COVID-19: FDA PUBLISHES ENFORCEMENT POLICIES – VENTILATOR/RESPIRATORY & REMOTE PATIENT MONITORING DEVICES

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U.S. Health Care and FDA Alert

The Food and Drug Administration ("FDA") recently published two policies related to the ongoing coronavirus ("COVID-19") pandemic. First, on March 22, 2020, FDA published guidance "to help expand the availability of ventilators as well as other respiratory devices and their accessories." [1] Second, on March 20, 2020, FDA published guidance "to help expand the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19." [2] The two policies are available online through the following links:

Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency

In both publications, FDA acknowledges the guidance was published without public comment and does not establish enforceable responsibilities. Instead, the policies describe FDA's current thinking and should be viewed only as recommendations.

VENTILATOR ENFORCEMENT POLICY

FDA, through the publication of this ventilator/respiratory device specific guidance, took an unprecedented step in addressing the impending strain on the nation's supply of ventilators and other respiratory devices, which are critical for the treatment of severe COVID-19 patients. Manufacturers and providers should take note of the changes in FDA policies and position themselves to take full advantage of the resulting opportunities to assist the U.S. health care system in treating COVID-19 patients.

FDA states succinctly, "FDA does not intend to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification . . . ." Generally, FDA indicates modifications might include changes to ventilator motors to allow an alternative supplier to meet design specifications or changes to ventilator tubing materials to allow sourcing from additional vendors. The permitted modifications, discussed in detail below, provide an unprecedented amount of flexibility for manufacturers of cleared devices to alter those devices to address the COVID-19 crisis.

First, FDA suggested possible examples of modifications of indications, claims, or functionality as follows:

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- The use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation;
- The use of ventilators outside their cleared environment of use (for example, use of a ventilator in a health care facility when it is only cleared for use at home or during transport);
- The use of devices indicated for sleep apnea (including noncontinuous ventilators delivering continuous positive airway pressure ("CPAP") or bilevel positive airway pressure ("BiPAP")) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization; and
- The use of oxygen concentrators for primary supply when medically necessary and clinically appropriate.

Second, FDA suggested possible examples of modifications to FDA-cleared hardware, software, or materials:

- Modifications to motors, batteries, or other electrical components;
- Material changes to components in the gas pathway or with other patient tissue contact;
- Introduction of filtration to minimize aerosolization;
- Software modifications intended to modify the ventilation parameters, including inspiratory pressure, tidal volumes, flow rates, and positive end-expiratory pressure ("PEEP") in accordance with any applicable device standard;
- Software modifications implementing physiological closed loop (automated) algorithms for oxygen titration where the algorithms/devices are the subject of an FDA-approved Investigational Device Exemption ("IDE");
- Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters (i.e., adjustment of parameters by trained health care providers from outside an isolation unit to avoid unnecessary exposures); and
- Modifying or adding to the hardware/software architectures to allow for increased remote monitoring and setting adjustment capability/availability to support additional claims or indications described above. One example is the addition of wireless and/or Bluetooth capability.

Third, FDA policy provides more flexibility to extend the shelf life of breathing circuit components, such as tubing, filters, and humidifiers. FDA suggests the following policy regarding extending duration of use/shelf life: "[T]he devices are used according to healthcare institutional protocols, or useful life is limited to the occurrence of malfunction or visible soiling."

Fourth, with regard to unapproved devices, FDA policy states that FDA is interested in interacting with manufacturers about undergoing the Emergency Use Authorization ("EUA") process. FDA requested manufactures of unapproved devices submit specific information related to the device, which FDA will "expeditiously review." The information requested by FDA included, without limitation:

1. General information, such as your contact information;
2. A copy of the product labeling;

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3. Whether the device currently has marketing authorization in another regulatory jurisdiction;
4. Whether the device has been designed, evaluated, and validated in accordance with the applicable FDA-recognized standards;
5. Whether the device is manufactured in compliance with 21 C.F.R. Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, or an equivalent quality system; and
6. Whether the device is designed with a power supply that is compatible with U.S. voltage, frequency, and plug-type standards.

