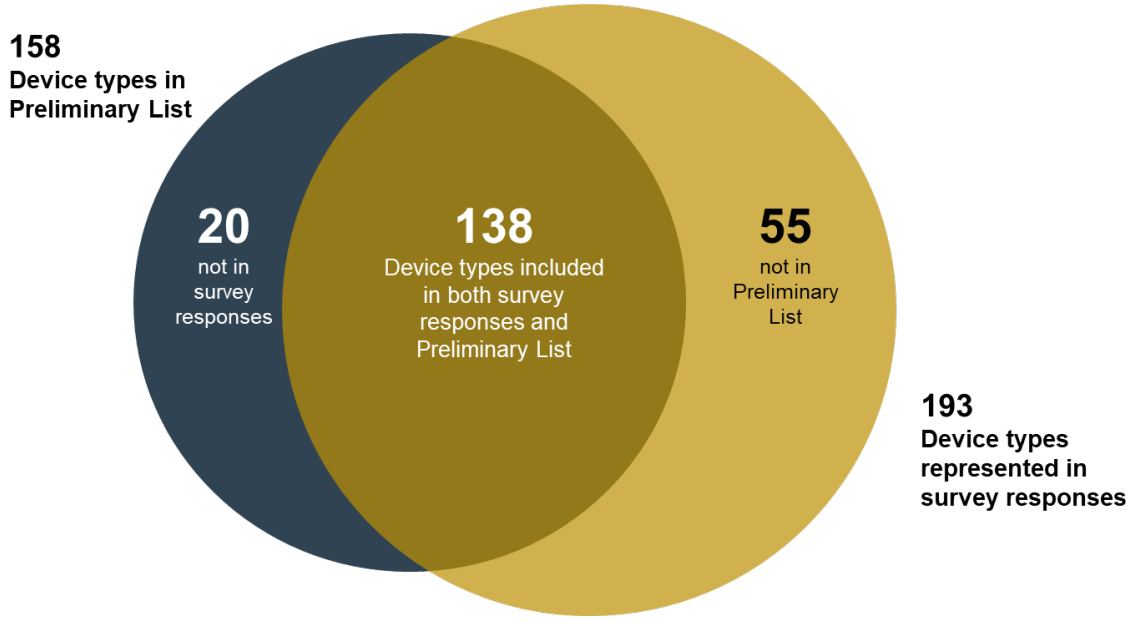

Figure 13. Critical Medical Devices and alignment with the draft CMDL

Medical Device Supply Chain

Surveys also contained open-ended questions regarding supply chain constraints, vulnerabilities and risks, and mitigations. Healthcare providers and healthcare systems responded with a variety of types of medical devices (e.g., PPE, IVs, feeding pumps, laboratory reagents/test kits, respiratory/airway devices, and ventilators) in a free text format. Stakeholders also mentioned a lack of alternative suppliers, logistics (e.g., shipping, complexity, and cost) as well as medical device and raw materials and component shortages (e.g., electronics such as chips/semiconductors and batteries) as factors that affect supply chain vulnerabilities and risks. Lead times and transparency were additional factors stated by multiple stakeholder groups.

Finally, respondents commented on mitigation and preparedness strategies to include government and industry partnership, utilization of suitable alternatives, effective product management within systems and organizations, and policy development, including incentives.

Appendix J − Limitations

The report design has the following limitations:

- The Task Group was established with representatives from five major stakeholder groups: healthcare providers, healthcare systems, medical device distributors, medical device manufacturers, and medical device group purchasing organizations. The individuals selected as representatives of these groups may not represent the opinions of all individuals and organizations within those stakeholder groups.
- In reviewing the working CMDL, Task Group members had the opportunity to discuss amongst themselves and ask FDA and external medical device experts questions about specific device types. Regardless, some task group members stated that "they did not have the expertise" to determine criticality for certain medical device types. As such, they "abstained" for those polls. This was not entirely unexpected, as Task Group members were recruited for their participation based on their expertise and representation of specific market and/or clinical sectors.

