

COVID-19 Regulatory Considerations for Medical Device Companies

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COVINGTON

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Introduction: COVID-19

The impact of COVID-19 is widespread and implicates a broad array of legal issues

Supply Chain

Contracting &
Disputes

Employment

Insurance

Defense
Production Act

Import/Export
Issues

Capital Market &
Liquidity Issues

Liability PREP
Act

Public Company
Reporting

Ongoing
Transactions

Government
contracts (NIH,
CDC, BARDA)

"Shelter-in-Place"
Orders

Privacy Issues

Lobbying &
Government
Relations

IP Issues

To assist our clients in navigating this unprecedented situation, we have created a COVID-19 Task Force and assembled a COVID-19 Toolkit

Please see our COVID-19 [Toolkit](#) and reach out to any of us or the Covington COVID-19 task force at COVID19@cov.com

COVID-19 Toolkit:
Legal and Business Considerations



Introduction: COVID-19

This slide deck focuses on FDA regulatory issues medical device manufacturers are and will be facing during the COVID-19 public health emergency

Mechanisms to Increase Availability of Devices for COVID-19

COVID-19 Diagnostics

Digital Health Tools for COVID-19

Impact of COVID-19 on Premarket Reviews

COVID-19 Effect on Postmarket Operations

US Legislative Developments

Key EU Considerations for COVID-19

FDA Mechanisms to Increase Availability of Products to Address COVID-19

How is FDA addressing the need for COVID-19 related devices?

FDA is principally using two mechanisms to permit the rapid manufacture and distribution of devices in response to COVID-19

Authorizing the
use of devices
through
Emergency Use
Authorizations
(EUAs)

Exercising
Enforcement
Discretion
through
Immediately in
Effect Guidance
Documents

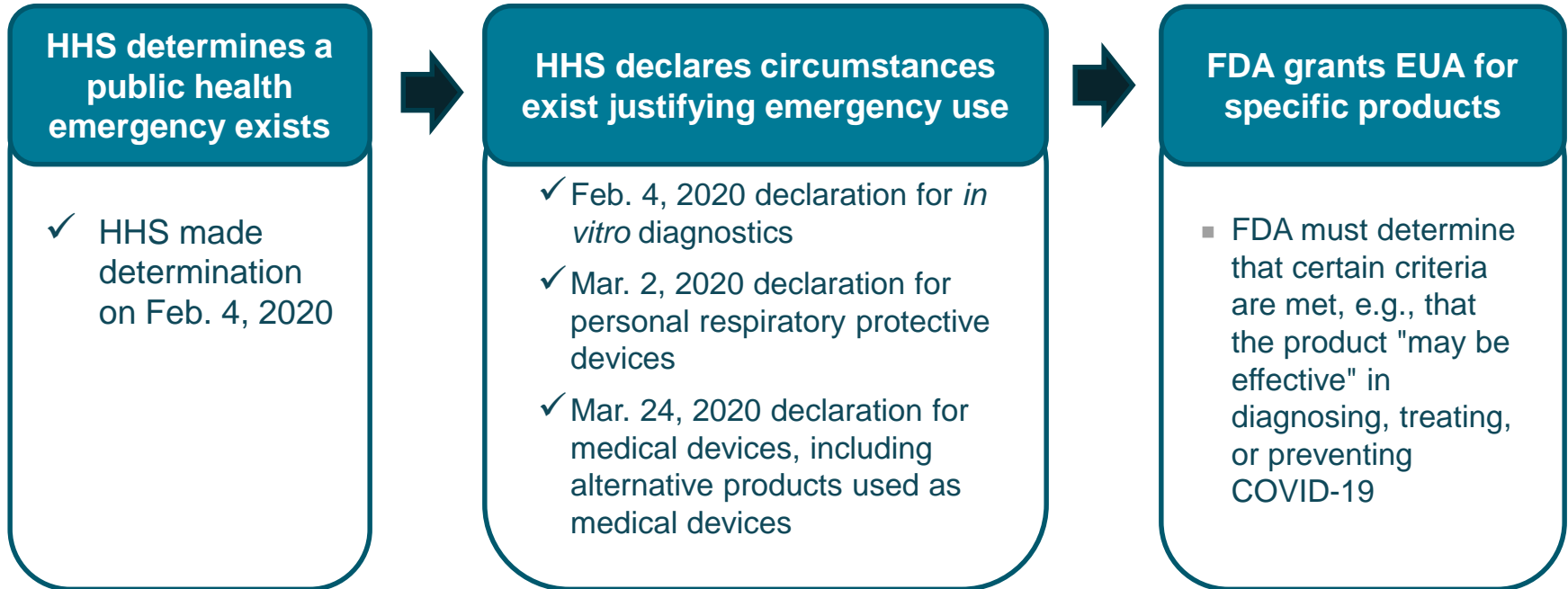
What is an Emergency Use Authorization (EUA)?

