FDA Announces Guidance for Non-Invasive Remote Monitoring Devices

- The FDA will allow for expanded use of non-invasive, vital sign-measuring devices to remotely monitor patients during the COVID-19 pandemic.
- The guidance is designed to reduce the need for hospital visits and risk of potential COVID-19 exposure.
- The expanded-use policies will last for the duration of the public health emergency.

The Food and Drug Administration (FDA) announced today that they would allow manufacturers of certain FDA-cleared, non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely (guidance). Part of the administration's efforts to address the ongoing COVID-19 pandemic, the guidance explains that devices that measure body temperature, respiratory rate, heart rate, blood pressure, and more will allow health providers to remotely monitor a patient's vital signs from home. The guidance is intended to reduce the need for hospital visits and minimize the risk of exposure to COVID-19 and reflects the administration's commitment to "ease burdens on health care providers and facilities as they face this public health emergency," according to FDA Principal Deputy Commissioner Dr. Amy Abernethy. The FDA clarified that the policy will only apply to certain modifications to the indications, claims, functionality, or hardware or software of FDA-cleared non-invasive remote monitoring devices, and the guidance will only be in effect during the public health emergency. Examples of modifications outlined by guidance include:

- The inclusion of monitoring statements related to patients with COVID-19 or co-existing conditions (such as hypertension or heart failure);
- For subject 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.

Due to the guidance being released in response to the public health emergency, the policies will go into effect for the duration of the public health emergency without comment period.