

## Overview of Federal, COVID-related Emergency Declarations

Contrary to popular belief, the federal government has not issued "a" COVID-19 emergency declaration. Rather, there have been at least *five* federal, COVID-related emergency declarations ("EDs"), each issued pursuant to a different federal statute, and each carrying its own legal and practical consequences. Importantly, the termination of one declaration does *not* necessarily have any effect on the other declarations.

Below is an overview of five federal, COVID-related ED's in order of issuance, addressing the following questions for each type of declaration:

- What federal statute authorizes the ED?
- Who can issue the ED?
- Under what circumstances?
- What are the consequences of the ED?
- When and how does the ED terminate?
- (1) Declaration of Public Health Emergency under Section 319 of the <u>Public Health Services</u> <u>Act</u> (PHSA), <u>42 U.S.C. §247d.</u>
- First Covid-related PHSA declaration, issued January 31, 2020, retroactive to January 27.
- Most recent COVID-related declaration under PHSA, issued January 11, 2023. This declaration automatically expires on May 11, 2023.
- Who issues? The Secretary of the Department of Health & Human Services (HHS).
- **Under what circumstances?** Secretary can declare a nationwide public health emergency when he determines that 1) a disease or disorder presents a public health emergency, or 2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. 42 U.S.C. §247d(a).
- What are the consequences? The declaration of a public health emergency under the PHSA gives the HHS Secretary many new powers. After making a declaration, the Secretary may "take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder..." The Secretary may distribute money from the Public Health Emergency Fund to public health agencies and other entities across the country; waive data submittal and reporting deadlines and aspects of the Paperwork Reduction Act; temporarily reassign federally-funded personnel, and more.
- **How does it terminate?** Automatically expires after 90 days but may be renewed by the Secretary.

- (2) Declaration under the Emergency Use Authorization (EUA) provision of the <u>Federal</u> Food, Drug and Cosmetic Act, 21 U.S.C.§360bbb-3.
  - First COVID-related EUA declaration, issued February 7, 2020.
  - EUA declaration issued March 20, 2023.
  - EUA Amendments announced April 18, 2023.
  - Who issues? The Secretary of the Department of Health and Human Services (HHS).
  - Under what circumstances? Secretary can issue the ED when he finds that circumstances justify introduction of a product into interstate commerce because (among other reasons) "there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents." 21 USC §360bbb-3(b)(1)(C)
  - What are the consequences? The declaration allows introduction of <u>EUA products</u> into interstate commerce.
  - **How does it terminate?** The ED terminates under the earlier of "(i) a determination by the <u>Secretary</u>, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances. . . have ceased to exist; or (ii) a change in the approval status of the <u>product</u> such that the circumstances. . . have ceased to exist." 21 USC §360bbb-3(b)(2)(A).

## (3) Declaration of National Emergency under <u>Sections 201, 202, and 301 of the National Emergencies Act</u>, <u>50 U.S.C. 1621</u>, et seq.

- Declaration of National Emergency, issued March 13, 2020
- Emergency ended April 10, 2023.
- Who issues? The President.
- **Under what circumstances?** The President can declare a national emergency when there is a "national emergency" (which is not otherwise defined).
- What are the consequences? The President's declaration of a national emergency allows the exercise of authority granted in other federal statutes that condition the exercise of that authority on the existence of a national emergency; the declaration is like the "on" switch for such authority. In the COVID context, the declaration of national emergency was used to invoke authority under the Social Security Act, 42 U.S.C. 1320b-5, to modify or waive certain requirements of Medicare, Medicaid and State Children's Health Insurance Programs, and HIPPA rules, while a COVID-19 public health emergency declaration (ED Type (1), above) is in effect.
- How does it terminate? <u>Terminates when President proclaims the emergency over, or by joint resolution of Congress, or on anniversary of the declaration if President does not renew within ninety days prior to the anniversary.</u>

- (4) Declaration under the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. § 247d-6d
- First COVID-related PREP Act declaration, issued March 17, 2020, retroactive to February 4, 2020.
- Tenth COVID-related PREP Act amendment, issued January 7, 2022.
- April 14, 2023 HHS Announcement of Intent to Amend PREP-Act Declaration for Medical Countermeasures Against COVID-19
- Who issues? The Secretary of the Department of Health & Human Services (HHS).
- **Under what circumstances?** Secretary can issue a PREP Act declaration when he determines that "a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." 42 U.S.C. §247d-6d(b)(1).
- What are the consequences? As part of the PREP Act declaration, the Secretary can recommend the manufacture, testing, development, distribution, administration, or use of one or more "covered countermeasures," which may include <a href="EUA products such as COVID-19 vaccines">EUA products such as COVID-19 vaccines</a>. The PREP Act declaration immunizes manufacturers, distributors, and others from any liability for injuries caused by a covered countermeasure, except in cases of "willful misconduct." Instead, any redress for those injuries must be sought through the <a href="Countermeasures Injury Compensation Program">COVID-19 vaccines</a>.
- **How does it terminate?** The PREP Act declaration lasts for the time-period specified by the Secretary.
- (5) Declaration of emergency or disaster under section 501(b) of the <u>Robert T. Stafford</u> <u>Disaster Relief and Emergency Assistance Act</u>, <u>42 U.S.C. §5121</u> et seq.
- Stafford Act Emergency Determination, issued March 13, 2020.
- Who issues? The President.
- Under what circumstances? President can declare a national emergency under the Stafford Act when he determines that "federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States." 42 U.S.C. §5122(1). President can declare a "major disaster" when a "natural catastrophe" causes sufficient damage to warrant major disaster assistance. 42 U.S.C. §5122(2). President can issue disaster declarations for individual states upon request.
- What are the consequences? Generally, the emergency declaration <u>authorizes various</u> forms of individual and <u>public assistance from the federal government</u> in states, tribes, and communities that have received major or emergency disaster declarations. <u>The COVID-19 ED authorized public assistance for various emergency protective measures</u>.
- **How does it terminate?** Declaration does not expire. <u>Instead, the Federal Emergency Management Agency (FEMA) determines that the "incident period" has ended. FEMA has announced that incident periods for all pandemic-related declarations will close on <u>May 11, 2023</u>.</u>

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