- FDCA § 564 gives FDA the authority to authorize the introduction into interstate commerce of unapproved medical products, or unapproved uses of approved medical products when there is a public health emergency related to a chemical, biological, radiological, or nuclear (CBRN) agent



When can FDA issue an EUA for COVID-19?

- For FDA to issue an emergency use authorization (EUA) for a particular product, three things must happen:



If I receive an EUA, what does that mean?

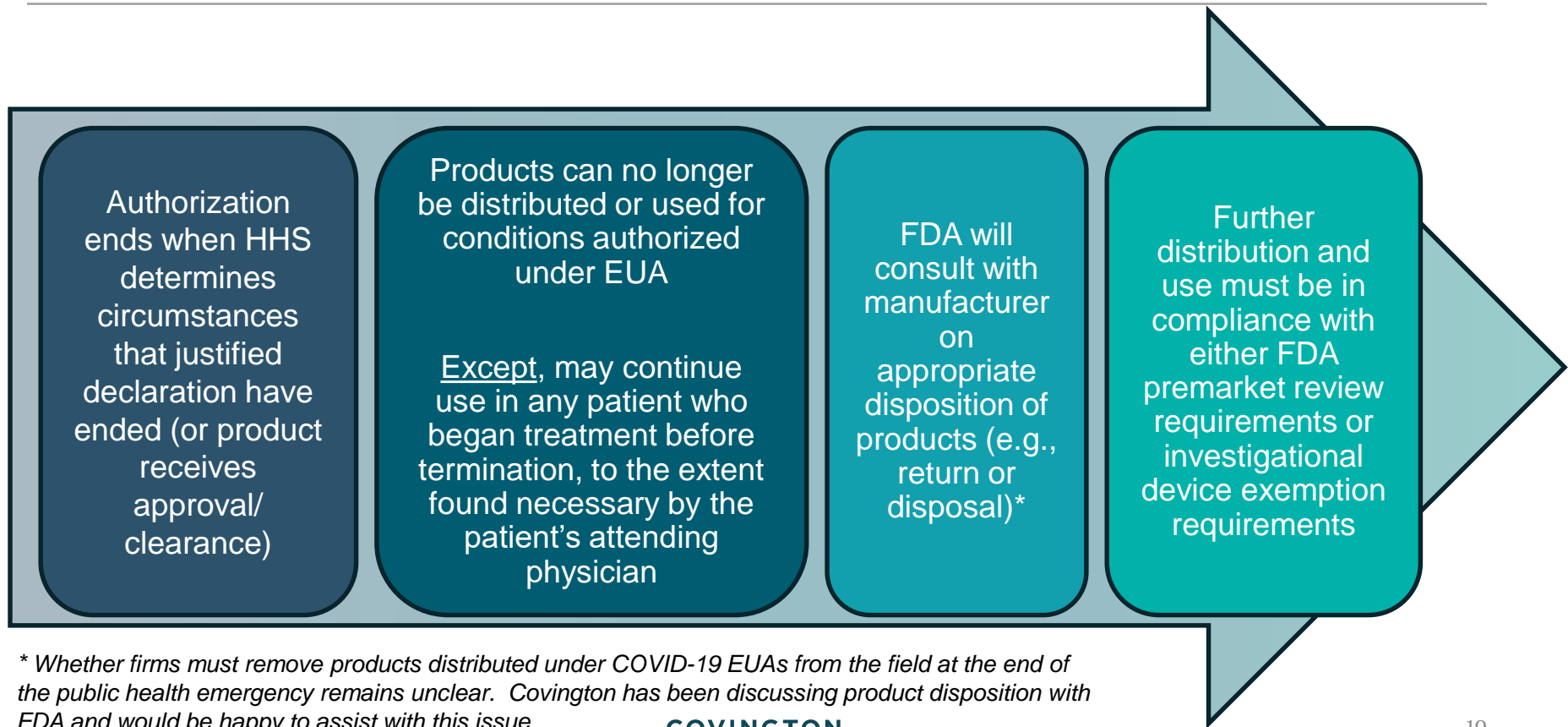
- Subject to conditions of the EUA, which may include:
 - Requirements to inform administering HCPs and recipients of product of key information (“Fact Sheet”), including:
 - Product subject to an EUA
 - Significant known benefits and risks
 - Alternatives
 - Description of product
 - Requirements to monitor and report adverse events
 - Limitations on distribution, administration, and advertising
- Authorization ends when HHS determines circumstances that justified declaration have ended (or product receives approval/clearance)

What liability protections may be available?

