

COMPLIANCE UPDATE

Q3, 2020

COVID-19 Pandemic Public Health Emergency Declaration (“COVID-19 PHE”)

What is a § 319 [public health emergency declaration](#) (“PHE”)?: As the Department of Health & Human Services (“HHS”) [states](#):

Under section 319 of the Public Health Service (“PHS”) Act, the Secretary of the [HHS] can declare a ... PHE if he determines, after consulting with such public health officials as may be necessary, that 1) a disease or disorder presents a PHE, or 2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. A PHE declaration allows the Secretary to take certain actions in response to the PHE. In addition, a public health emergency can be a necessary step in authorizing the Secretary to take a variety of discretionary actions to respond to the PHE under the statutes HHS administers.

For example, declaring a PHE is the first step for issuance of [Emergency Use Authorization\(s\)](#) under § 564 of the Federal Food, Drug and Cosmetic Act (“EUA’s”), which will be vital towards overcoming COVID-19. For a complete list of COVID-19 EUAs, please visit [fda.gov](#).

What you need to know:

- **When was the COVID-19 PHE first declared?** On January 31st, 2020, the Secretary of HHS declared that a PHE existed due to COVID-19 since January 27th, 2020 (the [“Initial Declaration”](#)).
- **Has the COVID-19 PHE been extended?** Yes. Prior to its April 25th expiration, HHS renewed the Initial Declaration, effective April 26th through July 25th (the [“First Renewal”](#)). As the number of COVID-19 cases continue to surge mid-summer, the [American Hospital Association](#) (among others) urged HHS to extend the COVID-19 PHE prior to the First Renewal’s expiration. On July 23rd, HHS renewed the Initial Declaration, which is effective July 25th (the [“Second Renewal”](#)) through October 23rd, 2020, unless otherwise extended or earlier terminated.
- **Can the COVID-19 PHE be extended again?** Yes. As FN10 of [FAQs about FFCRA and Coronavirus Aid, Relief, and Economic Security Act \(the “Cares Act”\) Part 42](#) makes clear:

Generally, under section 319 of the PHS Act, a [PHE] lasts until the Secretary of [HHS] declares that the public health emergency no longer exists, or upon the expiration of the 90-day period beginning on the date the Secretary declared a public health emergency exists, whichever occurs first. The Secretary may extend the [PHE] for subsequent 90-day periods for as long as the public health emergency continues to exist and may terminate the declaration whenever he determines that the public health emergency has ceased to exist.

The [PHE related to the Opioid Crisis](#), for example, has been in effect since October 26th, 2017.

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- **During the COVID-19 PHE:**
 - § 6001(a)(1) of the Families First Coronavirus Response Act (“FFCRA”) and § 3201 of the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) require certain insurers to cover medically appropriate COVID-19 testing and certain related services without patient cost sharing.
 - the Secretary of HHS is granted authority under [section 1135 of the Social Security Act](#) to temporarily waive or modify certain requirements of the Medicare, Medicaid, State Children’s Health Insurance programs, and of the [Health Insurance Portability and Accountability Act’s](#) (“HIPAA”) Privacy Rule.
 - various oversight entities, including HHS’ Office of Civil Rights, have indicated relaxed enforcement policies, including for certain [good faith telehealth issues](#) (which does not have an expiration date, but is based “upon the latest facts and circumstances”) or [uses and disclosures of PHI by Business Associates](#).
 - certain [telehealth changes](#) are allowed, including allowing controlled substance to be prescribed even if a patient is not at a hospital or DEA-registered clinic, how Medicare pays physicians for telehealth services, who is eligible under Medicare to access telehealth, etc. **Telehealth** is any two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site.
- **Are there any other deadlines that the COVID-19 PHE impacts?** Yes. During the “Outbreak Period” (March 1, 2020 until 60 days after the end of the “National Emergency” or other yet-to-be-announced date) certain deadlines, such as special enrollment periods, COBRA election periods, COBRA premium deadlines, etc. for certain employers are to be disregarded. For more information, see [Disaster Relief Notice 2020-01: Guidance and Relief for Employee Benefit Plans Due to the COVID-19 Outbreak](#) and <https://www.govinfo.gov/content/pkg/FR-2020-05-04/pdf/2020-09399.pdf>. Although the COVID-19 PHE is not itself determinative, the “Outbreak Period” (which can differ based on location) is based on “the same reasons underlying the issuance of the” COVID-19 PHE.
- **What happens when the COVID-19 PHE ends?** Most of the aforementioned allowances are explicitly tied to the COVID-19 PHE, leaving several important action items for certain employers:
 - **COVID-19 Tests and Relating Services:** Plans were only required to cover those “[certain] items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after” 18 March 2020.
 - **COVID-19 Testing:** Employers will need to determine if they’d like to continue to cover tests for COVID-19 which were required to be covered by § 6001(a)(1) of the FFCRA.
 - **COVID-19 Related Services:** Employers may also consider covering COVID-19 related services (such as antibody testing) for their members, and in doing so capture most (but not all) of those expenses which were required to be covered by § 6001(a)(2) of the FFCRA.
 - **Telehealth:** Given the likelihood that HHS may not wait until a vaccine exists to end the COVID-19 PHE, Employers who previously excluded telehealth may consider offering it to their members post-COVID-19 PHE with or without cost sharing and/or deductibles.