# Post COVID-19 Activities

June 16, 2020

The United States has taken unprecedented steps to respond to the COVID-19 pandemic. Myriad Federal and state laws, regulations and policies have been implemented, revised and repealed to enable the private sector's ability to respond effectively. These actions assisted the medical technology industry's response to quickly and efficiently meet the needs of patients and health care providers. Almost overnight, the industry refocused its operations and expanded production and capacity to develop and manufacture the medical technologies that are critical to our country's fight against the pandemic, and arming health workers on the frontlines with the tools they need to save lives. To ensure patients and healthcare providers continue to benefit from these new laws and policies, this document identifies key changes that should remain in place at the conclusion of the PHE.

## POST-COVID-19 GLOBAL ISSUES

### Policy

**Localization:** Governments around the world believe that global supply chains failed them, which raises the following issues:

1. Governments are likely to encourage domestic production of COVID-19-related products, even if not economically efficient, including by the WHO;
2. US is likely to adopt regulations, like "Buy American" without a clear understanding of the rationale for OUS supply chains and the additional cost of domestic production;
3. WTO needs measures/agreements to fight anti-globalization policies

**Section 301 Import Tariffs:** The Administration provided tariff relief due to the COVID-19 crisis. The President should maintain tariff relief long after the crisis has passed.

**"Essential" Industries:** As governments implemented lockdowns and other domestic restrictions, there were delays in determining what industries and people were essential and how they could continue to operate. Governments should codify appropriate rules to be prepared for the next global crisis.

**Retrenchment of National Healthcare Spending:** While governments around the world are allocating substantial financial resources to combat today's epidemic, nations may cut back on their healthcare budgets going forward. This phenomenon is likely to be compounded by the strain placed on national health budgets due to servicing vastly increased debt and from lower tax revenues caused by economic recession.

## Operational

**From Shortage to Surplus:** Capacity for the production of ventilators (and components), PPE, diagnostic tests and other COVID-19-related medical devices appears to be rising rapidly. While this is very encouraging during the crisis, excess capacity is likely to emerge after the virus has passed. The industry should consider the extent of this excess capacity.

**Stockpiling:** The US Government (and probably other governments) will consider the need for larger stockpiles. Industry should explain why stockpiling is usually much more efficient than forcing changes in supply chains and should have a voice in the quantity and quality of products.Link to Blue Ribbon Document

## POST-COVID-19 PAYMENT AND DELIVERY SYSTEM ISSUES

### Policy Issues

**Telehealth/Remote Monitoring and Face-to-Face Requirements:** CMS has waived many of the location, provider, and technology requirements for Medicare beneficiaries to receive telehealth, telemedicine and remote monitoring services. CMS has relaxed certain coverage criteria and expanded reimbursement for certain services. These have maintained patient access to certain services and allowed visits that could not be done in offices. CMS has also loosened requirements to allow facetime and skype "visits". We recommend making these changes permanent, or if not at a minimum providing a transition period so that they are not cut off immediately at the conclusion of the PHE.
Specific examples of telehealth and remote monitoring policy changes that should be transitioned beyond the PHE or made permanent can be found using the following link. **Hospitals-without-Walls:** The HwoW program allows ASCs and other non-hospital settings to serve as "hospitals" during the PHE. Turning these services "off" immediately could be a problem and a transition will be needed. This expands roles of ASCs and we will want to maintain some of this flexibility – at least transitionally – after the PHE.

**Expanded Ordering Privileges**: Order privileges for SARS/COV2 virus testing have been expanded to include all practitioners allowed to order tests up to the scope of their state license. This allows pharmacists and other practitioners in many states to order tests. This should continue after the PHE, and potentially be expanded to include other tests.

### Operational Issues

**Onsite testing and PPE Access:** Testing and access to PPE to identify and maintain COVID-19 and COVID-19-free sites will be critical for expanding service delivery for non-COVID-19 surgeries/procedures/treatments.

**Post COVID-19 Regulatory Issues**

## Policy Issues

### Emergency Use Authorization

Medical devices authorized under the Emergency Use Authorization will no longer be authorized when the COVID-19 emergency is declared to be over. The regulatory status of the EUA device once the emergency is declared to be over is not understood. A transition plan to allow for a streamlined regulatory process for a permanent market authorization with a 510(k), de novo or PMA should be clarified early on in a transparent manner and must be in place before the public health emergency is declared to be over.

### Medical Devices subject to FDA's enforcement discretion policies during the emergency

During the COVID-19 public health emergency, FDA issued guidance documents announcing enforcement discretion policies for many device types to allow for availability of the devices to address the public health concerns resulting from the COVID-19 pandemic. Once the public health emergency is declared to be over, the regulatory status of the device types or the indications added pursuant to enforcement discretion is unknown. A transition plan to allow for a streamlined regulatory process for a permanent market authorization with a 510(k), de novo or PMA should be in place before the public health emergency is declared to be over.
https://www.fda.gov/media/136290/download

### Availability of products in cases when the manufacturer does not choose to seek a 510(k), de novo or PMA.

In cases where the manufacturer does not choose to seek permanent marketing authorization for devices marketed under the EUA or enforcement discretion and when the public health emergency is declared to be over, a regulatory policy should be in place to address the regulatory status of the products already distributed. The policy should be developed to address the characteristics of the device type--capital equipment, digital health devices, consumable devices for example.

