



Press Release

Regulatory Provisions in the CARES Act

ALLISON EDWARDS | MARCH 20, 2020

The Coronavirus Aid, Relief, and Economic Security (CARES) Act introduced yesterday in the Senate aims to rectify two regulatory failures by the Food and Drug Administration: Its failure to cut red tape regarding laboratory-developed tests, and its lack of knowledge about shortages of critical medical devices. The bill's reforms cannot directly address some of the failings in the past weeks, note AAF's Director of Regulatory Policy Dan Bosch and Senior Regulatory Policy Analyst Dan Goldbeck, but they may mitigate ongoing issues in the health care sector as it combats the COVID-19 pandemic.

An excerpt:

As the pandemic's reach continues to grow, there are still concerns that the volume of deployable tests lags behind the volume of potential cases to identify.

The CARES Act seeks to address this shortage by including a provision that further expedites the process for tests specifically related to COVID-19 diagnosis. This provision allows test developers to essentially bypass the established Emergency Use Authorization process and instead get their tests to market faster after approval of the Secretary of Health and Human Services under the Public Health Service Act. There are, however, still important limits to this expedited process.

[Read the analysis.](#)