Health Policy and Legislation

Akin Gump

Life After Omicron: Critical COVID-19 Policy Areas to Watch in the Weeks Ahead

February 9, 2022

For the past two years, the United States government has had to deal with most major legislative and regulatory actions against the backdrop of the COVID-19 pandemic. In making policy, the federal government has been forced, either explicitly or implicitly, to account for the pandemic's effect on businesses, various segments of the health care industry, the nation's supply chain and everyday Americans. The most recent surge of the Omicron variant continues to highlight the enormous strain this pandemic has on the national economy and the health care system.

In recent days, however, there have been clear signs that the surge of the Omicron variant of the SARS-CoV-2 virus has begun to wane in the United States: the sevenday case average is down more than 50 percent from peak levels in mid-January and hospitalizations are showing similar rates of improvement. Unfortunately, as a lag indicator, the number of daily deaths has remained high over the last few weeks but is expected to begin improving in the days ahead.

An increasing number of policy makers, employers and the general public are asking whether we have reached a less dangerous endemic phase where we simply need to learn to live with the virus. Indeed, a number of European countries have started to take such an approach and are removing work-from-home requirements, reopening social venues and declaring the emergency over despite a significant increase in cases that, fortunately, did not result in the collapse of many European health systems that many had feared.

Many are openly asking whether the Biden administration should make a similar announcement and reset its approach to allow a return to more normal lives. With pandemic fatigue clearly taking hold—especially in the health care sector, which is facing a staffing crisis of epic proportions—health officials are considering when it will be appropriate to treat COVID-19 like other respiratory viruses, and perhaps most pointedly, when it will be advisable to remove masks and return to larger in-person gatherings for work and recreation.

This policy alert outlines the scientific and policy questions Washington will need to address as the Omicron variant recedes and we look ahead to future pandemic prevention and preparation efforts.

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When will the U.S. public health emergency be over?

Perhaps most importantly, it is critical to note that there is no clear definition of when a pandemic is "officially over." In fact, there is great disagreement on the issue.

In earlier days of the pandemic, there were many who argued that the virus would eventually mutate into something less virulent and dangerous, as observed with other influenza strains such as the 1918 flu. Indeed, that remains a possibility and an outcome that many experts watching Omicron's behavior hope signals an end of this virus's ability to cause serious illness. There is also a competing school of thought that Omicron may be but one variant circulating now, and that continuing drift to less virulence cannot be guaranteed. Perhaps future variants will be more dangerous or other variants will co-circulate in the months ahead.

In the face of uncertainty resulting from the competing views inside the scientific community, others have recently argued that we should treat the virus like other respiratory viruses and monitor health system utilization, with lower utilization as the best marker that the pandemic has ended. That argument is premised on the widespread availability of effective treatments like oral antivirals to help keep patients out of hospitals, thereby minimizing the health and economic costs of infection.

Finally, there is the question of innate immunity and just how much recovery from infection adds to the protection conferred by vaccination in contributing to the population's protection from additional variants. Although 64 percent of the U.S. population is fully vaccinated, that rate is relatively low compared to other industrialized countries including the United Kingdom (77 percent) and Canada (85 percent), and questions exist whether that leaves our nation open to additional surges in the future.

In the absence of a consensus definition for the end of the public health emergency, there are three areas to watch closely:

I. Ongoing Variant Surveillance and Monitoring

Recognizing that Omicron is unlikely to be the last COVID-19 variant, the U.S. response will continue to focus on domestic and international surveillance. In Congress, the Senate Health, Education, Labor and Pensions (HELP) Committee is attempting to advance the bipartisan Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act ("PREVENT Pandemics Act"), which includes provisions related to epidemiological surveillance and monitoring among other critical investments in pandemic preparedness. The legislation is currently in draft phase—the Committee solicited comments from stakeholders following the issuance of a discussion draft—but the bill's bipartisan nature has observers hopeful that the legislation will advance and deliver much-needed updates to our nation's medical and public health preparedness and response framework.

In the Executive Branch, the White House Office of Science and Technology Policy (OSTP) issued its own Pandemic Preparedness Plan (P3) last year at an unfunded cost of \$65 billion. OSTP has since established a Pandemic Innovation Task Force working to implement the plan while also looking to address future threats. Open questions remain, however, about whether the funding can be secured and how the plan will integrate with efforts of the National Security Council's Global Health Security and Biodefense office re-established under the Biden administration. That office is

working to support implementation of the Global Health Security Agenda focused on international health system strengthening, of which disease and variant surveillance is a critical component.

Finally, the Biden administration has supported the World Health Organization (WHO) while pressing for reform of the organization in the areas of governance and program management. The WHO plays a critical role in global biosurveillance, both by aggregating information itself and by serving as a convening authority for other organizations assembling data. It will be important to watch how these various work streams come together in the months ahead to see if any sort of integrated global surveillance architecture can be developed that will leave the United States better positioned to respond to future variants.

II. Hospitalizations and Health System Utilization

Recognizing the continued potential for the type of surprises this virus has previously delivered, there is nevertheless optimism that, for at least several months after the Omicron surge recedes, that U.S. health system utilization will significantly improve. As that occurs, it will be critical to watch how the Centers for Disease Control and Prevention (CDC) responds. In July 2021, CDC Director Rochelle Walensky issued updated guidance that everyone should wear a mask in areas of substantial and high community transmission regardless of vaccination status. At the time, substantial transmission was defined as a seven-day period with more than 50 cases/100,000 persons or a test positivity rate of 8-10 percent. As a result, a number of counties and local jurisdictions tied masking policies to CDC community transmission levels.

