Insight

Regulatory Provisions in the Phase 3 Stimulus Package

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Executive Summary

- The Coronavirus Aid, Relief, and Economic Security (CARES) Act aims to rectify two major Food and Drug Administration (FDA) failings during the COVID-19 emergency: its failure to waive red tape on laboratory-developed tests, and its apparent lack of knowledge about shortages of critical medical devices.
- The Act would codify FDA's recent decision to allow COVID-19 testing prior to the filing of an emergency-use authorization and to require medical device and drug manufacturers to share more information on discontinuances and shortages of critical devices and drugs.
- While the reforms cannot directly address some of the failings in recent weeks, there is hope that they will help ameliorate ongoing issues as the health care sector continues to combat this disease.

Introduction

The Coronavirus Aid, Relief, and Economic Security (CARES) Act recently introduced in the Senate contains provisions that aim to address two critical problems that exacerbated the spread of COVID-19. News reports have focused on the Food and Drug Administration's (FDA) failure to cut red tape regarding laboratory-developed tests and a shortage of ventilators and other medical supplies that would be needed to properly test and care for possible COVID-19 patients.

Expediting Testing

Under the Emergency Use Authorization (EUA) process, FDA can expedite the approval of

certain medical products that would otherwise need a more robust approval period. The first COVID-19 test approved under this process came on February 4 for the Centers for Disease Control and Prevention's original diagnostic tests. As the disease's reach grew, the need for tests from private labs proved to be increasingly apparent in order to handle the potential number of cases. Largely due to concerns of the earliest proposed tests' accuracy, FDA did not approve a private lab test until March 12. Since then, numerous other private entities have had their tests approved under the EUA process. 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 EUA process and instead get their tests to market faster after approval of the Secretary of Health and Human Services (HHS) under the Public Health Service Act. There are, however, still important limits to this expedited process. The labs involved must be duly certified under the Public Health Service Act's relevant criteria, the test product in question must still undergo the EUA process concurrently, and HHS can revoke this approval if necessary.

Addressing Shortages

The second major issue is that the federal government was caught seemingly unaware of the shortage of critical medical equipment, including ventilators for patients, personal protective equipment for health care workers, and testing components – such as swabs and reagents – needed to meet testing demands.

The CARES Act would add a new requirement that manufacturers of medical devices share information on possible discontinuances or shortages with the Secretary of HHS. The requirement would apply to those devices and equipment deemed by HHS to be critical to a public health emergency, or that HHS determines would be critical in advance of an emergency. These notifications must be submitted to HHS at least six months in advance, or as soon as practicable. HHS will make this information available to the public except in instances where HHS believes doing so would cause the public to "over purchase" the product in question.

The CARES Act would also expand current requirements to notify HHS of possible drug shortages by adding a provision covering drugs that may be necessary in a declared public health emergency. The legislation will also require the Government Accountability Office to report on FDA's "intra-agency coordination, communication, and decision-making" regarding device and drug shortages ahead of the current emergency, which may lead to

more reforms in these areas in the years to come.

Conclusion

The CARES Act aims to correct two regulatory policy failures that exacerbated current issues with testing and patient care during the COVID-19 emergency. The reforms will not provide much immediate help in the current crisis but may help prevent a repeat of similar mistakes, if only through lessons learned, in future public health emergencies.