March 10, 2020 PREP Act [declaration](#) by HHS provides liability immunity for certain activities related to covered countermeasures for COVID-19

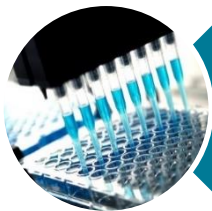
- **Activities** include development, manufacture, distribution, administration, and use
- **Covered countermeasures** include:
 - Devices under an EUA or a waiver under section 564A of FDCA
 - Cleared or approved devices
 - NIOSH-approved FFRs under an EUA
- **Limitations on distribution:**
 - Activities related to present or future federal contracts, agreements, grants or transactions
 - Activities authorized pursuant to federal, state, local authority response to a Declaration of Emergency

When does an EUA end and what happens then?



** Whether firms must remove products distributed under COVID-19 EUAs from the field at the end of the public health emergency remains unclear. Covington has been discussing product disposition with FDA and would be happy to assist with this issue.*

Has FDA granted any EUAs for COVID-19 products?



18 EUAs issued for diagnostics tests as of Mar. 26, 2020



NIOSH-approved respirators, certain imported disposable FFRs that are not NIOSH-approved, and a decontamination system for respirators



Ventilators, tubing connectors, and accessories

How do I receive authorization for my device under an EUA?

NIOSH-approved respirators

- Authorized if meet criteria listed in EUA [letter](#)

Imported non-NIOSH approved FFRs

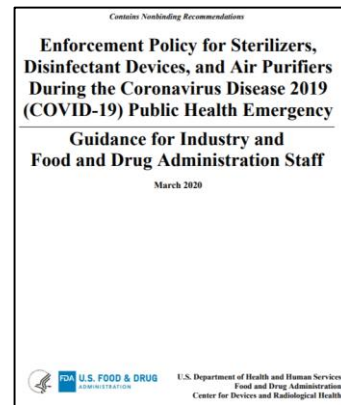
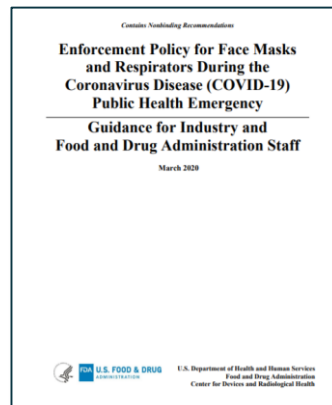
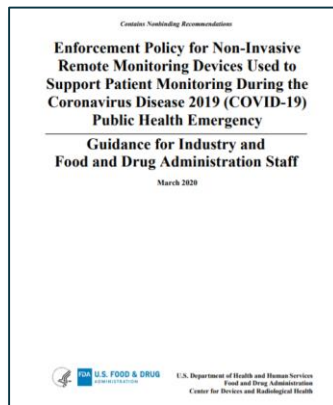
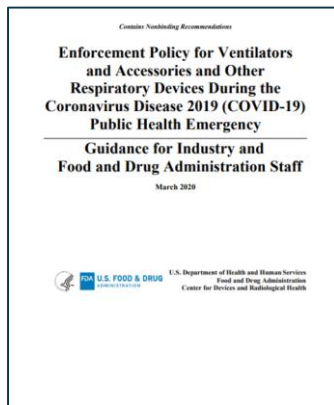
- If meet criteria in EUA [letter](#), e-mail request to be authorized to FDA, with info on manufacturer, model, current marketing authorization, number of devices to be imported, and copy of labeling

Ventilators and accessories

- Submit request for authorization that demonstrates device has met safety, performance and labeling criteria listed in EUA [letter](#)

What is Enforcement Discretion?

- FDA has issued several “Immediately in Effect” Guidance Documents
- These guidance documents, which are issued as final guidances, set forth the circumstances whereby FDA will not enforce provisions of the Food, Drug, and Cosmetic Act against manufacturers, importers, or distributors that offer products to address COVID-19 if they comply with the provisions of the guidance



Which devices are subject to an enforcement policy?

