

Publications

HHS Renews Public Health Emergency Declaration

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Jolie N. Havens

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Health Care

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On Thursday, July 23, 2020, Department of Health and Human Services (HHS) Secretary Alex Azar officially renewed the declaration that a Public Health Emergency (PHE) exists in connection with COVID-19. The PHE declaration, previously renewed on April 21 and set to expire July 25, is now expected to continue in effect through Friday, October 23, unless HHS determines sooner that the conditions giving rise to the PHE declaration are no longer present.

Because many key legal flexibilities granted during the COVID-19 pandemic are available only so long as the PHE declaration is in effect, this renewal is significant for companies across the health care industry. In particular, the renewal of the PHE declaration has effectively extended:

- Emergency Use Authorizations granted by the Food and Drug Administration (FDA) for distribution and use of otherwise uncleared medical devices, including diagnostic tests, face masks, and respirators;
- All waivers granted by the Centers for Medicare & Medicaid Services (CMS) under Section 1135 of the Social Security Act, including those expanding Medicare reimbursement for telehealth services;
- Blanket waivers granted under the Stark law and Anti-Kickback Statute by the HHS Secretary and Office of Inspector General, respectively;
- Various flexibilities granted by the Drug Enforcement Administration (DEA) with respect to the remote prescribing of controlled substances; and

- The policy of enforcement discretion announced by the HHS Office of Civil Right under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

If you have questions about the PHE renewal or its implications for your organization, please contact Jolie Havens, Matt Albers, Mairi Mull, or your regular Vorys attorney.

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Vorys COVID-19 Task Force

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at [vorys.com/coronavirus](https://www.vorys.com/coronavirus).