Appendix K – Abbreviations and Acronyms

Table 17. Abbreviations and Acronyms

Term	Definition
AdvaMed	Advanced Medical Technology Association
AHA	American Hospital Association
ANA	American Nurses Association
AORN	Association of periOperative Registered Nurses
ASPR	Administration for Strategic Preparedness and Response
CBRN	Chemical, Biological, Radiological, Nuclear
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health (FDA)
CEO	Chief Executive Officers
CIPAC	Critical Infrastructure Partnership Advisory Council
CMDL	Critical Medical Device List
CMS	Centers for Medicare & Medicaid Services
CSPS	Clinical and Scientific Policy Staff
EMS	Emergency Medical Services
EOs	Executive Orders
FDA	Food and Drug Administration
GPO	Group Purchasing Organization
HCA	Hospital Corporation of America
HDA	Healthcare Distribution Alliance
HHS	Department of Health and Human Services
HIDA	Health Industry Distributors Association
HPH	Healthcare and Public Health
HSCA	Healthcare Supply Chain Association
IBX	Industrial-Based Expansion
IHS	Indian Health Service
ISEA	International Safety Equipment Association
MDMA	Medical Device Manufacturers Association
MITA	Medical Imaging and Technology Alliance
NIOSH	National Institute for Occupational Safety & Health (CDC)
NPPTL	National Personal Protective Technology Laboratory (CDC)

Term	Definition
NSSC	National Supply Service Center (IHS)
OP	Office of Policy (FDA)
OPEQ	Office of Product Evaluation and Quality (FDA)
OST	Office of Strategic Partnerships and Technology Innovation (FDA)
PCI	Pharmaceutical Countermeasures & Infrastructure (ASPR)
PHE	Public Health Emergency
POAM	Plan of Action and Milestones
PPE	Personal Protective Equipment
RSCP	Resilient Supply Chain Program (FDA)
SCRWG	Supply Chain Resilience Working Group (ASPR)
SLTT	State, Local, Tribal, and Territorial
TGoE	Task Group of Experts
VA	Department of Veterans Affairs

Appendix L – Glossary

Table 18. Glossary

Term	Definition
Distributor	Any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. (Source: CFR.gov)
Group Purchasing Organization	An entity that helps healthcare providers such as hospitals, nursing homes and home health agencies, realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors. (Source: HSCA)
Healthcare Provider	A person who is trained and licensed to give health care. Also, a place that is licensed to give health care. Doctors, nurses, and hospitals are examples of healthcare providers. (Source: CMS.gov)
Healthcare System	An organization that includes at least one hospital and at least one group of physicians that provides comprehensive care (including primary and specialty care) who are connected with each other and with the hospital through common ownership or joint management. (Source: AHRQ.gov)
Manufacturer	Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions. (Source: CFR.gov)
Medical Device Industry	An industry consisting of medical device distributors, medical device manufacturers, and group purchasing organizations.
Medical Device Resilience Framework	A conceptual plan that ensures the ability of the medical device ecosystem to anticipate and prevent disruptive events and shortages and respond quickly to disruptions and/or shortages to mitigate their impact to public health.
Plan of Action and Milestones	The plan of action and milestone that provided the context, outcomes, scope, interdependencies, and roles and responsibilities for developing the CMDL recommendations.
Preparedness and Response	Proactive steps to improve the medical device ecosystem's ability to respond when a supply disruption or shortage takes place to quickly resolve the shortage and minimize or avoid patient harm.
Risk Assessment	A comprehensive assessment of supply chain risks. This assessment includes an analysis of the likelihood and severity of potential trigger events, the supply chain's ability to respond to those trigger events and vulnerabilities that may affect the supply chain's ability to respond.
Risk Mitigation	Proactive steps to reduce the likelihood of trigger events and minimize their effects, such as supply chain redundancy, inventory stockpiles, proactive response planning, etc.

Term	Definition
Resilience	Resilience is 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.
Task Group	The Task Group was assembled with the support of the FDA CDRH to develop a list of critical medical devices. The Task Group was established with representatives from five major stakeholder groups: healthcare providers, healthcare systems, medical device distributors, medical device manufacturers, and group purchasing organizations.
Trigger Event	A significant environmental, public health, transportation, or manufacturing event that disrupts production and/or delivery of a medical device.

Endnotes

[1] Executive Order 14001. Executive Order on a Sustainable Public Health Supply Chain | The White House

[2] National Strategy for a Resilient Public Health Supply Chain. National Strategy for a Resilient Public Health Supply Chain - July 2021 (phe.gov)

[3] Executive Order 14017. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains/

[4] Critical Infrastructure Partnership Advisory Council Charter. Critical Infrastructure Protection Advisory Council (CIPAC) 2022 Charter (cisa.gov)

[5] N95 and NIOSH approved are certification marks of the U.S. Department of Health and Human Services (HHS) registered in the U.S. and several international jurisdictions.

[6] A medical device resilience framework is a conceptual plan that ensures the ability of the medical device ecosystem to anticipate and prevent disruptive events and shortages and respond quickly to disruptions and/or shortages to mitigate their impact to public health.

[7] American Board of Medical Specialties. https://www.abms.org/