Patient monitoring devices

- No 510(k) required for modifications that do not create undue risk, e.g., change to use in home setting, changes to hardware to allow for increased remote monitoring capability

Ventilators and other respiratory devices

- No 510(k) required for modifications that do not create undue risk, e.g., changes to motors, material changes to components in gas pathway, use of ventilators outside cleared environment of use

Face masks and respirators

- Face masks not labeled as surgical masks or providing liquid barrier protection exempt from most requirements
- Surgical masks exempt from 510(k) or EUA requirement if they meet testing requirements

Sterilizers, disinfectant devices, and air purifiers

- No 510(k) or PMA supplement required for limited modifications to indications or functionality pertaining to a device's virucidal effectiveness against SARS-CoV-2 that do not create undue risk
- FDA does not intend to object to these devices intended to be effective at killing the SARS-CoV-2 virus that do not already have FDA marketing authorization and do not create undue risk

How is FDA approaching 3D printing of devices for COVID-19?

Increased interest in 3D printing devices and components to increase production of critical devices

- FDA regulates 3D printing of devices as the manufacture of devices
 - FDA guidance [Technical Considerations for Additive Manufactured Medical Devices](#) addresses application of quality system to 3D printing
- FDA issued [FAQs on 3D Printing](#) during COVID-19 pandemic
 - Recognizes 3D printing can play a role in production of devices in response to COVID-19 emergency
 - 3D printed devices (or devices incorporating new 3D printed components) subject to EUA requirements or FDA enforcement policies

Speeding the Availability of Diagnostics for COVID-19



What are the pathways for diagnostic tests?

IVDs

■ EUA Pathway

- Template available on FDA website
- May begin kit distribution after notifying FDA of validation completion
- Manufacturer must: (1) provide instructions for use & (2) post data concerning performance characteristics on company website
- Submit EUA within 15 business days of validation
- Submit modifications as EUA amendment

LDTs

■ EUA Pathway

- Generally same as IVD EUA pathway, *but* developer must include language on test report that test is validated but FDA review is pending
- FDA does not intend to object to use of a modified test when validated via bridging study to EUA-authorized test

■ State Pathway (MD, NV, NY, WA)

- EUA is not required; no FDA interaction
- Test must be developed under the legal authorities and established processes of the state in which lab resides
- State must take responsibility for testing by labs in that state

As of March 28, FDA has not authorized any COVID-19 tests for the home use or self-collection settings.

What is the pathway for a screening (serology) test?

- FDA does not intend to object to the development and distribution by manufacturers or test developers of serology tests to identify antibodies of COVID-19 under certain circumstances
- Intended for screening purposes only; not to be used as sole basis to diagnose or inform infection status
- Policy is limited to testing in laboratories or by healthcare workers at POC; does **not** apply to home testing
- FDA maintains a [list](#) of over 30 tests currently available under this policy



Validate
Test

Notify FDA
via Email

Outline
Limits in
Test
Report /
Labeling

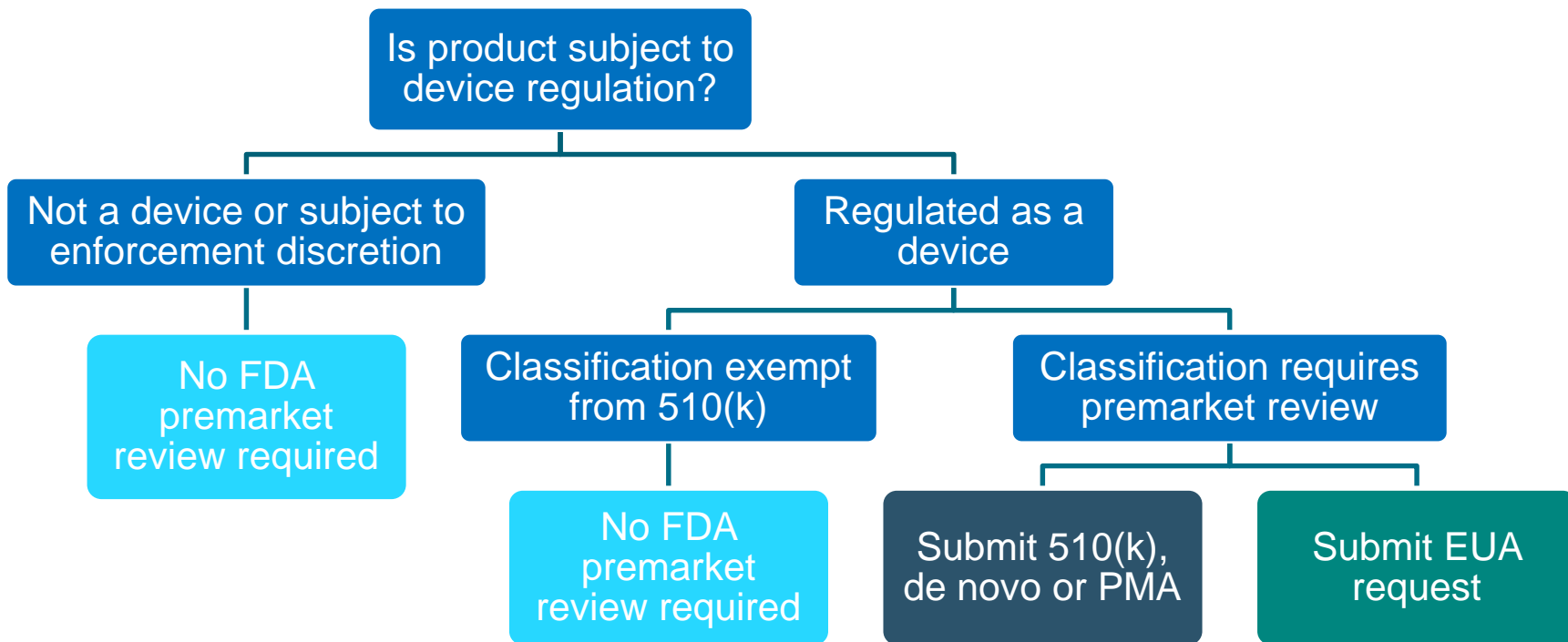
What other considerations should I keep in mind?

