

## The COVID-19 Public Health Emergency Officially Ends

After being in place for over three years – and after 1.1 million deaths and 6 million hospitalizations in the U.S. – the COVID-19 public health emergency (PHE) finally ended on May 11, 2023.<sup>1</sup> The PHE, which was originally declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, granted the federal government temporary powers to help alleviate the effects of the pandemic, particularly in the healthcare sector.<sup>2</sup> During the PHE, the federal government also took action to cushion the effect of the pandemic on providers, supporting public health efforts and stimulating the economy with investments of \$4.4 trillion through multiple legislative packages and the enactment of over 200 regulatory waivers.<sup>3</sup> The measures taken were able to support the vaccination and testing efforts, while expanding coverage and access to care, giving a lifeline to providers that were facing unprecedented challenges.<sup>4</sup>

The PHE was extended every 90 days after its initial declaration, until President Joseph Biden announced on January 30, 2023 that the PHE would no longer be extended.<sup>5</sup> The end of the PHE has triggered the expiration of most pandemic-related flexibilities and programs, including those implemented by the Centers for Medicare and Medicaid Services (CMS), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA), among other agencies.<sup>6</sup> However, these and other agencies have extended some of their regulatory flexibilities past the end of the PHE. For example, on May 10, 2023, the DEA announced their extension of certain exceptions, such as:

- An exception to the requirement that an authorized individual must sign an invoice at the time of the delivery of controlled substances to a program for narcotics treatment;
- An exception that allowed DEA-registered hospitals/clinics to use (non-registered) satellite hospital/clinic locations under certain conditions. A related exception allowed distributors to ship controlled substances directly to these satellite hospitals/clinics, even though they were non-registered locations;
- An exception that allowed an individual manufacturer's inventory to exceed 65% of estimated net disposals;
- An exception that allowed a DEA-registered practitioner to distribute controlled substances beyond 5% of the total number of dosage units of controlled substances distributed and dispensed

during the year without having to register as a distributor;

- An exception allowing deliveries to “safe zones” next to the purchaser’s registered location, as long as the delivery was still made in person; and
- An exception that allowed DEA-registered practitioners 15 days to provide a follow-up hard copy prescription to the pharmacy after issuing an emergency oral prescription, which prescription could be a photograph/scan of the written prescription and/or could be provided via fax.<sup>7</sup>

While many COVID-19 PHE flexibilities and policies have already been extended or made permanent for a certain amount of time, others expired as of May 11, 2023.<sup>8</sup> On May 9, 2023, HHS released a fact sheet detailing the agency’s post-PHE changes, including (but not limited to) the following:

- Certain waivers for Medicare and Medicaid, and other broad flexibilities for healthcare providers that are no longer necessary, ended. Many of these waivers and flexibilities were essential to expanding facility capacity and allowing the healthcare system to weather the strain created by COVID-19;
- COVID-19 coverage testing changed, with over-the-counter (OTC) COVID tests no longer covered by Medicare, and Medicaid coverage set to end on September 30, 2024. However, the government is maintaining stockpiles of tests, and channels for distribution, so that tests remain accessible at no cost in certain locations.
- HHS no longer has the authority to require COVID-19 data surveillance from laboratories, negatively affecting test results (and COVID-19 positivity rates). Data reporting for hospitals will continue as required through April 30, 2024, but reporting is reduced from the current daily reporting to weekly reporting.
- While the FDA will maintain their authority to detect and address other medical product shortages, it is seeking authorization from Congress to extend the requirement for device manufacturers to notify FDA of interruptions/discontinuances of critical devices outside of a PHE, which will strengthen the ability of FDA to help prevent or mitigate device shortages in the future.<sup>9</sup>

Other PHE-related policies that have ended include the 20% payment bump that hospitals received for the treatment of COVID-19 patients and waivers that allowed non-physician providers expanded scope of practice, with certified registered nurse anesthetists (CRNAs) no longer able to work without the supervision of a physician.<sup>10</sup> Additionally, HHS will resume on August 9, 2023 the enforcement of telehealth providers that violate Health Insurance Portability and Accountability Act (HIPAA) by utilizing non-compliant platforms such as Skype or FaceTime to conduct patient visits.<sup>11</sup>

The PHE flexibilities and waivers most popular with both providers and patients during the pandemic were those related to telehealth. In response to calls to keep expanded telehealth coverage, CMS released additional guidelines addressing agency-specific waivers and flexibilities related to the technology. For example, until December 31, 2024, Medicare beneficiaries can access telehealth services anywhere (in most cases), rather than only in rural areas. Beneficiaries can access telehealth from their homes, and certain visits can be conducted through just audio (if someone is unable to use both video and audio). Additionally, physicians and practitioners can continue to bill Medicare for telehealth services under the Medicare physician fee schedule for telehealth services through December 31, 2024.<sup>12</sup>

Perhaps one of the most significant changes post-PHE is the end of the Medicaid continuous enrollment requirement. In 2020, states agreed to an increased federal matching rate for Medicaid payments in exchange for not removing anyone from their Medicaid rolls for the duration of the COVID-19 PHE, even if that individual was no longer Medicaid-eligible.<sup>13</sup> Now that this has ended, states will have to

determine eligibility again, a task that is expected to take anywhere from a few months to a year.<sup>14</sup> The Urban Institute estimates that 18 million Americans could lose Medicaid coverage, with 4 million becoming completely uninsured.<sup>15</sup>

