Simpson Thacher

Memorandum

The Presidential Emergency Declaration and the HHS Public Health Emergency Determination: A Brief Overview

March 13, 2020

Today, President Trump invoked the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act") in response to the spread of the novel coronavirus disease 2019 ("COVID-19") in the U.S.

Stafford Act Emergency Declaration

The President's determination that an emergency exists under the Stafford Act will enable the federal government to provide emergency assistance to states under Title V of the Stafford Act, including:

- Federal agency authorities and resources, including personnel, equipment, supplies, facilities, and managerial, technical, and advisory services;
- Coordination of assistance provided by federal agencies, private organizations, and state and local governments;
- Technical and advisory assistance to affected state and local governments for the performance of essential community services, the provision of health and safety measures, and management, control, and reduction of immediate threats to public health and safety;
- Emergency assistance through federal agencies;
- Assistance to state and local governments in the distribution of medicine, food, and other consumable supplies, and emergency assistance; and
- Accelerated federal assistance and federal support to save lives, prevent human suffering or mitigate severe damage. Assistance and support provided pursuant to this last bullet may be provided to states in the absence of specific requests from the states, so that critical resources may be rapidly deployed, used, and distributed.

The President also waived a number of regulations for hospitals. For example, he waived requirements that Medicare critical access hospitals that are located in rural areas maintain no more than 25 inpatient beds and maintain an annual average length of stay of 96 hours or less per patient for acute inpatient care. President Trump and the Administrator of the Centers for Medicare & Medicaid Services also promised guidance that would restrict visitors to nursing homes, except in end-of-life situations. Additionally, the President waived

interest payments on all student loans held by federal government agencies until further notice, and authorized purchases of crude oil for the Strategic Petroleum Reserve.

President Trump highlighted U.S. Food and Drug Administration ("FDA") Emergency Use Authorizations ("EUAs") for in vitro diagnostic tests for detection and/or diagnosis of COVID-19. FDA's EUAs were made pursuant to a separate public health emergency determination issued by the U.S. Department of Health and Human Services ("HHS") Secretary. President Trump also announced a new approach to testing, which will allow individuals to locate drive-thru testing locations via the internet.

Public Health Emergency Determination

The Stafford Act emergency declaration discussed above provides the federal government with resources and authorities beyond those already provided by the public health emergency determination that the HHS Secretary made on January 31, 2020. On that day, Secretary Azar determined that a public health emergency existed as a result of confirmed cases of COVID-19 and had existed since January 27, 2020. The Secretary's public health emergency determination gave HHS the authority to take additional actions to respond to the public health emergency, with respect to contracts, grants, and awards, and enabled the Secretary to conduct and support investigations into the cause, treatment or prevention of COVID-19.

The President's declaration of a national emergency, combined with the existence of the HHS Secretary's public health emergency determination, triggered other emergency statutory authorities. For example, the combined emergency declaration and determination authorize the HHS Secretary to waive certain requirements to ensure that:

- sufficient health care items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid, or the Children's Health Insurance Program, and
- health care providers that furnish such health care items or services in good faith may be reimbursed and exempt from sanctions for noncompliance, absent any determination of fraud or abuse.

The public health emergency determination also served as a trigger for the FDA's emergency authorization to use medical products in ways that would not otherwise be permitted under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Specifically, the public health emergency determination enables FDA to issue EUAs that:

- permit the use of specified medical devices, drugs or biologics that FDA has *not* approved, licensed or cleared for commercial distribution; or
- permit the use of FDA-approved, conditionally approved, licensed or cleared medical devices, drugs or biologics for *unapproved* uses.

To date, FDA has issued two categories of EUAs that address emergency use of:

- in vitro diagnostic tests for detection and/or diagnosis of COVID-19, and
- personal protective equipment for use in healthcare settings by healthcare personnel to prevent the wearer from exposure during the COVID-19 outbreak.

FDA has issued three EUAs for in vitro diagnostic tests that authorize emergency use of diagnostic panels from the Centers for Disease Control and Prevention ("CDC") and the New York State Department of Public Health, and emergency use of Roche's cobas SARS-CoV-2 test for samples from patients who meet COVID-19 clinical or epidemiological criteria. FDA's personal protective equipment EUA pertains to disposable filtering facepiece respirators ("FFR") approved by the National Institute for Occupational Safety and Health ("NIOSH") as non-powered air-purifying particulate FFRs, and FFRs that were NIOSH-approved but have since passed the medical device manufacturers' recommended shelf-life.

Future EUAs may permit the use of additional diagnostic tests, and, potentially, vaccines if and when they become available.

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