- Interacting with FDA
 - 24/7 hotline
 - Use of EUA templates
- Reporting to state & local public health departments
- Importation & intended use codes
- CLIA considerations
 - On 3/26, CMS issued a [memo and FAQs](#) concerning CLIA laboratory guidance during COVID-19 public health emergency
 - Expedited review of CLIA applications
- Alternative sources of materials
 - Reagents, extraction kits, viral transport media, swabs, etc.
- Fraudulent tests and FDA enforcement



Digital Health Considerations for COVID-19 Products

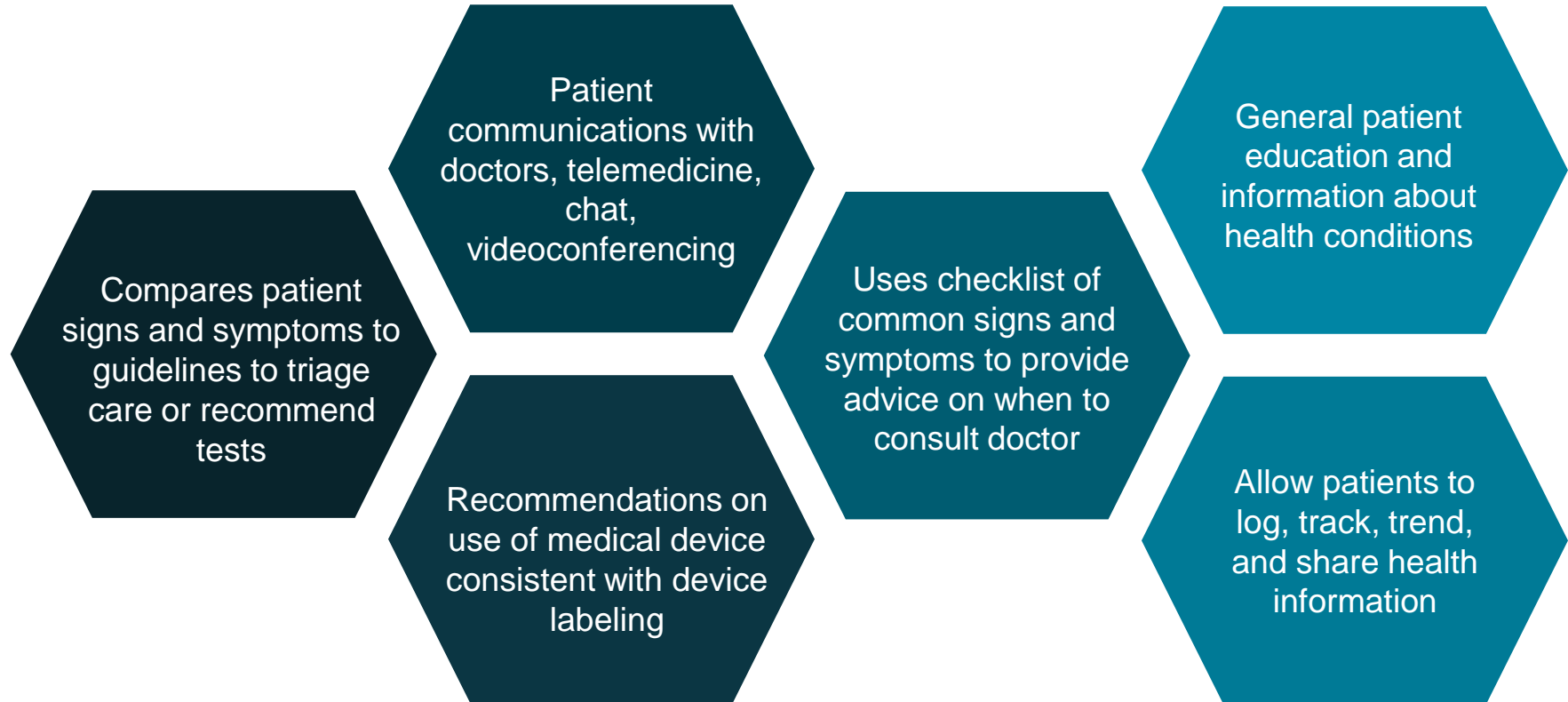
Is my COVID-19 digital health product subject to FDA review?