Interestingly, FDA states that "where appropriate under the circumstances, FDA will notify the manufacturer that it does not intend to object to the distribution and use of the device while the manufacturer is preparing, and FDA is reviewing, the EUA request." Additionally, FDA expressed its interest in working with manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices.

REMOTE PATIENT MONITORING DEVICE ENFORCEMENT POLICY

In a similar vein, FDA issued guidance on March 20, 2020, announcing its intent to exercise enforcement discretion with respect to the modification of certain labeling claims, indications, and functionality of non-invasive remote patient monitoring devices without the submission of a premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FDCA"). [3]

In the guidance, FDA acknowledges that the COVID-19 outbreak has placed an increased burden on the U.S. health care system and that increased use of remote patient monitoring technology could both (a) open valuable space in hospitals and other health care facilities, and (b) help to eliminate unnecessary patient contact.

In an effort to facilitate the increased use of and access to such technologies during the COVID-19 outbreak, FDA is allowing medical device companies to modify the claims, indications, or functionality for such devices in the following ways:

- The addition of monitoring statements related to patients with COVID-19 or co-existing conditions (e.g., hypertension, heart failure);
- For remote patient monitoring devices previously cleared only for use in hospitals or other health care facilities, a change to the indications or claims regarding use in the home setting; and
- Hardware or software changes to allow for increased remote monitoring capability to support additional claims or indications (e.g., the addition of wireless or Bluetooth technology).

In light of this guidance, medical device manufacturers should evaluate whether their currently approved medical devices might be used for remote patient monitoring, in the home setting or otherwise, given the addition of remote access technology or the simple addition of a monitoring indication for a COVID-19-related disease or condition. For instance, if the addition of Bluetooth technology to an existing 510(k) cleared pulse oximetry device would render the device usable as a home pulse oximetry unit, which might be monitored by a health care

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provider in a remote location, the manufacturer may now modify the device's functionality and labeled indication accordingly, without the need to submit a new 510(k)-seeking clearance of the changes.

The enforcement discretion described in this guidance apply to the following forms of non-invasive remote monitoring devices:

- Clinical electronic thermometer (21 C.F.R. §.880.2910);
- Electrocardiograph ("ECG") (21 C.F.R. §.870.2340);
- Cardiac monitor (21 C.F.R. § 870.2300);
- ECG software for over-the-counter use (21 C.F.R. § 870.2345);
- Pulse Oximetry (21 C.F.R. § 870.2700);
- Non-invasive Blood Pressure (21 C.F.R. § 870.1130);
- Respiratory Rate/Breathing Frequency (21 C.F.R. § 868.2375); and
- Electronic Stethoscope (21 C.F.R. § 870.1875).

CONCLUSION

As noted above, medical device manufacturers should evaluate their portfolio of existing products to determine whether any of their existing cleared or approved respirator or non-invasive remote patient monitoring devices might be modified as provided in either guidance described above. That said, FDA makes clear that modification of ventilators, respiratory care devices, and non-invasive remote patient monitoring devices should only occur when it does not create an undue risk in light of the public health emergency. Manufacturers should carefully consider whether any device modification might lead to a material change in the risk profile of the device or if the change represents a fundamental alteration to the cleared or approved use of the device.

As this public health and economic crisis continues to evolve, we are monitoring FDA's efforts to engage with stakeholders in the medical device industry to address the needs of the medical community, and we are working closely with clients to offer practical solutions to the unique challenges brought on by COVID-19. If you have questions, please do not hesitate to reach out to any of us at K&L Gates.

NOTES:

[1] FDA, OFF. OF MED. PRODUCTS AND TOBACCO, CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, FDA-2020-D-1138 (March 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.
[2] FDA, OFF. OF MED. PRODUCTS AND TOBACCO, CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, FDA-2020-D-1138 (March 2020), https://www.fda.gov/regulatory-information/search-fda-

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guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during.
[3] FDA, OFF. OF MED. PRODUCTS AND TOBACCO, CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, Enforcement Policy for Non-Invasive Remote Monitoring Devices Used During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, FDA-2020-D-1138 (March 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during.

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