Since that time, as a consequence of the Delta and Omicron variants, the U.S. has not had any more than a few states at any given time that would meet the threshold for low (< 10 cases/100,000 persons and test positivity < 5 percent) to moderate level transmission (10-50 cases/100,000 persons and positivity between 5-8 percent) where masks could be removed in public according to CDC guidance. Currently, no state would meet that threshold. As the U.S. vaccination rate has improved, however, and the Omicron variant fortunately proved less virulent at the individual level, there has been a dissociation between the number of cases and the number of persons hospitalized. Although the total number of hospitalizations in the U.S. has exceeded that of prior variants, the proportion compared to total cases has remained lower.

As a result, the CDC and policymakers face a critical junction. Either the CDC will need to update its guidance to recognize the increasing dissociation between cases and hospitalizations, or elected officials will have to push ahead of CDC guidelines if masks and distancing guidelines are to be removed in work and recreational settings. With increasing signs that the virus will continue to circulate at some level for the foreseeable future, areas that have tied masking ordinances to CDC levels of community transmission will find it difficult to reach levels low enough to allow mask removal. In fact, there are signs that some officials are already moving ahead. For example, lowa Governor Kim Reynolds recently announced the end of her state's COVID-19 disaster declaration and is shutting down vaccination and case count websites and is instead moving to weekly reporting similar to that used for influenza monitoring. It will be important to monitor other states for similar policy changes in the weeks ahead.

III. Access to Widespread Treatments and Advancements in COVID-19 Testing

The decision by the U.S. Supreme Court to strike down the Biden administration's proposed broad workplace vaccination-or-test rule, which was issued by the Occupational Safety and Health Administration (OSHA) as an Emergency Temporary Standard (ETS), means that a large segment of American society is likely to remain unvaccinated barring a significant change in current personal opinions. It is possible that having 35 percent of Americans unvaccinated will create a consistent demand for COVID-19-related services and care as the virus continues to circulate. There are open and unanswered questions for employers and responsibilities for workplace safety that exist even in the absence of the OSHA ETS. With the OSHA General Duty clause still in effect, it is unclear whether employers may be held liable for an outbreak that occurs in a workplace setting if masks are removed and there is open mixing of vaccinated and unvaccinated persons. While proving where exactly someone was infected has been historically difficult, the cost of litigation in this area is a considerable concern. Ultimately, the policy question to watch is how personal decisions to remain unvaccinated impact workplace practices when access to treatments improves later this year.

As a result, key policy decisions will need to be made around preparedness and response capacity in the near term, which could include the proposed:

- The PREVENT Pandemics Act, which would broadly update and overhaul public health emergency related activities.
- The Medical and Health Stockpile Accountability Act, which would create real-time, up-to-date monitoring of the supply chain for critical medical supplies.
- The Pharmaceutical Supply Chain and Defense and Enhancement Act, which would support the on-shoring of critical drug manufacturing here in the United States.

Critical decisions also remain to be made around regulatory authorities that would enable permanent access to telehealth, expanded access to over-the-counter (OTC) testing solutions and remote "test-to-treat" platforms, which could speed access to oral antiviral medicines that significantly improve outcomes and decrease the health and financial costs of becoming infected. The federal government has poured several billion dollars into fostering innovation to help combat the virus. Once COVID-19 is under control, several questions remain regarding the future of devices, diagnostics, treatments and vaccines that have received emergency use authorizations (EUAs) from the Food and Drug Administration (FDA) during COVID-19, and mandatory payer coverage of COVID-19-related health care. Congress also expanded Medicaid eligibility through its various relief bills, and the Urban Institute has estimated that approximately 15 million individuals could lose coverage once the public health emergency expires. This begs the question of how formerly eligible beneficiaries will access health care in the future, which could mean providers are faced with increased uncompensated care-related costs.

Conclusion

In a time of transition, with ongoing assessment of the lessons learned to date, significant policy and practical questions for consideration may include:

 How will varying state public health approaches impact the pace of both economic and public health recovery and reopening?

- How will the potential for future COVID-19 variants, or other emerging health conditions, be factored in?
- Has the COVID-19 pandemic fundamentally changed traditional practices in the health care provider sector necessary to ensure adequate levels of staffing and supplies?
- What does the expansion of telehealth and related technologies during the pandemic portend for the delivery of health care going forward?
- Will policy makers commit the resources necessary to support ongoing COVID-19 work and prepare for future public health emergencies?
- What new incentives may be created to encourage the timely development and manufacture of vital medical countermeasures for emerging health threats going forward?
- What will congressional oversight of the pandemic response look like if there are changes to which party is in the majority in the House and Senate?

While the receding Omicron surge of the past few weeks is a promising sign, there remains significant uncertainty about the policy path out of the pandemic. This next phase is likely to remain complex with difficult questions that must be answered before transitioning beyond the previous phases of the COVID-19 pandemic. The stage is set for this transition, but the weeks and months ahead will be busy with decisions on the issues above, which will have a critical impact on what recovery looks and feels like for stakeholder interests.

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