Has FDA issued any COVID-19 specific policies?

- FDA has not announced any new enforcement policies or approach to software in response to COVID-19
- FDA has provided examples of software for COVID-19 applications that would not be regulated under the agency's existing guidances
 - Digital Health Policies and Public Health Solutions for COVID-19 [website](#)
 - Clinical decision support for monitoring examples in [Enforcement Policy](#) for Patient Monitoring Devices

What kinds of software for COVID-19 are not regulated?



If my software is a device, how can I make it available?

■ Request EUA

- HHS Mar. 24 declaration for emergency use of “medical devices, including alternative products used as medical devices” includes software regulated as a device
- FDA is interested in engaging through EUA process for higher-risk digital health devices that are outside the agency’s COVID-19 policy
- EUA requests needs to demonstrate:
 - Sufficient performance and accuracy to show product “may be effective”
 - Benefit outweighs risks
 - No alternatives available

Impact of COVID-19 on Premarket Reviews

How will premarket interactions and reviews be affected?

- All eligible FDA employees are teleworking, and in-person meetings are being converted to telephone conferences
- Advisory Committee (Panel) meetings are being postponed
- Review times may increase for premarket submissions
- Extension of deadlines for certain applicant submissions
- See CDRH [Letter to Industry](#)



Is FDA extending submission due dates?

Response due date automatically extended by 60 days for:

Premarket Applications

- 510(k)s
- PMAs (original & supplement)
- De novo classification request
- Humanitarian Device Exemptions (original & supplement)



Conditions

- Application on hold as of Mar. 16, 2020
- Response due date on or before April 30, 2020

- For additional submission types (e.g., Post Approval or 522 Study reports, IDE annual reports, PMA reports), submit when possible
- Email CDRHPremarketProgramOperations@fda.hhs.gov for questions about response due dates

How should I handle disruptions to my clinical study?

Ensuring the safety of trial participants is paramount

Study Protocol

- Engage early with investigators and IRB to consider protocol changes
- Prospectively define procedures to prioritize reporting of deviations with safety impact
- Consult with review division regarding protocol modifications to effectiveness endpoints, or that affect data management and/or SAP
- Carefully document protocol changes and deviations

Policies and Procedures

- Informed consent
- Study visits & procedures
- Data collection
- Personnel (e.g., due to travel limitations, quarantine)
- Adverse event reporting
- Monitoring procedures
- Quarantine measures
- Measures to deal with COVID-19 illness

Final Clinical Study Report

- Description of implemented contingency measures
- List of affected participants & description of how participation was affected
- Analyses & discussions addressing impact of contingency measures on safety and effectiveness results

See Covington's [client alert](#)

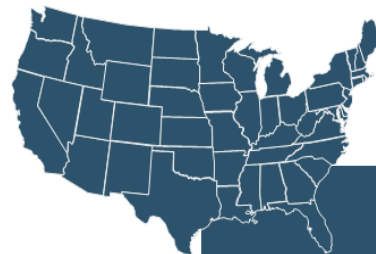
COVID-19 Effect on Postmarket Operations

Is FDA still conducting facility inspections?



