506J Implementation and Executive Order 13944

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Today's Topics

1. 506J
   - Overview
   - COVID-19 IIE Guidance
   - Implementation
2. Executive Order (EO) 13944
   - Medical Device Impacts

CDRH plays a critical role during COVID-19 Public Health Emergency

- COVID-19 pandemic triggered unprecedented increased demand for some devices, as well as significant disruptions to global medical device manufacturing and supply chain operations for some devices.

- The FDA has taken many actions to help ensure that patients and health care providers have timely and continued access to high-quality medical devices to respond effectively to the COVID-19 pandemic.

CDRH works collaboratively to prevent & mitigate medical device shortages

- Manufacturers
- Healthcare sector
- Professional societies
- Patient organizations
- International regulatory partners
- U.S. government
- Foreign governments
- Public health entities
- Supply chain entities
- Researchers / innovators

The CARES Act & Section 506J of the FD&C Act

- 506J requires manufacturers to notify FDA of:
  - a permanent discontinuance in the manufacture of certain devices, or
  - an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States
- This information will help prevent or mitigate shortages during the COVID-19 public health emergency.

FDA Issues Guidance to Help Prevent or Mitigate Medical Device Shortages

- **This immediately in effect guidance:**
  - Implements Section 506J of the Act during the COVID-19 public health emergency
  - Assists manufacturers in providing FDA timely, informative notifications about changes in the production of certain medical device products
  - Includes recommendations about who must notify the FDA, what information to include in the notification, and how to notify the FDA for the duration of the COVID-19 public health emergency
  - Is immediately in effect and is intended to remain in effect only for the duration of the public health emergency related to COVID-19.

Who must notify?

- Section 506J(a)(1)-(2) requires manufacturers of devices:
  - that are critical to public health during a public health emergency, or
  - for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency

to notify FDA of an interruption or permanent discontinuance in manufacturing of such devices.

Who must notify?

- In determining whether this requirement applies, the FDA recommends medical device manufacturers evaluate the following circumstances – whether the device or accessories are:
  - **life-supporting, life-sustaining,** or intended for use in **emergency medical care**;
  - intended for use **during surgery**;
  - used to **diagnose, cure, treat, mitigate or prevent COVID-19**; or
  - would be in **higher-than-typical demand during the response to COVID-19 pandemic** compared to a similar period of time.

When must the FDA be notified?

- Device manufacturers must notify the FDA at least six months before the date of the discontinuance or interruption or, if that is not possible, as soon as is practicable.
  - During the COVID-19 pandemic, the FDA considers “as soon as is practicable” to mean notification should be provided within 7 calendar days after the discontinuance or interruption in manufacturing occurs.
- After the initial notification, the FDA recommends updates every two weeks, including the expected timeline for recovery, until the shortage risk has been resolved. This ensures the FDA can act on the most current information.

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Medical Device Shortages During the COVID-19 Public Health Emergency

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Coronavirus (COVID-19) and Medical Devices

Antibody (Serology) Testing for COVID-19: Information for Patients

During the COVID-19 public health emergency (PHE), the FDA has taken many actions to help ensure that patients and health care providers have timely and continued access to high-quality medical devices to respond effectively to the COVID-19 public health emergency. These actions include issuing Emergency Use Authorizations (EUAs) and guidance documents to provide recommendations and help expand the availability and capability for various diagnostic, therapeutic, and protective medical devices in high

Content current as of:
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Regulated Product(s)
Medical Devices

