

PUBLICATION

COVID-19 Public Health Emergency Set to End May 11, 2023, Along with Many Waivers and Flexibilities

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After more than three years, the Public Health Emergency (PHE) related to COVID-19 is scheduled to end on Thursday, May 11, 2023. The PHE declaration under the Public Health Service Act has allowed the Secretary of the Department of Health and Human Services to temporarily modify or waive certain Medicare, Medicaid, CHIP, and HIPAA requirements to provide flexibility during the pandemic. After the PHE ends on May 11, waivers, and flexibilities still in effect that were contingent on the Secretary's PHE-related authority will end unless they have been specifically extended under other authority.

The Centers for Medicare and Medicaid Services (CMS) issued a flurry of [fact sheets](#) and guidance memos in the lead-up to this May 11, 2023 end date, and has continued to issue [new guidance](#) and [FAQs](#) into this [week](#).

Below are examples of some of the many waivers and flexibilities that will end on May 11, 2023. A discussion of the impact on telehealth can be found [here](#).

Laboratory Test Orders

During the PHE, Medicare flexibilities permitted certain laboratory tests to be performed without an order and expanded who could order certain tests. These flexibilities will end with the PHE. Once the PHE terminates, diagnostic laboratory tests, including COVID-19 tests performed by a laboratory, must be ordered by a physician or non-physician practitioner in order to be reimbursed by Medicare.

Supplier Enrollment

CMS implemented multiple Medicare provider/supplier enrollment flexibilities to make it easier to maintain enrollment and provide services during the pandemic. While some of these flexibilities have already expired, others remain in effect and will be impacted by the end of the PHE. For example, expedited enrollment application processing times will end on May 11. The ability for practitioners who have opted out of Medicare to cancel their opt-out status early is also ending, with requirements returning to those dictated by regulation prior to the PHE.

One enrollment waiver that will not end this week is the CMS policy permitting practitioners to provide telehealth services from their homes without reporting their home address on their Medicare enrollment. That waiver has been extended through the end of 2023, however beginning in 2024, practitioners will need to report their home address as a practice location if it is used to provide telehealth to Medicare patients.

Durable Medical Equipment (DME)

CMS has waived certain signature and proof of delivery requirements during the PHE where a signature could not be obtained due to COVID-19. These waivers will end with the PHE, with pre-pandemic signature and proof of delivery requirements reinstated going forward.

Long Term Care (LTC) Facilities

During the PHE, CMS waived the requirement that a Medicare beneficiary must have a three-day qualifying hospital stay to qualify for Part A skilled nursing facility (SNF) coverage. CMS also allowed certain beneficiaries

who exhausted their SNF benefits a one-time renewal of Part A coverage without first having to complete a 60-day wellness period. Both of these waivers terminate once the PHE ends, thus effective on or after May 12, the prior requirements must be met.

Physician Self-Referral Law Waivers

During the PHE, CMS issued a package of nearly twenty [Physician Self-Referral Law waivers](#) that waived broad swaths of the Physician Self-Referral Law, commonly referenced as the "Stark Law." Once the PHE ends Thursday, these waivers will no longer be available.

As one example, location requirements under the Physician Self-Referral Law's in-office ancillary services exception (Location Requirements) have generally been waived, so group practices could generally perform "designated health services" (DHS) in locations for which they did not meet the standard Location Requirements, such as the minimum number of hours per week open to the public. As soon as the PHE ends or the Physician Self-Referral Law waivers otherwise terminate, any billings for DHS at such locations would violate the Physician Self-Referral Law, and also potentially expose providers to False Claims Act liability if providers learn of the issue and do not timely report or return such overpayments. In our experience, a significant proportion of group practices have been relying on this waiver (whether intentionally or unintentionally), such that a large number of groups will need to immediately restructure their arrangements, whether through increasing hours, ceasing DHS at certain locations, or otherwise.

Other key waiver examples include the waiving of writing requirements and the waiver of fair market value requirements. In our experience, the waivers have served to legitimately backstop well over fifty percent of what otherwise would have been Stark Law violations under a traditional Stark Law analysis. With the backstop of the waivers no longer available, providers should prioritize compliance refresher training for managerial personnel to ensure a smooth transition.

Takeaways

The waivers and flexibilities highlighted above are just some of the many policies that will revert to pre-pandemic requirements on and after May 12, 2023. With the extended duration of the PHE, it is often hard to remember the status quo before 2020. Providers and suppliers that have not already done so should take inventory of the policy changes and flexibilities they have taken advantage of during the pandemic to assess what needs to be altered as we return to "normal." It is important to make sure that staff and decision makers, especially those involved in compliance and reimbursement, are aware of the impending changes and are reviewing the available guidance to make necessary adjustments to policies and practices.

For assistance or questions regarding specific waivers and flexibilities impacting your provider or supplier type, please contact [Kathleen R. Salsbury](#), [Joseph Keillor](#), or another member of the Baker Donelson [Health Law Group](#).