Foreign Inspections

- As of March 10, routine surveillance inspections postponed until May
- Alternative FDA tools
 - Increased import screening, examinations, and sampling at ports
- Expect delays in FDA's ability to generate and mail hard-copy Notices of FDA Action (release notices, sampling notices, etc.)
- Reliance on mutual recognition agreements with other governments
- Inspection record requests in lieu of onsite inspection



Domestic Inspections

- As of March 18, all domestic routine surveillance facility inspections are temporarily postponed
- All domestic “for cause” inspection assignments will be evaluated and will proceed if mission critical
- Alternative FDA tools
 - Inspection record requests in lieu of onsite inspection

How do I best utilize my limited quality resources?

Use a risk-based approach to prioritize quality operations

Assess patient risk of incomplete or delayed activities

- Update risk management file (RMF) to include recent complaints, adverse events, non-conformances, and health hazard evaluations (HHE)
- Document rationale for prioritization
- If patient risk unacceptable, take appropriate action

How do I maintain QSR compliance if understaffed?



Ensure procedures, work instructions, and/or process aides are easily accessible throughout the organization in case employees are tasked with unfamiliar activities



Ensure clear access to QSR element owners or a “go-to” person for any QSR related questions



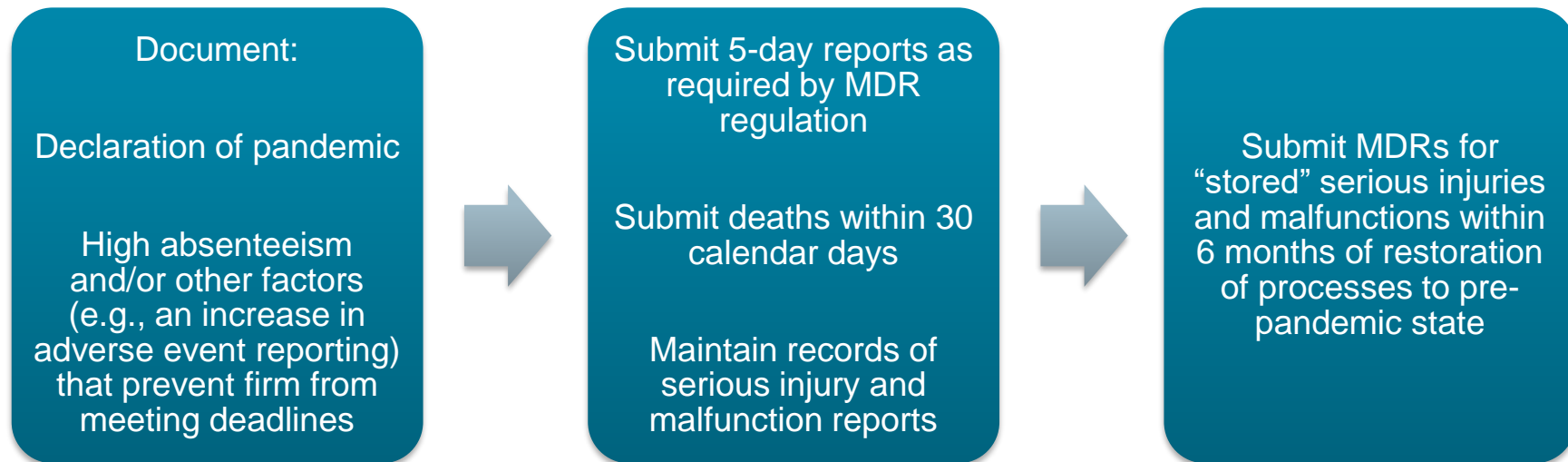
Conduct frequent check-ins with staff



Consider whether processes can be streamlined without compromising compliance

How do I keep up with MDR Reporting timelines?

- Maintain normal MDR Reporting processes to maximum extent possible
- If not possible due to high employee absenteeism then:



- See FDA [Guidance](#) and Covington's [client alert](#).

Do I have to notify FDA if personnel contract the virus?

There is no requirement to report the health of personnel to FDA.

But state or local boards of health may have notification requirements.

Conduct a health hazard assessment and document any product impact.

Clean and sanitize the facility.

Evaluate SOPs regarding control of personnel with communicable diseases and facility cleaning/disinfection.

In addition, interview affected persons, determine which other employees they interacted with, and notify other affected personnel, consistent with applicable privacy laws.

How do I import PPE and other devices?

- FDA issued [instructions](#) for manufacturers importing PPE and other devices in the following categories:

Non-FDA-regulated
general purpose PPE
(masks, respirators,
gloves, etc.)

- Entry information should not be transmitted to FDA; transmit to CBP using appropriate codes.

FDA-regulated devices
authorized by EUA

- Entry information should be submitted to FDA.
- Reduced FDA information is required for review.