www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency

Device Types to Consider

Device Types	Examples	Product Code
Clinical Chemistry Products	Critical Care Tests, Tests That May Monitor COVID-19 Progression	CEM, CEO, CFA, CGL, CGX, CGZ, CHL, CIC, CJY, JFL, JGJ, JGS, KHP, KHS, LFR, NBW, PZI, CGR, CIG, CIT, CIX, CJE, JFM, JFT
Dialysis-Related Products	Dialysis Accessories, Dialyzers	FID, PQK, FIG, FIR, FJD, FJF, FJI, FJK, FJT, FKB, FKJ, FKO, FKR, FLA, KDJ, KDL, KOC, KPF, KPO, LFK, LLB, MLW, MPB, MQS, MSD, MSY, NQJ, NYU, PEH, PFH, PKI, PPJ, FIL, FKP, FKQ, KDI
General ICU/Hospital Products	Air Purifiers, Beds, Cleaning Products, Feeding Tubes, GI Catheters	FRA, FRF, FNJ, FNK, FNL, FPO, KMG, MDZ, MEC, PSB, PSC, KNT, BSS, PIF, EZL, EOQ, KTI, PSV, FKK, KOD, FRR, LGM, LGN, PEZ, PWQ, FMK
Hematology Products	Oxygenation Tests, Clotting Tests	DAP, GJS, GKR, JKS, JPA, MVU
Infusion Pumps and Related Accessories	Infusion Pump Accessories, Pumps	FMG, FOX, FOZ, FPA, FPB, FPK, KPE, KZD, LDR, LJS, LJT, MJF, MRZ, OJA, PND, PTI, FRN, MEA
Microbiology Products	Flu Assay and Media	DCK, OEP, OTG, OZE, PSZ, QDS, QKP

www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-types-help-determine-section-506j-notification-obligations

CDRH List of Device Shortages

Posted	Category	Product Code	Interruption	Duration	Information
08/14/2020	Ventilation-Related Products	BZD (Non-continuous ventilator)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Ventilation-Related Products	CBK (Continuous ventilator, facility use)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Ventilation-Related Products	NOU (Continuous ventilator, home use)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Testing Supplies and Equipment	JJH (Clinical sample concentrator)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Testing Supplies and Equipment	JSM (Transport culture medium)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Testing Supplies and Equipment	KXG (Sterile swabs)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply
08/14/2020	Testing Supplies and Equipment	LIO (Microbiological specimen collection and transport device)	Demand increase for the device	Duration of COVID-19 PHE	**Availability:** Limited supply

www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage

EXECUTIVE ORDER

- On August 6, 2020, President Trump signed an Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States.
- Under the order, the FDA is directed to create a list of essential medicines, medical countermeasures, and critical inputs (the FDA Executive Order List) that are necessary to have available at all times in America.
  - Due Date: November 4, 2020
  - Actual Publication Date: October 30, 2020

THE FDA EXECUTIVE ORDER LIST (SECTION 3(c))

"Within 90 days of the date of this order, and periodically updated as appropriate, the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms."

CRITERIA FOR DEVICE MEDICAL COUNTERMEASURES

A device [as defined in section 201(h) of the FD&C Act] qualifies as an MCM, as defined in Section 7(j) of the EO, if the device meets the following criteria:

- Fits within the definition of one of four elements of the MCM definition provided in the EO;
- Is always medically necessary to have available in adequate supply;
- Is not able to be substituted by another device on the list; and
- Meets one or more of the following:
  - Diagnostic testing and supplies generally applicable to PCR testing to enable rapid test development and processing;
  - PPE needed to protect healthcare workers from airborne, blood-borne, water-borne, chemical, biological, radiological or nuclear events;
  - Devices that are not permanently implanted that are intended to provide acute mechanical support in treating an acute event or condition in a healthcare setting for vital physiologic functions and are not intended solely for the treatment of chronic conditions;
    - Devices that provide adequate vital signs monitoring in a healthcare setting to enable the use of the mechanical support MCM devices;
  - Devices used for the delivery of a vaccine that are intended to prevent or mitigate the spread of an epidemic or pandemic; or
  - Devices used for the acute management of injury or illness caused by chemical, biological, radiological or nuclear events.

CRITERIA FOR DEVICE CRITICAL INPUTS

A device component [as defined 21 CFR 820.3(c)] qualifies as a CI, as defined in Section 7(d) of the EO, on the basis that it is:

- A component of a medical device identified on the list;
- Always medically necessary to have available in adequate supply;
- Critical to assessing the safety and effectiveness of a device identified on the list, as established by meeting the following criteria:
  - Be critical for the use/manufacture of a device identified on the list;
  - Reasonable substitutes are not easily available:
    - Inputs are so unique that there are no or limited substitutes; or
    - Inputs are widely used in multiple devices identified on the list; and
  - Substitutions (or modifications or omissions) generally would require a reassessment of safety and effectiveness of the identified device;
- Expected to be part of most devices identified on the list for a specific device type (i.e., not a unique component specific to a proprietary device); and
- Not components for which their identification could potentially disclose confidential commercial information.