### Availability of flexible regulatory processes established by FDA during the emergency.

During the Covid-19 emergency, FDA established flexible regulatory approaches that we believe should be continued post-emergency. For example, FDA established a streamlined approach to making modifications to products authorized through a Humanitarian Device Exemption (HDE) or through the Premarket Approval (PMA) pathway.

://www.fda.gov/media/138265/download

**Post COVID-19 Legal Issues**

**Legal Process Issues**. Any agency withdrawing or changing a COVID-19 policy must give stakeholders reasonable notice and set out a transition plan with opportunity to comment. Agency policy changes should be made only upon fair advance notice and opportunity to share impact and comments.

**Liability Policy Issues**

***Expanded Liability Protections (3 categories)***

**CREATING RATIONAL RULES FOR THE CRITICAL WORKPLACE**

Companies must deal with this confusing legal landscape in addition to the already complex regulatory regime that ordinarily covers the workplace. For many essential companies, this has generated nearly impossible legal compliance quandaries. They are simply doing their best to follow guidance from the CDC, OSHA, and state and federal agencies.

Congress should protect the essential companies that have operated in good faith to help sustain the country during this crisis and in accordance with local, state and federal emergency designations and with retroactive application.

- Limiting lawsuits in state and federal courts claiming damages, and enforcement actions claiming penalties, based on COVID-19 exposure from essential operations to instances where the company had actual knowledge that an individual would be exposed to COVID-19 and acted with reckless indifference or conscious disregard as to whether they would contract it
- Requiring cases based on workplace transmission theories to be pled with particularity and to meet a clear and convincing evidence standard;
- Acknowledging the ever-evolving patchwork of available advice, industry practices and state responses that combine to make identifying a clear standard of care nearly impossible during a national emergency; and
- Providing employers with a safe harbor and liability exception under state and federal discrimination, wage/hour, workers' compensation, privacy, tort, or any other laws or regulations for collecting and exchanging relevant information related to employees' health status and for implementing reasonable measures to combat workplace

transmission of COVID-19, such as temperature checks, health screens, requirement to wear face mask/coverings, COVID-19 tests, and contact tracing.

**PROTECTING GOOD SAMARITANS**

Congress should remove barriers to producing important materials and protect those who act in good faith, consistent with CDC guidance, by and with retroactive application:

- Broadly protecting manufacturers, designers, sellers and distributors of non-federally-approved masks, respirators and other protective equipment from liability for state or federal claims arising out of the use of these items;
- Allowing manufacturers to deploy basic, nonregulated masks and other items designed to slow the spread of COVID-19-19 in their sites, without fear of liability, to ensure that health care workers on the front lines have priority access to the materials they need;
- Extending volunteer protections for employees who deliver protective equipment to hospitals;
- Generally limiting liability to those who manufactured, sold, designed, distributed or donated a defective product with actual knowledge of the product's defect in conscious disregard for the health and safety of others; and
- Requiring cases based on product liability or volunteer actions to be pled with particularity and to meet a clear and convincing evidence standard similar to existing protections under the PREP Act.

**PREVENTING THE INAPPROPRIATE EXPANSION OF STATE TORTS TO ADDRESS NATIONAL POLICY ISSUES**

Congress should safeguard critical industries that must continue to function during a national or global crisis by and with retroactive application:

- Placing state public nuisance claims based on the spread of pandemic disease off limits where there has been a declared national emergency;
- Insulating publicly traded companies from derivative claims based on hindsight evaluations of actions deemed inappropriate but conducted in good faith during uncertain times, including the decision to remain operational during the crisis or to close entirely or at specific sites, or for regulatory disclosures made based on the limited and imperfect information available at the time of the disclosure; and
- Preventing the creative use of state tort claims from undermining a response to this crisis or one yet to come.

## PRIVACY AND DATA SECURITY CONSIDERATIONS

The Office of Civil Rights has issued notices of enforcement discretion with regard to the application of Health Insurance Portability and Accountability Act regulations to telehealth services as well as disclosures by covered health care providers and business associates for public health and health oversight activities during the COVID-19 nationwide public health emergency. States such as California similarly have issued regulatory guidance regarding the application of state data protection laws in the context of the COVID-19 pandemic. These measures have helped to ensure continued or enhanced patient access to essential health services that might not have otherwise been possible, due to COVID-19 restrictions on in-person contacts. They also have helped to facilitate sharing of critical data essential to pandemic response and management. It may be appropriate to make permanent, and potentially to expand, the policies reflected in these notices of enforcement discretion to ensure that their benefits to patients and patient care continue beyond the duration of the pandemic.