FDA-regulated devices, not
authorized by EUA, subject
to enforcement discretion
under FDA guidance

- Entry information should be submitted to FDA.

U.S. Legislative Developments

How does the CARES Act affect medical devices?

Coronavirus Aid, Relief, and Economic Security (CARES) Act (enacted March 27, 2020) may impact medical device companies and laboratories in several ways

Medical Device Shortage Reporting

Sec. 3121: “Discontinuance or Interruption in the Production of Medical Devices”

Requires manufacturers to report:

- permanent discontinuance, or
- interruption in manufacture likely to lead to meaningful disruption in supply of certain devices

Applies to devices:

- critical to public health during a emergency; or
- for which FDA determines information on potential meaningful supply disruptions is needed

How does the CARES Act affect medical devices?

Strategic National Stockpile

Adds \$16 billion for the strategic national stockpile

Specifies that “other supplies” required to be maintained includes “[PPE], ancillary medical supplies, and other applicable supplies” for administration of products in the stockpile

PREP Act Liability Protection

Establishes permanent PREP Act liability protection for NIOSH-approved respirators during declared public health emergencies

How does the CARES Act affect clinical laboratories?

Laboratory Payer Reporting under Protecting Access to Medicare Act (PAMA) of 2014

PAMA requires reporting private payer payment rates for diagnostic laboratory tests from Jan. 1, 2021 to Mar. 31, 2021

- **CARES Act delayed reporting period by 1 year to Jan. 1, 2022 to Mar. 31, 2022**

PAMA set Medicare payment rates for diagnostic tests according to median private payer rates, with phased in reductions in Medicare payment rates through 2023

- **CARES Act freezes payment rates for 2021 at 2020 levels → no reduction for 2021; and extends phase-in period to 2024**

Laboratory Reporting of COVID-19 Cases

Laboratories diagnosing COVID-19 must report results to HHS

Applies to laboratories as prescribed by the Secretary

Key EU Considerations

General comments

- Many of the U.S. considerations will also apply to the EU, including:
 - COVID-19 disruptions to clinical investigations
 - need for appropriate utilization of resources
 - impact on internal audits
 - regulation of digital health (including software) products
- In the EU, there is no premarket review and approval of devices so interactions with regulators less likely to be relevant
- However, existing challenges with notified body engagement will inevitably worsen

Has the implementation of the MDR be delayed?

Medical
Devices
Regulation
(EU)
2017/745
comes into
effect on May
26, 2020

BUT European
Commission has
announced plans to
delay implementation for
1 year (until May 2021)

- Lack of notified bodies
was already a problem
- COVID-19 is adding to
lack of available
resource for
conformity
assessments

Official
communication
from European
Commission
expected early
April (before
MDR takes
effect)

Companies will
have extra time
to become
MDR-compliant
and can focus
on deploying
resources to
address
pandemic

Is there an emergency use authorization?

No EU-wide emergency use authorization to allow non-CE marked medical devices (including IVDs) to be placed on the market

- MDR (once effective) will introduce greater scope for EU-wide coordination
- Until then, Commission Recommendation advocates for coordinated approach

Requires a case-by-case assessment at the Member State level

- National competent authorities have their own exceptional use rules for approval to supply non-compliant medical devices
 - Typically apply on humanitarian grounds
 - Usually intended for the treatment of a single named patient
- National laws may also have scope for broader exemptions
 - For example, UK MHRA specification for “Rapidly Manufactured Ventilator System”

Impact on the supply chain

- Under the existing Medical Devices Directive, there is limited regulation of supply chains, so adjustments to supply chains may be straightforward
- MDR will introduce greater regulation of “economic operators,” including importers and distributors
- Increased regulation of supply chain may make it more difficult to react to COVID-19 related disruption, particularly for importers, which will be identified on product labeling
- However, this is now less of an issue given delayed implementation of MDR

Resources and Contact Information

Resources

- **COVID-19 Legal and Business Toolkit**: upcoming briefing calls and on-demand audio briefings; practical guidance; thought leadership on updates; and details on our COVID-19 task force
 - Reach out to our COVID-19 task force at COVID19@cov.com
- **Life Sciences Briefing Call**: our experts on global business offer an assessment of the complex concerns that life sciences industry companies should have at top of mind
 - Download the [audio recording](#)
- **Checklist for Technology Solutions for COVID-19**: to assist companies that are developing technology solutions to help predict, mitigate or contain the spread of COVID-19, our cross-practice digital health team has put together a checklist of considerations

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