EXECUTIVE ORDER LIST BY THE NUMBERS

96 Procodes for Medical Device MCMs

225 Drug Products

- **174** Essential Medicine products
- **51** MCM only products

More Information

Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs

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Introduction

On August 6, 2020, the President issued an Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States. This executive order directed the U.S. Food and Drug Administration (FDA) to identify a list of essential medicines, medical countermeasures and critical inputs that are medically

Content current as of:
10/30/2020

Regulated Product(s)
Biologics
Drugs
Medical Devices

Topic(s)

www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs

Downloadable List

Device Medical Countermeasures and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944

ProCode	Preferred Name	Critical Inputs
BTO	TUBE, TRACHEOSTOMY (W/WO CONNECTOR)	Connectors, valves, balloon cuffs
BTR	TUBE, TRACHEAL (W/WO CONNECTOR)	Connectors, valves, balloon cuffs
CAW	GENERATOR, OXYGEN, PORTABLE	molecular sieve, oxygen sensor, pressure chamber, pneumatic valves, mechanical
DQA	OXIMETER	red and infrared LEDs, photodetector
JOH	TUBE TRACHEOSTOMY AND TUBE CUFF	None
EOQ	BRONCHOSCOPE (FLEXIBLE OR RIGID)	optics (e.g., camera)
KTI	BRONCHOSCOPE ACCESSORY	None
BTM	VENTILATOR, EMERGENCY, MANUAL (RESUSCITATOR)	Mechanical bellows, gas filters (particulate/viral/bacterial), connectors for gas pathway,
BZE	HEATER, BREATHING SYSTEM W/WO CONTROLLER (NOT HUMIDIFIER OR NEBULIZER	None
FLS	APNEA MONITOR	sensor
BZH	PEAK FLOW METER	flow sensor
CBK	VENTILATOR, CONTINUOUS, FACILITY USE	sensors (flow, pressure, volume), expiratory pressure regulator, BZE
BYS	OXYGENATOR, LONG TERM SUPPORT GREATER THAN 6 HOURS	oxygenator fiber
MHX	MONITOR, PHYSIOLOGICAL, PATIENT(WITH ARRHYTHMIA DETECTION OR ALARMS)	ECG electrodes/leads, SpO2 sensors, Blood pressure cuff/pump and tubing,
PZS	DUAL LUMEN ECMO CANNULA	None
QJZ	EXTRACORPOREAL SYSTEM FOR LONG-TERM RESPIRATORY / CARDIOPULMONARY FAILURE	pump impeller, oxygenator fiber
FIL	SYSTEM, DIALYSATE DELIVERY, SINGLE PASS	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
FIZ	METER, CONDUCTIVITY, NON-REMOTE	conductivity sensor
FJD	DETECTOR, LEAK, BLOOD	leak sensors
FJF	DETECTOR, AIR BUBBLE	air sensors
FJI	DIALYZER, CAPILLARY, HOLLOW FIBER	dialyzer membrane
FJK	SET, TUBING, BLOOD, WITH AND WITHOUT ANTI-REGURGITATION VALVE	None
FKB	CONNECTOR, BLOOD TUBING, INFUSION T	None
FKP	SYSTEM, DIALYSATE DELIVERY, SINGLE PATIENT	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
KDI	DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE SYSTEM	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
KDL	SET, PERFUSION, KIDNEY, DISPOSABLE	None
MQS	SYSTEM, HEMODIALYSIS, ACCESS RECIRCULATION MONITORING	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
MSE	HEMODIALYZER, RE-USE, LOW FLUX	dialyzer membrane
MSF	HEMODIALYZER, RE-USE, HIGH FLUX	dialyzer membrane
PSX	CHLORINE METER	chlorine sensor
FMF	SYRINGE, PISTON	None
FMI	NEEDLE, HYPODERMIC, SINGLE LUMEN	None
FRN	PUMP, INFUSION	pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, air-in-line detector), FPB
[illegible]	[illegible]	pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, [illegible]

QUESTIONS