The anticipated end of the PHE had prompted responses from healthcare industry stakeholders such as the American Hospital Association (AHA) and the Medical Group Management Association (MGMA). Stacey Hughes, the AHA Executive Vice President for Government Relations and Public Policy, stated that the decision to end the declaration represented progress made, but that the progress should not end with the PHE.<sup>16</sup> She also stated that the AHA will work with the Biden Administration to build on lessons learned during COVID-19, and the organization strongly urges that many of the flexibilities granted during the PHE be made permanent.<sup>17</sup> Additionally, MGMA has urged Congress to pass a permanent expansion of the telehealth services that were expanded during the PHE.<sup>18</sup> MGMA's suggestions included allowing permanent coverage of audio-only telehealth services and eliminating in-person requirements for mental telehealth services.<sup>19</sup>

Although the COVID-19 PHE has expired, the White House's COVID-19 Response Coordinator, Dr. Ashish Jha, warned that the pandemic itself is not over, and stated that he sees the end of the PHE "as a transition out of this emergency phase into a very different phase."<sup>20</sup> Dr. Jha also mentioned that while pandemic preparedness has come a long way, the U.S. is nowhere near where it needs to be for the next pandemic.<sup>21</sup> It is clear that there is more work to be done, including building better platforms for vaccines, bringing more rapid tests to the market, and tackling the greater healthcare issues and disparities the pandemic highlighted.<sup>22</sup>

1 "What Happens When COVID-19 Emergency Declarations End? Implications for Coverage, Costs, and Access" By Juliette Cubanski, et al., Kaiser Family Foundation, January 31, 2023, <https://www.kff.org/coronavirus-covid-19/issue-brief/what-happens-when-covid-19-emergency-declarations-end-implications-for-coverage-costs-and-access/> (Accessed 5/17/23); "The public health emergency has ended. What's next in post-PHE world?" By Heather Landi, Fierce Healthcare, May 12, 2023, <https://www.fiercehealthcare.com/providers/covid-19-public-health-emergency-has-ended-here-are-biggest-changes-you-need-know> (Accessed 5/17/23).

2 Cubanski, et al., Kaiser Family Foundation, January 31, 2023.

3 Landi, Fierce Healthcare, May 12, 2023.

4 *Ibid.*

5 Cubanski, et al., Kaiser Family Foundation, January 31, 2023.

6 Landi, Fierce Healthcare, May 12, 2023.

7 "Drug Enforcement Administration Diversion Control Division Guidance Document: COVID-19 Flexibility Updates" Drug Enforcement Administration, May 10, 2023, [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-072\)\(EO-DEA277\)\\_Dear\\_Registrant\\_Letter\\_PHE\\_Exceptions\\_Ending\\_and\\_d\\_Continuing\\_HHS\\_Comments\\_-\\_Fina2.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-072)(EO-DEA277)_Dear_Registrant_Letter_PHE_Exceptions_Ending_and_d_Continuing_HHS_Comments_-_Fina2.pdf) (Accessed 5/17/23).

8 "Fact Sheet: End of the COVID-19 Public Health Emergency" HHS Press Office, Department of Health and Human Services, May 9, 2023, [https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html?utm\\_source=news-releases-email&utm\\_medium=email&utm\\_campaign=may-15-2023](https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html?utm_source=news-releases-email&utm_medium=email&utm_campaign=may-15-2023) (Accessed 5/17/23).

9 *Ibid.*

10 "The COVID-19 public health emergency is ending. Here's what's changing." By Lauren Berryman, Modern Healthcare,

May 11, 2023, <https://www.modernhealthcare.com/policy/covid-19-public-health-emergency-phe-end-telehealth-medicare-reimbursements> (Accessed 5/18/23).

11 *Ibid.*

12 "FAQ: CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency" Centers for Medicare and Medicaid Services, <https://www.modernhealthcare.com/policy/covid-19-public-health-emergency-phe-end-telehealth-medicare-reimbursements> (Accessed 5/18/23).

13 Landi, Fierce Healthcare, May 12, 2023.

14 *Ibid.*

15 *Ibid.*

16 "Administration to End COVID-19 Emergency Declarations on May 11" American Healthcare Association, January 31, 2023, <https://www.aha.org/news/headline/2023-01-31-administration-end-covid-19-emergency-declarations-may-11> (Accessed 5/17/23).

17 *Ibid.*

18 "MGMA Washington Connection 02/02/2023: Biden Administration To End COVID-19 PHE on May 11" MGMA Missouri, February 2, 2023, <https://mgma-mo.org/news/13082814> (Accessed 5/17/23).

19 *Ibid.*

20 "'I don't see this as an end to the pandemic': Ashish Jha on the end of Covid public health emergency" By Ambar Castillo, Stat News, May 10, 2023, <https://www.statnews.com/2023/05/10/public-health-emergency-ashish-jha/> (Accessed 5/18/23).

21 *Ibid.*

22 *Ibid.*



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