



# Health Law Diagnosis

## Monitoring the Pulse of Health Care and Life Sciences

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The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. For more updates on news and developments for the health care and life sciences industries, we invite you to [subscribe to our Health Law Diagnosis blog](#).

### [CMS Issues Guidance for Providers on Waivers, Flexibilities and End of COVID-19 Public Health Emergency](#)

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The Centers for Medicare & Medicaid Services (CMS) recently issued a Fact Sheet [Fact Sheet](#) providing guidance on the impact of the end of the federal COVID-19 Public Health Emergency (PHE) on certain regulatory waivers, legislative changes, and flexibilities that have been established during the PHE. The government previously announced that the PHE will expire at the end of the day on May 11, 2023. CMS is providing this guidance as part of efforts to ease the transition for health care providers, patients, and other industry stakeholders away from pandemic-era policies and practices tied to PHE authorities. CMS emphasizes that many of the waivers and flexibilities are or will become permanent or extended, and others are intended to end on or soon following May 11, 2023.

Below please find a summary of key guidance provided by CMS in the Fact Sheet and in related CMS PHE guidance documents issued recently:

#### **I. Telehealth Access**

##### Medicare

- Telehealth flexibilities during the PHE for individuals with Medicare coverage will be extended through December 31, 2024, including the following:
  - Beneficiaries will be able to receive telehealth services regardless of their geographic location (urban or rural).
  - Patients can continue receiving telehealth services from their home.
  - Audio-only telehealth services will continue to be covered by Medicare if the individual cannot use an audio-video device.

##### Medicaid & CHIP Beneficiaries

- CMS clarifies that existing telehealth flexibilities are not dependent upon the end of the federal PHE, but coverage decisions vary by and depend upon the state.

##### Other Telehealth Considerations

- The Drug Enforcement Administration (DEA) has proposed rules to enable continued prescribing via telehealth in certain circumstances. Please see our [recent blog post](#) for more details.
- [Section 4113\(d\) of the 2023 Consolidated Appropriations Act](#) delays the in-person visit requirements for Medicare patients receiving mental health treatment via telehealth until at least 2025. This means that Medicare beneficiaries can continue to access mental health services via telehealth until January 1, 2025, without needing to first have an in-person visit with their provider.

- HIPAA Enforcement Discretion – The Office for Civil Rights (OCR) has been exercising [enforcement discretion](#) throughout the COVID-19 pandemic regarding telehealth and remote communications. OCR has indicated in guidance that its enforcement discretion will [end at the expiration of the PHE](#) on May 11, 2023, and that OCR will issue a notice confirming the end of such discretion. Covered health care providers who continue to offer telehealth services should seek to ensure their telehealth care delivery systems align with HIPAA’s privacy and security requirements.

## II. COVID-19 Vaccines, Testing, and Treatment

### Medicare

- Medicare beneficiaries will continue to have access to COVID-19 vaccines without cost sharing when the PHE expires.
- Medicare beneficiaries will also continue to have access to COVID-19 testing, both PCR and antigen, without cost sharing when the test is ordered by an authorized provider and performed by a laboratory. However, free over-the-counter testing will end with the expiration of the PHE on May 11, 2023.
- Higher reimbursements for novel COVID-19 treatments under the New COVID-19 Treatments Add-on Payment scheme will continue through the end of fiscal year 2023. After this, CMS will reimburse for monoclonal antibodies as it does for other biological products.
- Current COVID-19 vaccine reimbursement rates for in-home and outpatient vaccine administration will continue through 2023. Beginning January 1, 2024, CMS will set the payment rate for administering COVID-19 vaccines to align with the rate for other Part B preventive vaccines.

### Medicaid & CHIP

- Pursuant to the American Rescue Plan Act of 2021 (ARPA), states must [continue to provide Medicaid and CHIP coverage](#) for COVID-19 vaccines, testing, and treatment through September 30, 2024. After this date, coverage for COVID-19 treatment and testing will likely vary by state.
- CMS also states that “under federal law” Medicaid coverage to the uninsured for COVID-19 vaccines, testing, and treatment will end at the expiration of the PHE.

## III. COVID-19 Waivers – Health Care Providers and Suppliers

### Blanket Waivers for Disaster Responses

- CMS indicates that [blanket waivers](#) issued in response to the COVID-19 emergency will end at the expiration of the PHE. These waivers include, but are not limited to, waivers of the three-day prior inpatient hospitalization for Medicare coverage of a skilled nursing facility stay, waivers regarding limitations of inpatient beds and lengths of stay at Critical Access Hospitals, and waivers allowing acute care patients to be housed in other facilities.

### Hospital at Home

- The CMS Acute Hospital Care at Home initiative has been extended by legislation through December 31, 2024. This allows hospitals to expand their inpatient care capacity by providing inpatient care in an individual’s home.

### Nurse Aide Training for Nursing Homes

- All nursing aide training emergency waivers that allowed facilities to employ nurse aides who had not completed approved training within four months will end when the PHE expires. Upon the expiration of the PHE, nursing homes and other facilities will have four months, or until September 10, 2023, to ensure all nurse aides hired prior to the end of the PHE complete state-approved training programs. Nurse aides hired after the end of the PHE will have four months from their hiring date to complete the mandatory trainings.

### Virtual Supervision

- The flexibilities that allowed direct supervision from a supervising health care professional to occur through a virtual, real-time audio-video presence instead of requiring physical presence will end on December 31, 2023.

### Scope of Practice

- During the pandemic, CMS waived the requirement that a certified registered nurse anesthetist (CRNA) supervised by a physician, to allow CRNAs to be supervised at the discretion of a hospital or Ambulatory Surgical Center and in accordance with existing state law. This waiver will end with the expiration of the PHE, but states may apply for an exemption to this requirement from CMS.

## Health and Safety Requirements

- Many regulatory waivers regarding health and safety requirements will end with the expiration of the PHE, including without limitation the requirement to complete medical records upon discharge of a patient.

## Stark Law Blanket Waivers

- CMS stated in [guidance](#) updated February 24, 2023 that the current blanket waivers of the Stark Law “will terminate” when the PHE ends, and at that time “physicians and entities must immediately comply with all provisions of the Stark Law.” The Stark Law is a strict liability statute which provides significant civil penalties for violators, so this immediate compliance requirement should be noted by parties currently relying on a blanket waiver to protect an arrangement.
- As a reminder, the Stark Law blanket waivers included waivers allowing for (i) payments above or below fair market value for physician services, (ii) payments below fair market value for equipment rentals or certain purchases, and (iii) enhanced benefits for medical staff physicians, among other things, where certain requirements were met related to the PHE. Based on the CMS guidance, it appears that these arrangements will need to be wound down before the PHE ends.

## Physician Licensure

- Throughout the PHE, [CMS waived the federal Medicare requirement](#) that out-of-state physicians and practitioners be licensed in their state of practice; however, this waiver did not necessarily extend to licensure requirements under state law (which varied). When the PHE ends, CMS has [advised](#) that CMS will continue to defer to state law regarding licensure of out-of-state practitioners.

Health care providers, patients, and other industry stakeholders would be well-advised to carefully consider the waivers and flexibilities on which they are currently relying to deliver care, and to assess how those waivers and flexibilities may be changing or ending in the coming months.

If you have any questions, please contact any member of Robinson+Cole's [Health Law Group](#).

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