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Healthcare Alert

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How healthcare providers can plan ahead for COVID-19 emergency declaration expiration

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We outline what healthcare providers and companies need to know in advance as certain federal COVID-19 emergency declarations are scheduled to end in May.

What's the Impact?

- Healthcare providers and companies must assess any operational changes implemented during the COVID-19 pandemic
- Determining whether any legislative or regulatory action extended or made certain temporary regulatory waivers permanent will be key to avoiding compliance issues after the various COVID-19 emergency declarations expire

The COVID-19 pandemic made the last three years particularly challenging for healthcare providers and companies. In early 2020, in response to the remarkable strain COVID-19 placed on the US healthcare system, several emergency declarations were made by different branches of the federal government. Those emergency declarations gave the Department of Health and

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Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) the ability to waive regulatory requirements to help providers better meet the challenges of the pandemic.

As time has passed, the dizzying clinical (and resulting regulatory) pace has slowed as COVID-19 has evolved into a more understood and manageable illness. While this is of course a welcome development, it also means that some of the regulatory flexibility provided by the federal government will soon expire as the various COVID-19-related emergency periods come to an end.

Over the duration of the pandemic, some of the temporary waivers issued by the federal government were extended, independent of any emergency declaration, or made permanent by statute. The coming end of the COVID-19 public health emergency means that healthcare providers and companies must assess their operations for any changes that were enabled by any of the emergency waivers to determine whether they will survive. Our experience suggests that once a waiver is operationalized, providers may sometimes continue those operations after the expiration of the waiver because they are either unaware the waiver is no longer in effect or do not understand that the operational change was premised on a temporary waiver. Regulatory noncompliance can and often does result.

This alert will briefly describe the various emergency declarations made in 2020 and discuss some of the regulatory waivers in detail. More broadly, we also include an Appendix that details the post-public health emergency status of many of the more notable federal emergency actions.[2]

Summary of COVID-19 Federal Emergency Declarations and Status

The various federal emergency declarations and their expiration dates are:

- The following expire on May 11, 2023:
  - A public health emergency (PHE) declared by the Secretary of HHS on January 31, 2020, pursuant to Section 319 of the Public Health Service Act.
  - A national emergency declaration issued by former President Donald J. Trump on March 13, 2020, pursuant to Sections 201 and 301 of the National Emergencies Act.
- An emergency declaration was issued by the Secretary of HHS on February 4, 2020, pursuant to Section 564 of the Federal Food, Drug and Cosmetic Act. The emergency declaration enabled the emergency use authorization (EUA) of medical countermeasures for COVID-19. This Section 564 declaration remains in effect until terminated by the HHS Secretary. It is ***not*** among the declarations that will expire on May 11, 2023.
- The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity from tort liability (except for willful misconduct) for activities related to the manufacture, distribution, or dispensing of medical countermeasures to combat a disease that is determined by HHS to present a public health emergency. Pursuant to Section 319F-3 of the

[2] *Please note that neither this alert nor the Appendix is intended as a comprehensive catalog of all federal waivers issued and emergency actions taken during the pandemic.*

Public Health Service Act, on February 4, 2020, the Secretary of HHS declared COVID-19 to constitute such a public health emergency. This declaration will expire on October 1, 2024.

Telehealth

One of the pandemic's silver linings was the increase in use of telehealth to help expand patient access to care. In the earlier stages of the pandemic, telehealth offered patients a way to receive care that they may otherwise have decided not to receive in person for fear of exposure to COVID-19 at a facility or practice. To increase access to telehealth, CMS took the following actions:

- Authorized the use of telehealth beyond only rural areas to Medicare beneficiaries in all geographic areas.
- Allowed Medicare beneficiaries to remain in their homes for telehealth visits, rather than requiring them to travel to a healthcare facility.
- Permitted telehealth visits via audio-only equipment (i.e., video capability was no longer necessary).
- Expanded the list of Medicare-covered services that could be provided by telehealth.
- Allowed federally qualified health centers and rural health clinics to provide telehealth services as distant site providers. Previously, FQHCs and rural health clinics could only serve as originating site providers (i.e., the site where the patient is located).

Also, HHS took the following steps:

- Waived penalties for noncompliance with HIPAA in connection with the good faith provision of telehealth, which allowed providers to communicate with patients via widely used services like FaceTime or Skype.
- In cooperation with the federal Drug Enforcement Administration, allowed DEA-registered providers to write prescriptions for controlled substances without first conducting an in-person patient visit.

The Consolidated Appropriations Act, 2023 (CAA) extended all the above telehealth flexibilities granted by CMS through December 31, 2024. Other CMS telehealth waivers, largely focused on behavioral and mental telehealth services, were made permanent.

However, the above HHS waivers will ***not*** survive the expiration of the PHE. For its part, the DEA is currently working on regulations that may allow a controlled substance prescription without an in-person patient visit under some circumstances. While that is welcome news to many providers, many providers are finding it difficult to plan for the unknown while we wait to see what flexibility the DEA's rulemaking might provide.

Acute Hospital Care at Home

Under waivers issued during the PHE, CMS created the Acute Hospital Care at Home (AHCH) program. A hospital that obtains an AHCH program waiver from CMS is permitted to provide services to low-acuity patients in alternative settings (e.g., the home), yet the hospital receives the same reimbursement from Medicare as if the care was provided on an inpatient basis. Among other rules, the waiver relaxed certain Medicare Conditions of Participation otherwise applicable to hospitals. Specifically, the waiver states that the requirement for providing 24-hour nursing services and immediate availability of nursing services may be satisfied by providing 24/7 virtual access to nurses or physicians. Also, hospital physical structure requirements under the life safety code are satisfied when residences are found to be safe and appropriate for the AHCH program's services. As of January 31, 2023, 260 hospitals have been approved by CMS to operate an AHCH across thirty-seven states.

Under the AHCH program, hospitals must still comply with state licensure requirements. In response to CMS's creation of the AHCH program, states have implemented correlating flexibilities to allow hospitals to provide acute care at home services while remaining in compliance with state licensure requirements. For example, the California Department of Public Health (CDPH) created its own "Acute Hospital Care at Home Program." California's program is specifically conditioned on the existence of the PHE and availability of the CMS waivers. Other state licensing agencies require hospitals to obtain similar approvals or submit a certificate of need to operate these programs.

The CAA extended the AHCH program through December 31, 2024. The CAA, which includes flexibilities and requirements consistent with the CMS waiver, no longer ties the AHCH program to the PHE. Notwithstanding the continuation of the federal program under the CAA, hospitals must remain in compliance with applicable state licensing requirements, which are not addressed by the CAA. The continuation of such state-based flexibilities may not be automatic in states where the flexibilities and related programs are conditioned on the existence of the PHE. For example, in California, hospitals that seek to extend existing programs (or implement new ones) beyond the expiration of the PHE must obtain approval from CDPH. Approval will be granted on a case-by-case basis unless CDPH provides for a blanket extension of the state program.

Looking ahead

Our Healthcare team will continue to monitor the status of the emergency declarations, and other government-issued guidance, that will have an impact on the industry. For the status of any waiver or action not listed here, please contact any of the authors of this alert or your regular Nixon Peabody attorney.

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